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FEDERAL REGISTER

Vol. 82 Monday,
No. 155 August 14, 2017

Book 1 of 2 Books
Pages 37805–37988

OFFICE OF THE FEDERAL REGISTER

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2016–8030; Special Conditions No. 25–698–SC]

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

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for Garmin International (Garmin) for modifications to Beechcraft Corporation (Beechcraft) Model 400A airplanes. These airplanes, as modified by Garmin, will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport-category airplanes. This design feature incorporates the Garmin G5000 satellite-based navigation system into the airplanes. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: This action is effective on Garmin on August 14, 2017. We must receive your comments by September 28, 2017.

ADDRESSES: Send comments identified by docket number FAA–2016–8030 using any of the following methods:

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

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

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

FOR FURTHER INFORMATION CONTACT: Varun Khanna, FAA, Airplane and Flightcrew Interface, ANM–111, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone 425–227–1298; facsimile 425–227–1320.

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

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

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

Comments Invited

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

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

Background

On February 13, 2014, Garmin applied for a supplemental type certificate to install the Garmin G5000 satellite-based navigation system in Beechcraft Model 400A airplanes. These airplanes, which are currently approved under Type Certificate No. A16SW, are twin-engine corporate turbojet airplanes with a maximum takeoff weight of 16,100 lbs., and seating for 7 to 9 passengers and 2 crew members.

Type Certification Basis

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

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

Special conditions are initially applicable to the model for which they are issued. Should the applicant apply for a supplemental type certificate to modify any other model included on the same type certificate to incorporate the

same novel or unusual design feature, these special conditions would also apply to the other model under § 21.101.

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

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

Novel or Unusual Design Features

The Beechcraft Model 400A airplanes, as modified by Garmin, will incorporate the following novel or unusual design feature:

Installation of the Garmin G5000 satellite-based navigation system into the airplanes.

Discussion

The Garmin G5000 satellite-based navigation-system design, installed in Beechcraft Model 400A airplanes, introduces the potential for unauthorized persons, accessing the passenger-services domain, to access the airplane-control domain and airplane information-services domain; and further may introduce security vulnerabilities related to the introduction of viruses, worms, user errors, and intentional sabotage of airplane networks, systems, and databases.

The operating systems for current airplane systems usually are proprietary. Therefore, they are not as susceptible to corruption from worms, viruses, and other malicious actions as are more widely used commercial operating systems, such as Microsoft Windows, because access to the design details of these proprietary operating systems is limited to the system developer and airplane integrator. Some systems installed on the Beechcraft Model 400A airplanes will use operating systems that are widely used and commercially available from third-party software suppliers. The security vulnerabilities of these operating systems may be more widely known than proprietary operating systems currently used by avionics manufacturers.

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

Applicability

As discussed above, these special conditions are applicable to Beechcraft Model 400A airplanes modified by Garmin. Should Garmin apply at a later date for a supplemental type certificate to incorporate the same novel or unusual design feature for any other model included on the same type certificate, these special conditions would apply to that model as well.

Conclusion

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

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

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

The Special Conditions

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

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

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

Issued in Renton, Washington, on July 31, 2017.

Victor Wicklund,

Manager, Transport Standards Branch, Aircraft Certification Service.

[FR Doc. 2017–17071 Filed 8–11–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2017–0316; Special Conditions No. 25–699–SC]

Special Conditions: Embraer S.A. Model ERJ 190–300 Airplane; Flight Envelope Protection: High Incidence Protection System

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Embraer S.A. (Embraer) Model ERJ 190–300 airplane. This airplane will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport-category airplanes. This design feature is a high-incidence protection function that limits the angle of attack (AOA) at which the airplane can be flown during normal low-speed operation, and that cannot be overridden by the flightcrew. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: This action is effective on Embraer S.A. on August 14, 2017. We must receive your comments by September 28, 2017.

ADDRESSES: Send comments identified by docket number FAA–2017–0316 using any of the following methods:

- *Federal eRegulations Portal:* Go to *http://www.regulations.gov/*and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
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Docket: Background documents or comments received may be read at *http://www.regulations.gov/* at any time. Follow the online instructions for accessing the docket or go to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Joe Jacobsen, FAA, Airplane and Flight Crew Interface, ANM–111, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone 425–227–2011; facsimile 425–227–1320.

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

In addition, since the substance of these special conditions has been subject to the public comment process in several prior instances with no substantive comments received, the FAA finds it unnecessary to delay the effective date and finds that good cause exists for adopting these special conditions upon publication in the **Federal Register**.

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

Comments Invited

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

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

Background

On September 13, 2013, Embraer applied for an amendment to Type Certificate No. A57NM to include the new Model ERJ 190–300 airplane. The Model ERJ 190–300 airplane, which is a derivative of the Embraer Model ERJ 190–100 STD airplane currently approved under Type Certificate No. A57NM, is a 97- to 114-passenger transport-category airplane, designed with a new wing with a high aspect ratio and raked wingtip, and a new electrical-distribution system. The maximum take-off weight is 124,340 lbs (56,400 kg).

Type Certification Basis

Under the provisions of title 14, Code of Federal Regulations (14 CFR) 21.101, Embraer must show that the Model ERJ 190–300 airplane meets the applicable provisions of the regulations listed in Type Certificate No. A57NM, or the applicable regulations in effect on the date of application for the change, except for earlier amendments as agreed upon by the FAA.

If the Administrator finds that the applicable airworthiness regulations (*i.e.,* 14 CFR part 25) do not contain adequate or appropriate safety standards for the Model ERJ 190–300 airplane because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

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

In addition to the applicable airworthiness regulations and special conditions, the Embraer Model ERJ 190–300 airplane must comply with the fuel-vent and exhaust-emission requirements of 14 CFR part 34, and the noise-certification requirements of 14 CFR part 36.

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

Novel or Unusual Design Features

The Embraer Model ERJ 190–300 airplane will incorporate the following novel or unusual design feature:

A high-incidence protection function that limits the angle of attack (AOA) at which the airplane can be flown during normal low-speed operation, and that cannot be overridden by the flightcrew.

Discussion

The Model ERJ 190–300 airplane design has a complex, full-digital flight-control system, referred to as fly-by-wire (FBW) architecture. This FBW architecture provides closed-loop flight-control laws and multiple protection functions.

The Model ERJ 190–300 airplane is equipped with a high-incidence protection function that limits the angle of attack (AOA) at which the airplane can be flown during normal low-speed operation, and cannot be overridden by the flightcrew. The application of this AOA limit impacts the stall-speed determination, the stall characteristics and stall-warning demonstration, and the longitudinal airplane-handling characteristics. The high-incidence protection function prevents the airplane from stalling at low speeds and, therefore, a stall warning system is backed up during normal flight conditions. If the high-incidence protection function has a failure that is not shown to be extremely improbable, stall warning must be provided in a conventional manner. Also, the flight characteristics at the AOA for V_{CLmax} (AOA at the maximum lift co-efficient and associated speed) must be suitable in the traditional sense. Per 14 CFR 21.16, therefore, special conditions are needed to address the unique features of the high-incidence protection function installed on the Model ERJ 190–300 airplane.

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

Applicability

As discussed above, these special conditions are applicable to the Model ERJ 190–300 airplane. Should Embraer apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, these special conditions would apply to that model as well.

Conclusion

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

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

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

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for the Embraer Model ERJ 190–300 airplane.

Flight Envelope Protection: High Incidence Protection System

The current airworthiness standards do not contain adequate safety standards for the unique features of the high incidence protection system on the Embraer Model ERJ 190–300 airplane. Part I of the following special conditions are issued in lieu of the specified paragraphs of §§ 25.103, 25.145, 25.201, 25.203, 25.207, and 25.1323 of title 14, Code of Federal Regulations (CFR) or in addition to the requirements of § 25.21. Part II are in lieu of the specified paragraphs of §§ 25.103, 25.105, 25.107, 25.121, 25.123, 25.125, 25.143, and 25.207 of title 14 CFR.

Special Conditions Part I

Stall Protection and Scheduled Operating Speeds

The following special conditions are in lieu of §§ 25.103, 25.145(a), 25.145(b)(6), 25.201, 25.203, 25.207, and 25.1323(d) or in addition to the requirements of § 25.21.

Foreword

In the following paragraphs, ''in icing conditions'' means with the ice accretions (relative to the relevant flight phase) as defined in 14 CFR part 25, Amendment 121, appendix C.

1. Definitions

The following are terms relating to the novel or unusual design features these special conditions address:

- *High incidence protection system:* A system that operates directly and automatically on the airplane's flying controls to limit the maximum angle of attack that can be attained to a value below that at which an aerodynamic stall would occur.
- *Alpha-limit:* The maximum angle of attack at which the airplane stabilizes with the high incidence protection system operating, and the longitudinal control held on its aft stop.
- V_{min}*:* The minimum steady flight speed in the airplane configuration under consideration with the high incidence protection system operating. See Part I, section 3 of these special conditions.
- $V_{min}1g$*:* V_{min} corrected to 1g conditions. See Part I, section 3 of these special conditions. It is the minimum calibrated airspeed at which the airplane can develop a lift force normal to the flight path and equal to its weight when at an angle of attack not greater than that determined for V_{min}.

2. Capability and Reliability of the High Incidence Protection System

The capability and reliability of the high incidence protection system can be established by flight test, simulation, and analysis as appropriate. The capability and reliability required are as follows:

1. It must not be possible during pilot-induced maneuvers to encounter a stall, and handling characteristics must be acceptable, as required by section 5 of Part I of these special conditions.
2. The airplane must be protected against stalling due to the effects of wind-shears and gusts at low speeds as required by section 6 of Part I of these special conditions.
3. The ability of the high incidence protection system to accommodate any reduction in stalling incidence must be verified in icing conditions.
4. The high incidence protection system must be provided in each abnormal configuration of the high lift devices that is likely to be used in flight following system failures.
5. The reliability of the system and the effects of failures must be acceptable in accordance with § 25.1309.

3. Minimum Steady Flight Speed and Reference Stall Speed

In lieu of § 25.103, the following requirements apply:

(a) The minimum steady flight speed, V_{min}, is the final stabilized calibrated airspeed obtained when the airplane is decelerated until the longitudinal control is on its stop in such a way that the entry rate does not exceed 1 knot per second.

(b) The minimum steady flight speed, V_{min}, must be determined if it is used to determine compliance with a required performance standard or other requirements demonstrations in icing or non-icing conditions with:

(1) The high incidence protection system operating normally;

(2) Idle thrust and automatic thrust system (if applicable) inhibited;

(3) All combinations of flap settings and landing gear position for which V_{min} is required to be determined;

(4) The weight used when reference stall speed, V_{SR}, is being used as a factor to determine compliance with a required performance standard;

(5) The most unfavorable center of gravity allowable; and

(6) The airplane trimmed for straight flight at a speed selected by the applicant, but not less than 1.13 V_{SR} and not greater than 1.3 V_{SR}.

(c) The 1-g minimum steady flight speed, $V_{min}1g$, is the minimum calibrated airspeed at which the airplane can develop a lift force (normal to the flight path) equal to its weight, while at an angle of attack not greater than that at which the minimum steady flight speed of subparagraph (a) was determined. It must be determined if it is used to determine compliance with a required performance standard or other requirements demonstrations in icing or non-icing conditions.

(d) The reference stall speed, V_{SR}, is a calibrated airspeed defined by the applicant. V_{SR} may not be less than a 1g stall speed. V_{SR} must be determined in non-icing conditions (and as an option, in icing conditions) and expressed as:

$$V_{SR} \geq \frac{V_{CL_{MAX}}}{\sqrt{n_{zw}}}$$

where—

V_{CLmax} = Calibrated airspeed obtained when the load factor-corrected lift coefficient ($\frac{n_{zw}W}{qS}$) is first a maximum during the maneuver prescribed in sub-paragraph (e)(7) of this paragraph.

N_{zw} = Load factor normal to the flight path at V_{CLmax}

W = Airplane gross weight;

S = Aerodynamic reference wing area; and

q = Dynamic pressure.

(e) V_{CLmax} is determined with:

(1) Engines idling, or, if that resultant thrust causes an appreciable decrease in stall speed, not more than zero thrust at the stall speed;

(2) The airplane in other respects (such as flaps, landing gear, and ice accretions) in the condition existing in the test or performance standard in which V_{SR} is being used;

(3) The weight used when V_{SR} is being used as a factor to determine compliance with a required performance standard;

(4) The center of gravity position that results in the highest value of reference stall speed;

(5) The airplane trimmed for straight flight at a speed achievable by the automatic trim system, but not less than 1.13 V_{SR} and not greater than 1.3 V_{SR}; and

(6) The high incidence protection system adjusted or disabled, at the option of the applicant, to allow higher incidence than is possible with the normal production system.

(7) Starting from the stabilized trim condition, apply the longitudinal control to decelerate the airplane so that the speed reduction does not exceed 1 knot per second.

4. Stall Warning

In lieu of § 25.207, the following requirements apply:

4.1 Normal Operation

If the capability requirements of the high incidence protection system are successfully demostrated, then the conditions of section 2, ''Capability and Reliability of the High Incidence Protection System,'' are satisfied. These conditions provide safety equivalent to § 25.207, *Stall warning,* so the provision of an additional, unique warning device is not required.

4.2 High Incidence Protection System Failure

Following failures of the high incidence protection system, not shown to be extremely improbable, such that the capability of the system no longer satisfies items (1), (2), and (3) of section 2, ''Capability and Reliability of the High Incidence Protection System,'' stall warning must be provided and must protect against encountering unacceptable stall characteristics and against encountering stall.

(a) Stall warning with the flaps and landing gear in any normal position must be clear and distinctive to the pilot and meet the requirements specified in paragraphs (d) and (e) below.

(b) Stall warning must also be provided in each abnormal configuration of the high lift devices that is likely to be used in flight following system failures.

(c) The warning may be furnished either through the inherent aerodynamic qualities of the airplane or by a device that will give clearly distinguishable indications under expected conditions of flight. However, a visual stall warning device that requires the attention of the crew within the cockpit is not acceptable by itself. If a warning device is used, it must provide a warning in each of the airplane configurations prescribed in paragraph (a) above and for the conditions prescribed in paragraphs (d) and (e) below.

(d) In non-icing conditions stall warning must provide sufficient margin to prevent encountering unacceptable stall characteristics and encountering stall in the following conditions:

(1) In power off (engine power or thrust at flight idle) straight deceleration not exceeding 1 knot per second to a speed 5 knots or 5 percent calibrated airspeed, whichever is greater, below the warning onset.

(2) In turning flight stall deceleration at entry rates up to 3 knots per second when recovery is initiated not less than 1 second after the warning onset.

(e) In icing conditions stall warning must provide sufficient margin to prevent encountering unacceptable characteristics and encountering stall, in power-off (engine power or thrust at flight idle) straight and turning flight decelerations not exceeding 1 knot per

second, when the pilot starts a recovery maneuver not less than three seconds after the onset of stall warning.

(f) An airplane is considered stalled when the behavior of the airplane gives the pilot a clear and distinctive indication of an acceptable nature that the airplane is stalled. Acceptable indications of a stall, occurring either individually or in combination are:

(1) A nose-down pitch that cannot be readily arrested;

(2) Buffeting, of a magnitude and severity that is strong and effective deterrent to further speed reduction; or

(3) The pitch control reaches the aft stop and no further increase in pitch attitude occurs when the control is held full aft for a short time before recovery is initiated.

(g) An aircraft exhibits unacceptable characteristics during straight or turning flight decelerations if it is not always possible to produce and to correct roll and yaw by unreversed use of aileron and rudder controls, or abnormal nose-up pitching occurs.

5. Handling Characteristics at High Incidence

In lieu of §§ 25.201 and 25.203, the following requirements apply:

5.1 High Incidence Handling Demonstration

In lieu of § 25.201:

(a) Maneuvers to the limit of the longitudinal control, in the nose-up pitch, must be demonstrated in straight flight and in 30° banked turns with:

(1) The high incidence protection system operating normally;

(2) Initial power conditions of:

i. Power off (engine power or thrust at flight idle); and

ii. The power necessary to maintain level flight at 1.5 V_{SR1}, where V_{SR1} is the reference stall speed with flaps in approach position, the landing gear retracted, and maximum landing weight;

(3) Flaps, landing gear, and deceleration devices in any likely combination of positions;

(4) Representative weights within the range for which certification is requested; and

(5) The airplane trimmed for straight flight at a speed selected by the applicant, but not less than 1.13 V SR and not greater than 1.3 V_{SR}.

(b) The following procedures must be used to show compliance in non-icing and icing conditions:

(1) Starting at a speed sufficiently above the minimum steady flight speed to ensure that a steady rate of speed reduction can be established, apply the longitudinal control so that the speed reduction does not exceed 1 knot per second until the control reaches the stop;

(2) The longitudinal control must be maintained at the stop until the airplane has reached a stabilized flight condition and must then be recovered by normal recovery techniques;

(3) Maneuvers with increased deceleration rates:

(i) In non-icing conditions, the requirements must also be met with increased rates of entry to the incidence limit, up to the maximum practical entry rate; and

(ii) In icing conditions, with the anti-ice system working normally, the requirements must also be met with increased rates of entry to the incidence limit, up to 3 knots per second; and

(4) Maneuver with ice accretion prior to operation of the normal anti-ice system. With the ice accretion prior to operation of the normal anti-ice system, the requirements must also be met in deceleration at 1 knot per second. The deceleration must be continued until one second after the activation of the tactile stall warning system or three seconds after reaching full back stick, whichever occurs first. A primary ice detection system must automatically activate the ice protection.

5.2 Characteristics in High Incidence Maneuvers

In lieu of § 25.203:

In icing and non-icing conditions:

(a) Throughout maneuvers with a rate of deceleration of not more than 1 knot per second, both in straight flight and in 30° banked turns, the airplane's characteristics must be as follows:

(1) There must not be any abnormal nose-up pitching.

(2) There must not be any uncommanded nose-down pitching, which would be indicative of stall. However, reasonable attitude changes associated with stabilizing the incidence at Alpha limit as the longitudinal control reaches the stop would be acceptable.

(3) There must not be any uncommanded lateral or directional motion and the pilot must retain good lateral and directional control, by conventional use of the controls, throughout the maneuver.

(4) The airplane must not exhibit buffeting of a magnitude and severity that would act as a deterrent from completing the maneuver specified in paragraph 5.1(a).

(b) In maneuvers with increased rates of deceleration, some degradation of characteristics is acceptable, associated with a transient excursion beyond the stabilized Alpha limit. However, the airplane must not exhibit dangerous characteristics or characteristics that would deter the pilot from holding the longitudinal control on the stop for a period of time appropriate to the maneuver.

(c) It must always be possible to reduce incidence by conventional use of the controls.

(d) The rate at which the airplane can be maneuvered from trim speeds associated with scheduled operating speeds such as V_2 and V_{REF} up to Alpha limit must not be unduly damped or be significantly slower than can be achieved on conventionally controlled transport airplanes.

5.3 Characteristics Up to Maximum Lift Angle of Attack

Also in lieu of § 25.201:

(a) In non-icing conditions:

Maneuvers with a rate of deceleration of not more than 1 knot per second up to the angle of attack at which V_{CLmax} was obtained as defined in section 3, ''Minimum Steady Flight Speed and Reference Stall Speed,'' must be demonstrated in straight flight and in 30° banked turns in the following configurations:

(1) The high incidence protection deactivated or adjusted, at the option of the applicant, to allow higher incidence than is possible with the normal production system;

(2) Automatic thrust increase system inhibited (if applicable);

(3) Engines idling;

(4) Flaps and landing gear in any likely combination of positions; and

(5) The airplane trimmed for straight flight at a speed selected by the applicant, but not less than 1.13 V_{SR} and not greater than 1.3 V_{SR}.

(b) In icing conditions:

Maneuvers with a rate of deceleration of not more than 1 knot per second up to the maximum angle of attack reached during maneuvers from paragraph 5.1(b)(3)(ii) must be demonstrated in straight flight with:

(1) The high incidence protection deactivated or adjusted, at the option of the applicant, to allow higher incidence than is possible with the normal production system;

(2) Automatic thrust increase system inhibited (if applicable);

(3) Engines idling;

(4) Flaps and landing gear in any likely combination of positions, and

(5) The airplane trimmed for straight flight at a speed achievable by the automatic trim system.

(c) During the maneuvers used to show compliance with paragraphs (a) and (b) above, the airplane must not exhibit dangerous characteristics, and it

must always be possible to reduce angle of attack by conventional use of the controls. The pilot must retain good lateral and directional control, by conventional use of the controls, throughout the maneuver.

6. Atmospheric Disturbances

Operation of the high incidence protection system must not adversely affect aircraft control during expected levels of atmospheric disturbances, nor impede the application of recovery procedures in case of wind-shear. This must be demonstrated in non-icing and icing conditions.

7. Proof of Compliance

In addition to the requirements of § 25.21, the following requirement applies:

(b) The flying qualities must be evaluated at the most unfavorable center-of-gravity position.

8. Sections 25.145(a), 25.145(b)(6), and 25.1323(d)

The following requirements apply:

• For § 25.145(a), add ''V_{min}'' in lieu of ''stall identification.''

• For § 25.145(b)(6), and ''V_{min}'' in lieu of ''V_{SW}.''

• For § 25.1323(d), add ''From 1.23 V_{SR} to V_{min} . . .,'' in lieu of, ''1.23 V_{SR} to the speed at which stall warning begins . . .,'' and, ''. . . speeds below V_{min} . . .'' in lieu of, ''. . . speeds below stall warning.''

Special Conditions Part II

Credit for Robust Envelope Protection in Icing Conditions

The following special conditions are in lieu of the specified paragraphs of §§ 25.103, 25.105, 25.107, 25.121, 25.123, 25.125, 25.143, and 25.207.

1. Define the stall speed as provided in these special conditions, Part I, in lieu of § 25.103.

2. In lieu of § 25.105(a)(2)(i), the following requirement applies:

(i) The V_2 speed scheduled in non-icing conditions does not provide the maneuvering capability specified in § 25.143(h) for the takeoff configuration, or

3. In lieu of § 25.107(c) and (g), the following requirements apply, with additional sections (c′) and (g′):

Takeoff speeds:

(c) In non-icing conditions V_2, in terms of calibrated airspeed, must be selected by the applicant to provide at least the gradient of climb required by § 25.121(b) but may not be less than—

(1) V_{2MIN};

(2) V_R plus the speed increment attained (in accordance with § 25.111(c)(2)) before reaching a height of 35 feet above the takeoff surface; and

(3) A speed that provides the maneuvering capability specified in § 25.143(h).

(c′) In icing conditions with the ''takeoff ice'' accretion defined in part 25, appendix C, V_2 may not be less than—

(1) The V_2 speed determined in non-icing conditions; and

(2) A speed that provides the maneuvering capability specified in § 25.143(h).

(g) In non-icing conditions, V_{FTO}, in terms of calibrated airspeed, must be selected by the applicant to provide at least the gradient of climb required by § 25.121(c), but may not be less than—

(1) 1.18 V_{SR}; and

(2) A speed that provides the maneuvering capability specified in § 25.143(h).

(g′) In icing conditions with the ''final takeoff ice'' accretion defined in part 25, appendix C, V_{FTO}, may not be less than—

(1) The V_{FTO} speed determined in non-icing conditions.

(2) A speed that provides the maneuvering capability specified in § 25.143(h).

4. In lieu of §§ 25.121(b)(2)(ii)(A), 25.121(c)(2)(ii)(A), and 25.121(d)(2)(ii), the following requirements apply:

In lieu of § 25.121(b)(2)(ii)(A):

(A) The V_2 speed scheduled in non-icing conditions does not provide the maneuvering capability specified in § 25.143(h) for the takeoff configuration; or

In lieu of § 25.121(c)(2)(ii)(A):

(A) The V_{FTO} speed scheduled in non-icing conditions does not provide the maneuvering capability specified in § 25.143(h) for the en-route configuration; or

In lieu of § 25.121(d)(2)(ii):

(d)(2) The requirements of subparagraph (d)(1) of this paragraph must be met: (ii) In icing conditions with the approach ice accretion defined in appendix C, in a configuration corresponding to the normal all-engines-operating procedure in which $V_{min}1g$ for this configuration does not exceed 110% of the $V_{min}1g$ for the related all-engines-operating landing configuration in icing, with a climb speed established with normal landing procedures, but not more than 1.4 V_{SR} (V_{SR} determined in non-icing conditions).

5. In lieu of § 25.123(b)(2)(i), the following requirements apply:

(i) The minimum en-route speed scheduled in non-icing conditions does not provide the maneuvering capability specified in § 25.143(h) for the en-route configuration, or

6. In lieu of §§ 25.125(b)(2)(ii)(B) and 25.125(b)(2)(ii)(C), the following requirements apply:

(B) A speed that provides the maneuvering capability specified in § 25.143(h) with the landing ice accretion defined in part 25, appendix C.

(C) 1.17 $V_{min}1g$.

7. In lieu of § 25.143(j)(1), the following requirement applies:

(1) The airplane is controllable in a pull-up maneuver up to 1.5 g load factor or lower if limited by angle of attack protection; and

8. In lieu of § 25.207, *Stall warning,* to read as the requirements defined in these special conditions Part I, Section 4.

Issued in Renton, Washington, on July 31, 2017.

Victor Wicklund,

Manager, Transport Standards Branch, Aircraft Certification Service.

[FR Doc. 2017–17072 Filed 8–11–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2017–0484; Special Conditions No. 25–700–SC]

Special Conditions: Textron Aviation Inc. Model 700 Airplanes; Use of Automatic Power Reserve for Go-Around Performance Credit

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Textron Aviation Inc. (Textron) Model 700 airplane. This airplane will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport-category airplanes. This design feature is an Automatic Takeoff Thrust Control System (ATTCS), referred to as an Automatic Power Reserve (APR), to set the performance level for approach-climb operation after an engine failure. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: This action is effective on Textron on August 14, 2017. Send your comments by September 28, 2017.

ADDRESSES: Send comments identified by docket number FAA–2017–0484 using any of the following methods:

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

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

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

FOR FURTHER INFORMATION CONTACT: Joe Jacobsen, FAA, Airplane and Flightcrew Interface, ANM–111, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone 425–227–2011; facsimile 425–227–1320.

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

In addition, since the substance of these special conditions has been subject to the public comment process in several prior instances with no substantive comments received, the FAA finds it unnecessary to delay the effective date and finds that good cause exists for adopting these special conditions upon publication in the **Federal Register**.

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

Comments Invited

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

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

Background

On November 20, 2014, Textron applied for a type certificate for their new Model 700 airplane. The Model 700 airplane is a turbofan-powered executive-jet airplane with seating for two crewmembers and 12 passengers. This airplane will have a maximum takeoff weight of 38,514 pounds.

Type Certification Basis

Under the provisions of Title 14, Code of Federal Regulations (14 CFR) 21.17, Textron must show that the Model 700 airplane meets the applicable provisions of part 25, as amended by Amendments 25–1 through 25–139, 25–141, and 25–143.

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

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

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

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

Novel or Unusual Design Features

The Model 700 airplane will incorporate the following novel or unusual design feature: An Automatic Takeoff Thrust Control System, referred to as an Automatic Power Reserve, to set the performance level for approach-climb operation after an engine failure.

Discussion

Textron proposes using the ATTCS function of the Model 700 airplane during go-around and requests approach-climb performance credit for the use of the additional power. The Model 700 powerplant control system comprises a Full Authority Digital Electronic Control (FADEC) for the AS907–2–1S engine. The control system includes an ATTCS feature, referred to as Maximum Takeoff Thrust (MTO), and in the airplane flight manual (AFM), Automatic Power Reserve.

Section 25.904 and part 25, appendix I, limit the application of performance credit for ATTCS to takeoff only. Because the airworthiness regulations do not contain appropriate safety standards for approach-climb performance using ATTCS, special conditions are required to ensure a level of safety equivalent to that established in the regulations.

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

Applicability

As discussed above, these special conditions are applicable to the Textron Model 700 airplane. Should Textron apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, these special conditions would apply to that model as well.

Conclusion

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

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

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

The Special Conditions

The Textron Model 700 airplane must comply with the requirements of 14 CFR 25.904, and appendix I, and the following requirements for the go-around phase of flight:

1. Definitions

a. Takeoff/go-around (TOGA): Throttle lever in takeoff or go-around position.

b. Automatic Takeoff Thrust Control System: The ATTCS in Model 700 airplanes is defined as the entire automatic system available during takeoff and in go-around mode, including all devices, both mechanical and electrical, that sense engine failure, transmit signals, actuate fuel controls or power levers (or increase engine power by other means on operating engines to achieve scheduled thrust or power increase), and furnish cockpit information on system operation.

c. Critical time interval:

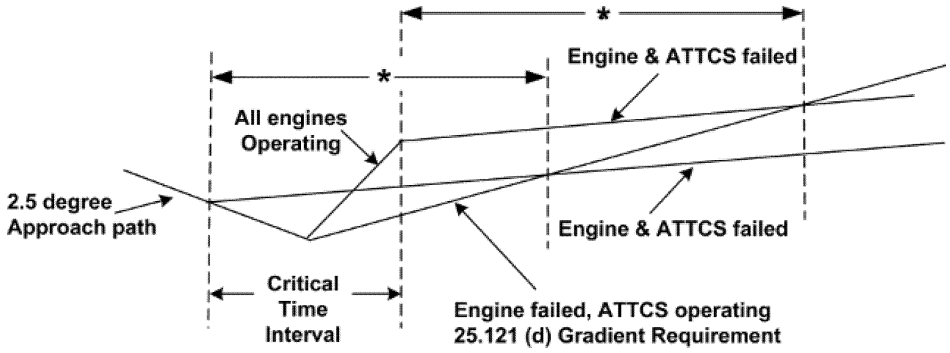
(1) When conducting an approach for landing using ATTCS, the critical time interval is defined as follows:

(i) The critical time interval begins at a point on a 2.5-degree approach glide path from which, assuming a simultaneous engine and ATTCS failure, the resulting approach-climb flight path intersects a flight path originating at a later point on the same approach path that corresponds to the part 25 one-engine-inoperative approach-climb gradient. The period of time from the point of simultaneous engine and ATTCS failure, to the intersection of these flight paths, must be no shorter than the time interval used in evaluating the critical time interval for takeoff, beginning from the point of simultaneous engine and ATTCS failure and ending upon reaching a height of 400 feet.

(ii) The critical time interval ends at the point on a minimum performance, all-engines-operating go-around flight path from which, assuming a simultaneous engine and ATTCS failure, the resulting minimum approach-climb flight path intersects a flight path corresponding to the part 25 minimum one-engine-inoperative approach-climb gradient. The all-engines-operating go-around flight path, and the part 25 one-engine-inoperative approach-climb gradient flight path, originate from a common point on a 2.5-degree approach path. The period of time from the point of simultaneous engine and ATTCS failure, to the intersection of these flight paths, must be no shorter than the time interval used in evaluating the critical time interval for the takeoff, beginning from the point of simultaneous engine and ATTCS failure and ending upon reaching a height of 400 feet.

(2) The critical time interval must be determined at the altitude resulting in the longest critical time interval for which one-engine-inoperative approach-climb performance data are presented in the airplane flight manual.

(3) The critical time interval is illustrated in the following figure:



* The engine and ATTCS failed time interval must be no shorter than the time interval from the point of simultaneous engine and ATTCS failure to a height of 400 feet used to comply with I25.2(b) for ATTCS use during takeoff.

2. Performance and system reliability requirements: The applicant must comply with the performance and ATTCS reliability requirements as follows:

a. An ATTCS failure or a combination of failures in the ATTCS during the critical time interval:

(1) Must not prevent the insertion of the maximum approved go-around thrust or power, or must be shown to be a remote event.

(2) Must not result in a significant loss or reduction in thrust or power, or must be shown to be an extremely improbable event.

b. The concurrent existence of an ATTCS failure and an engine failure during the critical time interval must be shown to be extremely improbable.

c. All applicable performance requirements of part 25 must be met with an engine failure occurring at the most critical point during go-around with the ATTCS functioning.

d. The probability analysis must include consideration of ATTCS failure occurring after the time at which the flightcrew last verifies that the ATTCS is in a condition to operate until the beginning of the critical time interval.

e. The propulsive thrust obtained from the operating engine, after failure of the critical engine during a go-around used to show compliance with the one-engine-inoperative climb requirements of § 25.121(d), may not be greater than the lesser of:

(1) The actual propulsive thrust resulting from the initial setting of power or thrust controls with the ATTCS functioning, or

(2) 111 percent of the propulsive thrust resulting from the initial setting of power or thrust controls with the ATTCS failing to reset thrust or power, and without any action by the flightcrew to reset thrust or power.

3. Thrust setting

a. The initial go-around thrust setting on each engine at the beginning of the go-around phase may not be less than any of the following:

(1) That required to permit normal operation of all safety-related systems and equipment dependent upon engine thrust or power lever position; or

(2) That are shown to be free of hazardous engine-response characteristics, and not to result in any unsafe airplane operating or handling characteristics when thrust or power is advanced from the initial go-around position to the maximum approved power setting.

b. For approval to use an ATTCS for go-arounds, the thrust-setting procedure must be the same for go-arounds initiated with all engines operating as for go-around initiated with one engine inoperative.

4. Powerplant controls

a. In addition to the requirements of § 25.1141, no single failure or malfunction, or probable combination thereof, of the ATTCS, including associated systems, may cause the failure of any powerplant function necessary for safety.

b. The ATTCS must be designed to:

(1) Apply thrust or power to the operating engine(s), following any one-engine failure during a go-around, to achieve the maximum approved go-around thrust without exceeding the engine operating limits;

(2) Permit manual decrease or increase in thrust or power up to the maximum go-around thrust approved for the airplane, under the existing conditions, through the use of the power lever. For airplanes equipped with limiters that automatically prevent the engine operating limits from being exceeded under existing ambient conditions, other means may be used to increase the thrust in the event of an ATTCS failure, provided that the means:

(i) Is located on or forward of the power levers;

(ii) Is easily identified and operated under all operating conditions by a single action of either pilot with the hand that is normally used to actuate the power levers; and

(iii) Meets the requirements of § 25.777(a), (b), and (c).

(3) Provide a means to verify to the flightcrew, before beginning an approach for landing, that the ATTCS is in a condition to operate (unless it can be demonstrated that an ATTCS failure, combined with an engine failure during an entire flight, is extremely improbable); and

(4) Provide a means for the flightcrew to deactivate the automatic function. This means must be designed to prevent inadvertent deactivation.

5. Powerplant instruments: In addition to the requirements of § 25.1305:

a. A means must be provided to indicate when the ATTCS is in the OFF or FAILED condition; and

b. If the inherent flight characteristics of the airplane do not provide adequate warning that an engine has failed, a warning system that is independent of the ATTCS must be provided to give the pilot a clear warning of any engine failure during a go-around.

Issued in Renton, Washington, on August 8, 2017.

Victor Wicklund,

Manager, Transport Standards Branch, Policy and Innovation Division, Aircraft Certification Service.

[FR Doc. 2017–17073 Filed 8–11–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2017–0222; Airspace Docket No. 17–AWP–8]

Amendment of Class D and E Airspace; Hilo, HI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule, technical amendment, correction.

SUMMARY: This action corrects a final rule, technical amendment published in **Federal Register** on June 22, 2017, that amends Class E airspace designated as an extension at Hilo International, General Lyman Field, Hilo, HI. The airport name is corrected to Hilo International Airport, Hilo, HI, removing ''General Lyman Field'' from the airport name to match the FAA's aeronautical database. This technical amendment also corrects the airport name in Class D, Class E surface area airspace, and Class E airspace extending upward from 700 feet above the surface.

DATES: Effective 0901 UTC, August 17, 2017. The Director of the Federal Register approves this incorporation by reference action under Title 1, Code of Federal Regulations, Part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Robert LaPlante, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA 98057; telephone (425) 203–4566.

SUPPLEMENTARY INFORMATION:

History

The FAA published a final rule, technical amendment in the **Federal Register** (82 FR 28404, June 22, 2017) Docket No. FAA–2017–0222, amending Class E Airspace designated as an extension, removing the Notice to Airmen (NOTAM) part-time status at Hilo International, General Lyman Field, Hilo, HI. Subsequent to publication, the FAA found the airport name was incorrect and is now corrected from Hilo International, General Lyman Field, to Hilo International Airport.

In making the airport name change in Class E airspace designated as an extension, the FAA realized that the airport name change for Hilo International Airport also affects Class D airspace, Class E surface area airspace, and Class E airspace extending upward from 700 feet above the surface. This technical amendment correction includes amending the above airspace areas by removing General Lyman Field from the airport name, and does not affect the boundaries or operating requirements of the airport in the associated airspace.

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

Correction to Final Rule

■ Accordingly, pursuant to the authority delegated to me, in the **Federal Register** of June 22, 2017 (82 FR 28404) FR Doc. 2017–13048, Amendment of Class E Airspace; Hilo HI, is corrected as follows:

§ 71.1 [Amended]

Paragraph 5000 Class D Airspace.

* * * * *

AWP HI D Hilo, HI [Amended]

Hilo International Airport, HI

(Lat. 19°43′13″ N., long. 155°02′55″ W.)

That airspace extending upward from the surface to and including 2,500 feet MSL within a 4.3-mile radius of Hilo International Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Pacific Chart Supplement.

Paragraph 6002 Class E Airspace Areas Designated as a Surface Area.

* * * * *

AWP HI E2 Hilo, HI [Amended]

Hilo International, HI

(Lat. 19°43′13″ N., long. 155°02′55″ W.)

That airspace extending upward from the surface within a 4.3-mile radius of Hilo International Airport. This Class E airspace area is effective during the specific dates and

times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Pacific Chart Supplement.

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

* * * * *

AWP HI E4 Hilo, HI [Corrected]

Hilo International Airport, HI
(Lat. 19°43′13″ N., long. 155°02′55″ W.)
Hilo VORTAC
(Lat. 19°43′17″ N., long. 155°00′39″ W.)

That airspace extending upward from the surface within 3 miles each side of the Hilo VORTAC 090° radial, extending from the 4.3-mile radius of Hilo International Airport to 8.7 miles east of the Hilo VORTAC.

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

* * * * *

AWP HI E5 Hilo, HI [Amended]

Hilo International Airport, HI
(Lat. 19°43′13″ N., long. 155°02′55″ W.)
Hilo VORTAC
(Lat. 19°43′17″ N., long. 155°00′39″ W.)

That airspace extending upward from 700 feet above the surface within a 4.3-mile radius of Hilo International Airport and within 3 miles each side of the Hilo VORTAC 090° radial, extending from the 4.3-mile radius to 8.7 miles east of the VORTAC and that airspace extending from the 4.3-mile radius to the 7.4-mile radius of the Hilo International Airport extending clockwise from a line 1.8 miles southwest of and parallel to the Hilo VORTAC 321° radial to a line 3 miles north of and parallel to the Hilo VORTAC 090° radial.

Issued in Seattle, Washington, on August 3, 2017.

Byron Chew,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2017–17004 Filed 8–11–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 133

[Docket No. FDA–2017–D–4713]

Ultrafiltered Milk in the Production of Standardized Cheeses and Related Cheese Products: Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled ''Ultrafiltered Milk in the Production of Standardized Cheeses and Related Cheese Products: Guidance for Industry.'' The guidance advises manufacturers who wish to use ultrafiltered milk (UF milk) or ultrafiltered nonfat milk (UF nonfat milk) in the production of standardized cheeses and related cheese products that, pending completion of a rulemaking regarding the use of UF milk in the production of these products, we intend to exercise enforcement discretion regarding the use of fluid UF milk and fluid UF nonfat milk in the production of standardized cheeses and related cheese products. We also intend to exercise enforcement discretion regarding the declaration of ingredients in the labeling of standardized cheeses and related cheese products when fluid UF milk and fluid UF nonfat milk are used as ingredients.

DATES: The announcement of the guidance is published in the **Federal Register** on August 14, 2017. Submit either electronic or written comments on FDA guidance at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–D–4713 for ''Ultrafiltered Milk in the Production of Standardized Cheeses and Related Cheese Products: Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management

Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to the Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Terri Wenger, Center for Food Safety and Applied Nutrition (HFS–800), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2373.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled ''Ultrafiltered Milk in the Production of Standardized Cheeses and Related Cheese Products: Guidance for Industry.'' We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

Our regulations specify the standards of identity for cheeses and related cheese products in part 133 (21 CFR part 133). The general provisions within part 133, in part, define ''milk'' and ''nonfat milk'' that may be used in the manufacture of cheeses and related cheese products. The definitions for ''milk'' and ''nonfat milk'' in § 133.3(a) and (b), respectively, list different forms of milk and nonfat milk, including concentrated, reconstituted, and dried forms, that may be used in the making of cheeses and related cheese products. However, fluid or dried filtered forms of milk obtained through mechanical filtration of milk or nonfat milk are not included within these definitions. Therefore, while current regulations permit the use of concentrated, reconstituted, and dried forms of milk and nonfat milk as basic dairy ingredients (*i.e.,* the only difference in these ingredients is the amount of water), they do not provide for the use of fluid or dried filtered milk or fluid or dried filtered nonfat milk as basic dairy ingredients in standardized cheeses and related cheese products.

Mechanical filtration technologies available for milk processing include ultrafiltration. For purposes of this guidance, we consider filtration to be a process whereby milk is passed over a series of semipermeable membranes with varying pore sizes. Ultrafiltration retains macromolecules and particles larger than about 0.001–0.02 micrometers. In dairy processing, ultrafiltration is typically used to retain all protein components of milk, including casein and whey proteins, while some of the lactose, minerals, and water soluble vitamins present in milk are lost along with water.

For purposes of the guidance, UF milk means raw or pasteurized milk that is passed over one or more semipermeable membranes to partially remove water, lactose, minerals, and water-soluble vitamins without altering the casein::whey protein ratio of the milk and resulting in a liquid product. UF nonfat milk is defined similarly, except that raw or pasteurized nonfat milk is used.

In the **Federal Register** of October 19, 2005 (70 FR 60751), we issued a proposed rule that would amend our regulations to provide for the use of fluid UF milk in the manufacture of standardized cheeses and related cheese products. We tentatively concluded that the proposed rule, if finalized, would promote honesty and fair dealing in the interest of consumers and, to the extent practicable, achieve consistency with existing international standards of identity for cheeses and related cheese products.

While we have not completed the rulemaking as of August 2017, we are aware of issues regarding UF milk in the United States. In brief, due to recent developments in the export market, the United States dairy industry is experiencing an oversupply of and pricing challenges with domestically produced UF milk (Refs. 1 and 2). Additionally, we have received requests to exercise enforcement discretion while the rulemaking is pending, in part to mitigate the impact on U.S. companies producing UF milk (Ref. 3).

FDA believes that food standards should provide for flexibility in manufacturing procedures and ingredients, provided that the basic nature and essential characteristics of the food are preserved. Given the oversupply of UF milk and the pending rulemaking, through this guidance we are announcing our intent to exercise enforcement discretion regarding the use of fluid UF milk and fluid UF nonfat milk in the production of standardized cheeses and related cheese products under part 133, in addition to the other required dairy ingredients, provided that the physical, chemical, and organoleptic properties of the cheese or cheese product are not affected. FDA is also announcing its intent to exercise enforcement discretion with respect to the labeling of standardized cheeses and related cheese products, when, in addition to milk or nonfat milk, fluid UF milk or fluid UF nonfat milk is used as an ingredient, but is not declared in the ingredient statement, provided that milk or nonfat milk is declared in the ingredient statement. We are exercising enforcement discretion with respect to the labeling of fluid UF milk and fluid UF nonfat milk in recognition of the costs and logistics involved in label changes; however, we encourage industry to identify these ingredients as ''ultrafiltered milk'' and ''ultrafiltered nonfat milk'' to the extent feasible and appropriate. We intend to exercise enforcement discretion until we have completed a rulemaking process amending our regulations with respect to the issues covered by this guidance, or announce in the **Federal Register** our determination not to proceed with such a rulemaking.

We are issuing this guidance without prior public comment under 21 CFR 10.115(g)(2) because we have determined that prior public participation is not feasible or appropriate, as this guidance implements a temporary enforcement policy to address an oversupply of UF pending the completion of rulemaking regarding the use of UF milk in the production of standardized cheeses and related cheese products. The oversupply of UF milk would be worsened if we deferred exercising of enforcement discretion regarding the matters in the guidance while providing an opportunity for prior public comment. (We also note that, as we stated in the preamble to the 2005 proposed rule, we tentatively conclude that fluid UF milk can be used in standardized cheeses while maintaining the essential characteristics of those cheeses specified in the individual standards of identity in part 133 (see 70 FR 60751 at 60756 through 60757).) However, as with all Agency guidances, the public may comment on the guidance at any time. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/FoodGuidances* or *https://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

III. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. Letter from Senator Amy Klobuchar, Senator Al Franken, Representative Collin Peterson, and Representative Tim Walz, to President Donald J. Trump, accessed on the Web at *https://www.klobuchar.senate.gov/public/index.cfm/2017/4/klobuchar-franken-peterson-walz-urge-administration-to-support-minnesota-dairy-farmers-through-strong-enforcement-of-our-trade-laws-with-canada.*
2. Congressional Research Service, ''New Canadian Dairy Pricing Regime Proves Disruptive for U.S. Milk Producers,'' dated April 20, 2017, accessed on the Web at *https://www.everycrsreport.com/reports/IN10692.html.*
3. Letter from Michael D. Dykes, D.V.M., President and CEO, International Dairy Foods Association, to Stephen Ostroff, M.D., Deputy Commissioner for Foods and Veterinary Medicine, Food and Drug Administration, dated June 22, 2017.

Dated: August 9, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–17118 Filed 8–11–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9777]

RIN 1545–BG41; 1545–BH38

Arbitrage Guidance for Tax-Exempt Bonds; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains a correction to final regulations (TD 9777) that were published in the **Federal Register** on Monday, July 18, 2016 (81 FR 46582). The final regulations relate to the arbitrage restrictions under section 148 of the Internal Revenue Code applicable to tax-exempt bonds and other tax-advantaged bonds issued by State and local governments.

DATES: This correction is effective August 14, 2017 and applicable July 18, 2016.

FOR FURTHER INFORMATION CONTACT: Spence Hanemann at (202) 317–6980 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9777) that are the subject of this correction are under section 148 of the Internal Revenue Code.

Need for Correction

As published, the final regulations (TD 9777) contain an error that may prove to be misleading and are in need of clarification.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

Accordingly, 26 CFR part 1 is amended by making the following correcting amendment:

PART 1—INCOME TAXES

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

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

§ 1.148–11 [Amended]

■ **Par. 2.** Amend § 1.148–11(k)(1) by adding ''1.148–6(d)(3)(iii)(A);'' before ''1.148–6(d)(4)''.

Martin V. Franks,

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

[FR Doc. 2017–17135 Filed 8–11–17; 8:45 am]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2017–0034; FRL–9965–26–Region 9]

Approval of California Air Plan Revisions, San Joaquin Valley Unified Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve a revision to the San Joaquin Valley Unified Air Pollution Control District (SJVUAPCD or ''the District'') portion of the California State Implementation Plan (SIP). This revised rule concerns emissions of oxides of nitrogen, carbon monoxide, oxides of sulfur, and particulate matter of 10 microns or less from boilers, steam generators and process heaters. We are approving a local rule that regulates these emission sources under the Clean Air Act (CAA or the Act).

DATES: This rule will be effective on September 13, 2017.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2017–0034. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *http://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Nancy Levin, EPA Region IX, (415) 972–3848, *levin.nancy@epa.gov.*

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

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I. Proposed Action
II. Public Comments and EPA Responses
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I. Proposed Action

On March 21, 2017 (82 FR 14496), the EPA proposed to approve the following rule into the California SIP.

Local agency	Rule No.	Rule title	Amended	Submitted
SJVUAPCD	4307	Boilers, Steam Generators, and Process Heaters—2.0 MMBtu/hr to 5.0 MMBtu/hr.	4/21/16	8/22/16

We proposed to approve this rule because we determined that it complied with the relevant CAA requirements. Our proposed action contains more information on the rule and our evaluation.

II. Public Comments and EPA Responses

The EPA's proposed action provided a 30-day public comment period. During this period, we received one comment.

Comment: The commenter asked how the rule revisions would affect San Joaquin Valley residents, who would benefit from the revisions, and whether the project's impact on human health and the environment outweigh the costs of implementing the revisions.

Response: This comment does not provide any new information or basis for either supporting or opposing EPA's proposal. It merely poses three questions that were previously addressed by EPA's proposal and supporting docket materials. Nonetheless, out of courtesy to the commenter, we summarize our previous analysis, as follows. Prior to the rule revision, the rule exempted tree-nut pasteurizers fired exclusively on natural gas. The revisions expand the exemption to tree-nut pasteurizers fired by liquefied petroleum gas (LPG). The District anticipates a handful of new LPG-fired tree-nut pasteurizers will benefit from the rule revisions, but predicts that the difference in emissions from LPG instead of natural gas will be negligible. The District states that ''[T]he proposed amendment would not result in new or more stringent regulatory controls and would not affect air quality or emission limitations . . . [and that] no costs are associated with this proposed rule amendment.'' [1]

III. EPA Action

No comments were submitted that change our assessment of the rule as described in our proposed action. Therefore, as authorized in section 110(k)(3) of the Act, the EPA is fully approving this rule into the California SIP.

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with the requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the SJVUAPCD rule described in the amendments to 40 CFR part 52 set forth below. The EPA has made, and will continue to make, these documents available through *www.regulations.gov* and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

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

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

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

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 13, 2017. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

[1] San Joaquin Valley Unified Air Pollution Control District, Final Draft Staff Report: Rule 4307 (Boilers, Steam Generators, and Process Heaters—2.0 MMBtu/hr to 5.0 MMBtu/hr), April 21, 2016.

List of Subjects in 40 CFR Part 52

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

Dated: June 21, 2017.

Alexis Strauss,

Acting Regional Administrator, Region IX.

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

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(447)(i)(B)(*2*) and (c)(488)(i)(B) to read as follows:

§ 52.220 Identification of plan-in part.

* * * * *

(c) * * *

(447) * * *

(i) * * *

(B) * * *

(*2*) Previously approved on February 12, 2015 in paragraph (c)(447)(i)(B)(*1*) of this section and now deleted with replacement in (c)(488)(i)(C)(*1*), Rule 4307, ''Boilers, Steam Generators, and Process Heaters—2.0 MMBtu/hr to 5.0 MMBtu/hr,'' amended on May 19, 2011.

* * * * *

(488) * * *

(i) * * *

(B) San Joaquin Valley Unified Air Pollution Control District.

(*1*) Rule 4307, ''Boilers, Steam Generators, and Process Heaters—2.0 MMBtu/hr to 5.0 MMBtu/hr,'' amended on April 21, 2016.

* * * * *

[FR Doc. 2017–16485 Filed 8–11–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2017–0150; FRL–9965–92-Region 1]

Air Plan Approval; Connecticut; Nonattainment New Source Review Permit Requirements for the 2008 8-Hour Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking direct final action to approve the state implementation plan (SIP) revision submitted on March 9, 2017, by the State of Connecticut, through the Connecticut Department of Energy and Environmental Protection (CT DEEP), addressing the nonattainment new source review (NNSR) requirements for the 2008 8-hour ozone National Ambient Air Quality Standards (NAAQS). The SIP revision addresses both of Connecticut's ozone nonattainment areas for the 2008 ozone NAAQS; the Greater Connecticut area and the Connecticut portion of the New York-N. New Jersey-Long Island, NY–NJ–CT area. The Connecticut portion of the New York-N. New Jersey-Long Island, NY–NJ–CT ozone nonattainment area consists of Fairfield, New Haven, and Middlesex counties. The Greater Connecticut nonattainment area includes the rest of the State. This action is being taken pursuant to the Clean Air Act (CAA or Act) and its implementing regulations.

DATES: This direct final rule is effective October 13, 2017 without further notice, unless EPA receives adverse comments by September 13, 2017. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R01–OAR–2017–0150 at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Donald Dahl, U.S. Environmental Protection Agency, EPA New England Regional Office, Office of Ecosystem Protection, Air Permits, Toxics, and Indoor Programs Unit, 5 Post Office Square—Suite 100, (Mail code OEP05–2), Boston, MA 02109–3912. Mr. Dahl's telephone number is (617) 918–1657; email address: *dahl.donald@epa.gov.*

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

Organization of this document. The following outline is provided to aid in locating information in this preamble.

I. Background and Purpose
II. Analysis of Connecticut's Nonattainment New Source Review Requirements
III. Final Action
IV. Statutory and Executive Order Reviews

I. Background and Purpose

On March 12, 2008, EPA promulgated a revised 8-hour ozone NAAQS of 0.075 parts per million (ppm). *See* 73 FR 16436 (March 27, 2008). Under EPA's regulations at 40 CFR 50.15, the 2008 8-hour ozone NAAQS is attained when the 3-year average of the annual fourth-highest daily maximum 8-hour average ambient air quality ozone concentrations is less than or equal to 0.075 ppm. Ambient air quality monitoring data for the 3-year period must meet a data completeness requirement. The ambient air quality monitoring data completeness requirement is met when the average percent of days with valid ambient monitoring data is greater than 90 percent, and no single year has less than 75 percent data completeness as determined in Appendix I of part 50.

Upon promulgation of a new or revised NAAQS, the CAA requires EPA to designate as nonattainment any area that is violating the NAAQS based on the three most recent years of ambient air quality data at the conclusion of the designation process. The two Connecticut areas were designated nonattainment for the 2008 8-hour ozone NAAQS on April 30, 2012

(effective July 20, 2012) using 2009–2011 ambient air quality data. *See* 77 FR 30088 (May 21, 2012). At the time of designation, both Connecticut areas were classified as marginal nonattainment areas. On March 6, 2015, EPA issued a final rule entitled, ''Implementation of the 2008 National Ambient Air Quality Standards for Ozone: State Implementation Plan Requirements'' (SIP Requirements Rule), which establishes the requirements that state, tribal, and local air quality management agencies must meet as they develop implementation plans for areas where air quality exceeds the 2008 8-hour ozone NAAQS.[1] *See* 80 FR 12264. Areas that were designated as marginal ozone nonattainment areas were required to attain the 2008 8-hour ozone NAAQS no later than July 20, 2015, based on 2012–2014 monitoring data. *See* 40 CFR 51.1103. The Connecticut areas did not attain the 2008 8-hour ozone NAAQS by July 20, 2015, and therefore on April 11, 2016, the EPA Administrator signed a final rule reclassifying both Connecticut areas from marginal nonattainment areas to moderate nonattainment areas for the 2008 8-hour ozone standard. *See* 81 FR 26697 (May 4, 2016). Moderate areas are required to attain the 2008 8-hour ozone NAAQS no later than July 20, 2018, six years after the effective date of the initial nonattainment designations. *See* 40 CFR 51.1103.

Based on the initial nonattainment designation for the 2008 8-hour ozone standard, Connecticut was required to develop a SIP revision addressing certain CAA requirements for both nonattainment areas. One component of that was a SIP addressing nonattainment new source review. *See* 40 CFR 51.1114. On March 9, 2017, Connecticut submitted a SIP revision addressing the NNSR requirements related to the 2008 8-hour ozone NAAQS for both nonattainment areas.[2] EPA's analysis of how this SIP revision addresses the NNSR requirements for the 2008 8-hour ozone NAAQS is provided below.

II. Analysis of Connecticut's Nonattainment New Source Review Requirements

The minimum SIP requirements for NNSR permitting programs for the 2008 8-hour ozone NAAQS are located in 40 CFR 51.165. These NNSR program requirements include those promulgated in the ''Phase 2 Rule'' implementing the 1997 8-hour ozone NAAQS (70 FR 71612 (November 29, 2005)) and the SIP Requirements Rule implementing the 2008 8-hour ozone NAAQS. Under the Phase 2 Rule, the SIP for each ozone nonattainment area must contain NNSR provisions that: Set major source thresholds for NO_X and VOC pursuant to 40 CFR 51.165(a)(1)(iv)(A)(*1*)(*i*) through (*iv*) and (a)(1)(iv)(A)(*2*); classify physical changes at a major source if the change would constitute a major source by itself pursuant to 40 CFR 51.165(a)(1)(iv)(A)(3); consider any significant net emissions increase of NO_X as a significant net emissions increase for ozone pursuant to 40 CFR 51.165(a)(1)(v)(E); consider increases of VOC emissions in extreme ozone nonattainment areas as significant net emissions increases and major modifications for ozone pursuant to 40 CFR 51.165(a)(1)(v)(F); set significant emissions rates for VOC and NO_X as ozone precursors pursuant to 40 CFR 51.165(a)(1)(x)(A) through (C) and (E); contain provisions for emissions reductions credits pursuant to 40 CFR 51.165(a)(3)(ii)(C)(*1*) and (*2*); provide that the requirements applicable to VOC also apply to NO_X pursuant to 40 CFR 51.165(a)(8); and set offset ratios for VOC and NO_X pursuant to 40 CFR 51.165(a)(9)(i) through (iii) (renumbered as (a)(9)(ii) through (iv) under the SIP Requirements Rule for the 2008 8-hour ozone NAAQS). Under the SIP Requirements Rule for the 2008 8-hour ozone NAAQS, the SIP for each ozone nonattainment area designated nonattainment for the 2008 8-hour ozone NAAQS and designated nonattainment for the 1997 ozone NAAQS on April 6, 2015, must also contain NNSR provisions that include the anti-backsliding requirements at 40 CFR 51.1105.

Connecticut's longstanding SIP-approved NNSR program, established in Regulations of Connecticut State Agencies (RCSA) Sections 22a–174–1 (definitions), and 22a–174–3a (applicability and substantive requirements) applies to the construction and modification of stationary sources, including major stationary sources in nonattainment areas. In its SIP revision, Connecticut certifies that the version of RCSA Sections 22a–174–1 and 22a–174–3a in the current SIP meet the federal NNSR requirements for both ozone nonattainment areas within Connecticut. EPA last approved revisions to the SIP-approved version of Connecticut's NNSR rule in 2015 addressing, among other things, the NNSR requirements that apply when a major source or major modification causes a significant impact in an area that is violating the $PM_{2.5}$ ambient air quality standard.

Connecticut's SIP-approved NNSR regulation retains the NNSR requirements applicable to serious and severe nonattainment areas, even though the two nonattainment areas in the State are now classified as moderate nonattainment under the 2008 8-hour ozone NAAQS. Connecticut's SIP-approved NNSR regulation defines the term ''Severe nonattainment area for ozone'' as including the cities and towns that were historically part of the severe New York-N. New Jersey-Long Island, NY–NJ–CT ozone nonattainment area designated on November 15, 1990 for the 1-hr ozone NAAQS. The term ''Serious nonattainment area for ozone'' is defined to include ''all towns within the State of Connecticut, except those towns located in the severe non-attainment area for ozone.'' This is the portion of the State that was historically part of the serious Greater Connecticut nonattainment area designated on November 15, 1990 for the 1-hr ozone NAAQS. The SIP's definition of ''Major stationary source'' then uses these terms to define the NO_X and VOC emission thresholds when determining if a source is major for ozone. The SIP's major stationary source threshold for NO_X and VOC in the area defined as a ''Severe nonattainment area for ozone'' is 25 tons per year. The SIP's major stationary source threshold for NO_X and VOC in the area defined as a ''Serious nonattainment area for ozone'' is 50 tons per year. These thresholds for NO_X and VOC are consistent with EPA regulations.

Connecticut's NNSR SIP also properly addresses the thresholds for VOC and NO_X, as precursors to ozone, in the definition of ''Major modification'' by

[1] The SIP Requirements Rule addresses a range of nonattainment area SIP requirements for the 2008 ozone NAAQS, including requirements pertaining to attainment demonstrations, reasonable further progress (RFP), reasonably available control technology, reasonably available control measures, major new source review, emission inventories, and the timing of SIP submissions and of compliance with emission control measures in the SIP. The rule also revokes the 1997 ozone NAAQS and establishes anti-backsliding requirements.

[2] States have three years after the effective date of designation for the 2008 8-hour ozone NAAQS to submit SIP revisions addressing NNSR for their nonattainment areas. *See* 40 CFR 51.1114. Connecticut's SIP revision certified that its SIP-approved state regulation addressing nonattainment new source review for all new stationary sources and modified existing stationary sources in the State exceeds the requirements of section 182(a)(2)(C) for the 2008 8-hour ozone NAAQS. However, EPA does not believe that the two-year deadline contained in CAA section 182(a)(2)(C) applies to NNSR SIP revisions for implementing the 8-hour ozone NAAQS. *See* 80 FR 12264, 12267 (March 6, 2015); 70 FR 71612, 71683 (November 29, 2005). The submission of NNSR SIPs due on November 15, 1992, satisfied the requirement for states to submit NNSR SIP revisions to meet the requirements of CAA sections 172(c)(5) and 173 within two years after the date of enactment of the 1990 CAA Amendments. *Id.*

establishing the threshold for either of these ozone precursors at 25 tons per year. This threshold for a major modification is consistent with EPA regulations. Lastly, since Connecticut's NNSR SIP retains the definitions ''Serious nonattainment area for ozone'' and ''Severe nonattainment area for ozone'' that are based on how the State was designated nonattainment on November 15, 1990 for the 1-hr ozone standard, the State's SIP meets the anti-backsliding requirements.

III. Final Action

EPA is approving Connecticut's March 9, 2017, SIP revision addressing the NNSR requirements for the 2008 8-hour ozone NAAQS for both nonattainment areas in the State. The approval encompasses both the original designations under the 2008 8-hour ozone NAAQS of marginal and the subsequent reclassification of both nonattainment areas to moderate. The approval also includes the applicable NNSR provisions of Connecticut's regulations that satisfy the CAA's anti-backsliding requirements. As discussed above in this notice, Connecticut's SIP retains the NNSR requirements applicable to serious and severe nonattainment areas, even though the two nonattainment areas in the State are now classified as moderate nonattainment areas. EPA has concluded that the State's submission fulfills the 40 CFR 51.1114 revision requirement and meets the requirements of CAA section 110 and the minimum SIP requirements of 40 CFR 51.165.

The EPA is publishing this action without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision should relevant adverse comments be filed. This rule will be effective October 13, 2017 without further notice unless the Agency receives relevant adverse comments by September 13, 2017.

If the EPA receives such comments, then EPA will publish a notice withdrawing the final rule and informing the public that the rule will not take effect. All public comments received will then be addressed in a subsequent final rule based on the proposed rule. The EPA will not institute a second comment period on the proposed rule. All parties interested in commenting on the proposed rule should do so at this time. If no such comments are received, the public is advised that this rule will be effective on October 13, 2017 and no further action will be taken on the proposed rule. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

In addition, Connecticut was issued a finding of failure to submit, which started an 18 month sanctions clock and a 24 month Federal Implementation Plan (FIP) clock. *See* 82 FR 9158 (February 3, 2017). The 18 month sanctions clock was stopped when Connecticut submitted the SIP and we determined it complete on April 19, 2017. The 24 month FIP clock will stop upon the effective date of our final approval, October 13, 2017.

IV. Statutory and Executive Order Reviews

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

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

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

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 13, 2017. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that

EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

Dated: July 24, 2017.

Deborah A. Szaro,

Acting Regional Administrator, EPA New England.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart H—Connecticut

■ 2. Section 52.377 is amended by adding paragraph (r) to read as follows:

§ 52.377 Control strategy: Ozone.

* * * * *

(r) *Approval.* Submittal from the Connecticut Department of Energy and Environmental Protection dated March 9, 2017, to address the nonattainment new source review requirements for the 2008 8-hour ozone NAAQS for the Greater Connecticut and the New York-N. New Jersey-Long Island, NY–NJ–CT ozone nonattainment areas, as it meets the requirements for both the State's marginal and moderate classifications.

[FR Doc. 2017–17021 Filed 8–11–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

[EPA–HQ–OAR–2016–0382; FRL–9966–25–OAR]

RIN 2060–AT15

Revisions to Procedure 2—Quality Assurance Requirements for Particulate Matter Continuous Emission Monitoring Systems at Stationary Sources

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is finalizing revisions to Procedure 2 that were proposed in the **Federal Register** on November 21, 2016. Procedure 2 includes quality assurance/quality control (QA/QC) procedures for particulate matter (PM) continuous emission monitoring systems (CEMS) used for compliance determination at stationary sources. The QA procedures specify the minimum requirements necessary for the control and assessment of the quality of PM CEMS data submitted to the EPA and other regulatory authorities. This action establishes consistent requirements for ensuring and assessing the quality of PM data measured by CEMS that meet initial acceptance requirements in Performance Specification (PS) 11 of appendix B to part 60.

DATES: This final rule is effective on September 13, 2017.

ADDRESSES: *Docket:* The EPA has established a docket for this rulemaking under Docket ID No. EPA–HQ–OAR–2016–0382. All documents in the docket are listed at *https://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the EPA Docket Center, Room 3334, EPA WJC West Building, 1301 Constitution Avenue NW., Washington, DC 20004. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Ms. Kimberly Garnett, Office of Air Quality Planning and Standards, Air Quality Assessment Division, Measurement Technology Group (Mail Code: E143–02), U.S. Environmental Protection Agency, Research Triangle Park, NC 27709; telephone number: (919) 541–1158; fax number: (919) 541–0516; email address: *garnett.kim@epa.gov.*

SUPPLEMENTARY INFORMATION:

The information in this document is organized as follows:

I. General Information
- A. Does this action apply to me?
- B. Where can I get a copy of this document and other related information?
- C. Judicial Review

II. Background

III. Final Revisions to Procedure 2

IV. Summary of Major Comments and Responses

V. Statutory and Executive Order Reviews
- A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
- B. Paperwork Reduction Act (PRA)
- C. Regulatory Flexibility Act (RFA)
- D. Unfunded Mandates Reform Act (UMRA)
- E. Executive Order 13132: Federalism
- F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
- G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
- H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
- I. National Technology Transfer and Advancement Act (NTTAA)
- J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations
- K. Congressional Review Act (CRA)

I. General Information

A. Does this action apply to me?

The entities potentially affected by this rule include any facility that is required to install and operate a PM CEMS under any provision of title 40 of the Code of Federal Regulations. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

B. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this action is available on the Internet through the EPA's Technology Transfer Network (TTN) Web site, a forum for information and technology exchange in various areas of air quality management, measurement standards and implementation, etc. Following publication in the **Federal Register**, the EPA will post the **Federal Register** version of the promulgation and key technical documents on the TTN at *http://www.epa.gov/ttn/emc/promulgated.html.*

C. Judicial Review

Under section 307(b)(1) of the Clean Air Act (CAA), judicial review of this final rule is available only by filing a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit by October 13, 2017. Under

section 307(d)(7)(B) of the CAA, only an objection to this final rule that was raised with reasonable specificity during the period for public comment can be raised during judicial review. Moreover, under section 307(b)(2) of the CAA, the requirements established by this final rule may not be challenged separately in any civil or criminal proceedings brought by the EPA to enforce these requirements. Section 307(d)(7)(B) of the CAA further provides that ''[o]nly an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review.'' This section also provides a mechanism for the EPA to convene a proceeding for reconsideration, ''[i]f the person raising an objection can demonstrate to the EPA that it was impracticable to raise such objection within [the period for public comment] or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule.'' Any person seeking to make such a demonstration to us should submit a Petition for Reconsideration to the Office of the Administrator, U.S. EPA, Room 3000, William Jefferson Clinton Building, 1200 Pennsylvania Avenue NW., Washington, DC 20460, with a copy to both the person(s) listed in the preceding **FOR FURTHER INFORMATION CONTACT** section, and the Associate General Counsel for the Air and Radiation Law Office, Office of General Counsel (Mail Code 2344A), U.S. EPA, 1200 Pennsylvania Avenue NW., Washington, DC 20460. Filing a petition for reconsideration by the Administrator of this final action does not affect the finality of this action for the purposes of judicial review, nor does it extend the time within which a petition for judicial review must be filed, and shall not postpone the effectiveness of this action.

II. Background

On January 12, 2004, the EPA promulgated Procedure 2—Quality Assurance Requirements for Particulate Matter Continuous Emission Monitoring Systems at Stationary Sources (69 FR 1786). Procedure 2, sections 10.4 (5) and (6), contain a requirement for conducting the annual Relative Correlation Audit (RCA) or Relative Response Audit (RRA) QA/QC test procedures, in which a specified amount of the required number of PM CEMS response values, or data points, must lie within the PM CEMS response range used to develop the PM CEMS correlation curve. In other words, when conducting the annual QA/QC tests, the PM CEMS response values should not be higher or lower than the values used to develop the correlation curve for that PM CEMS. Recently, as PM emission limits have been reduced and facilities have installed more robust PM emission control devices, a number of facilities have found that their PM emissions are lower than their PM CEMS correlation curve and, as a result, the facilities are now unable to meet the criteria needed to pass the annual Procedure 2 QA/QC tests. The EPA proposed to modify this language in Procedure 2 through a direct final rule (81 FR 83160; November 21, 2016) and a parallel proposed rule (81 FR 83189; November 21, 2016). In the direct final rule, the EPA stated that if the agency received any significant and relevant adverse comments to the direct final rule, it would withdraw the direct final rule and address all public comments in a subsequent final rule based on the proposed rule. The EPA stated it would not institute a second comment period on the proposed rule (81 FR 83161, November 21, 2016). The EPA received one significant and relevant adverse comment and, therefore, published a withdrawal of the direct final rule (81 FR 10711; February 15, 2017). With this action, the EPA is responding to the adverse comment and finalizing revisions to Procedure 2.

III. Final Revisions to Procedure 2

This action finalizes the changes to Procedure 2 that were proposed on November 21, 2016 (81 FR 83189), and responds to the adverse comment received in response to that proposal by addressing conflicting language in sections 10.4(5) and 10.4(6).

IV. Summary of Major Comments and Responses

A commenter stated that the revisions to Procedure 2, as proposed by the EPA on November 21, 2016, do not achieve the intended result. As the commenter points out, sections 10.4(5) and 10.4(6) still contain language which requires that a portion of the data points from the RRA and RCA ''*must lie within the PM CEMS output range used to develop your correlation curve.*'' The commenter suggested that language in sections 10.4(5)(ii) and 10.4(6)(ii) be removed. The EPA agrees with the commenter and removed the language in sections 10.4(5)(ii) and 10.4(6)(ii). In addition, the language allowing the extension of the correlation curve to accommodate points that are lower than the original curve has been moved to make it clear that it is needed only when determining if the RRA and RCA meet the ± 25 percent criteria originally contained in sections 10.4(5)(iii) and 10.4(6)(iii).

V. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was, therefore, not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA. This action provides performance criteria and QA/QC test procedures for assessing the acceptability of PM CEMS performance and data quality. These criteria and QA/QC test procedures do not add information collection requirements beyond those currently required under the applicable regulation.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. There are no small entities in the regulated industry for which Procedure 2 applies.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

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

This action does not have tribal implications, as specified in Executive Order 13175. Procedure 2 is applicable to facility owners and operators who are responsible for one or more PM CEMS used for monitoring emissions. Thus, Executive Order 13175 does not apply to this action.

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

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

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

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

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

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

The EPA believes that this action will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. This action will help to ensure that emission control devices are operated properly and maintained as needed, thereby helping to ensure compliance with emission standards, which would benefit all affected populations.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 60

Environmental protection, Administrative practice and procedure, Air pollution control, Continuous emission monitoring systems, Particulate matter, Performance specifications, Test methods and procedures.

Dated: August 7, 2017.

E. Scott Pruitt,

Administrator.

For the reasons stated in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 60—STANDARDS OF PERFORMANCE FOR NEW STATIONARY SOURCES

■ 1. The authority citation for part 60 continues to read as follows:

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

■ 2. In Appendix F, Procedure 2, in section 10.4, paragraphs (5) and (6) are revised to read as follows:

Appendix F to Part 60—Quality Assurance Procedures

* * * * *

Procedure 2—Quality Assurance Requirements for Particulate Matter Continuous Emission Monitoring Systems at Stationary Sources

* * * * *

10.4 * * *

(5) What are the criteria for passing a RCA? To pass a RCA, you must meet the criteria specified in paragraphs (5)(i) and (ii) of this section. If your PM CEMS fails to meet these RCA criteria, it is out of control.

(i) For all 12 data points, the PM CEMS response value can be no greater than the greatest PM CEMS response value used to develop your correlation curve.

(ii) At least 75 percent of a minimum number of 12 sets of PM CEMS and reference method measurements must fall within a specified area on a graph of the correlation regression line. The specified area on the graph of the correlation regression line is defined by two lines parallel to the correlation regression line, offset at a distance of ±25 percent of the numerical emission limit value from the correlation regression line. If any of the PM CEMS response values resulting from your RCA are lower than the lowest PM CEMS response value of your existing correlation curve, you may extend your correlation regression line to the point corresponding to the lowest PM CEMS response value obtained during the RCA. This extended correlation regression line must then be used to determine if the RCA data meets this criterion.

(6) What are the criteria to pass a RRA? To pass a RRA, you must meet the criteria specified in paragraphs (6)(i) and (ii) of this section. If your PM CEMS fails to meet these RRA criteria, it is out of control.

(i) For all three data points, the PM CEMS response value can be no greater than the greatest PM CEMS response value used to develop your correlation curve.

(ii) At least two of the three sets of PM CEMS and reference method measurements must fall within the same specified area on a graph of the correlation regression line as required for the RCA and described in paragraph (5)(ii) of this section.

* * * * *

[FR Doc. 2017–17123 Filed 8–11–17; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 300

[Docket No. 170329334–7665–01]

RIN 0648–XF578

Western and Central Pacific Fisheries for Highly Migratory Species; 2017 Bigeye Tuna Longline Fishery Closure

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

ACTION: Temporary rule; fishery closure.

SUMMARY: NMFS is closing the U.S. pelagic longline fishery for bigeye tuna in the western and central Pacific Ocean because the fishery has reached the 2017 catch limit. This action is necessary to ensure compliance with NMFS regulations that implement decisions of the Western and Central Pacific Fisheries Commission (WCPFC).

DATES: Effective 12:01 a.m. local time September 1, 2017, 2017, through December 31, 2017.

ADDRESSES: NMFS prepared a plain language guide and frequently asked questions that explain how to comply with this rule; both are available at *https://www.regulations.gov/docket?D=NOAA-NMFS-2017-0092.*

FOR FURTHER INFORMATION CONTACT: Jarad Makaiau, NMFS Pacific Islands Region, 808–725–5176.

SUPPLEMENTARY INFORMATION: Pelagic longline fishing in the western and central Pacific Ocean is managed, in part, under the Western and Central Pacific Fisheries Convention Implementation Act (Act). Regulations governing fishing by U.S. vessels in accordance with the Act appear at 50 CFR part 300, subpart O.

NMFS established a calendar year 2017 limit of 3,138 metric tons (mt) of bigeye tuna (*Thunnus obesus*) that may be caught and retained in the U.S. pelagic longline fishery in the area of application of the Convention on the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean (Convention Area) (82 FR 36341, August 4, 2017). NMFS monitored the retained

catches of bigeye tuna using logbook data submitted by vessel captains and other available information, and determined that the 2017 catch limit would be reached by September 1, 2017.

In accordance with 50 CFR 300.224(e), this rule serves as notification to fishermen, the fishing industry, and the general public that the U.S. longline fishery for bigeye tuna in the Convention Area will be closed during the dates provided in the **DATES** heading. The fishery is scheduled to reopen on January 1, 2018. This rule does not apply to the longline fisheries of American Samoa, Guam, or the Commonwealth of the Northern Mariana Islands, collectively ''the territories,'' as described below.

During the closure, a U.S. fishing vessel may not retain on board, transship, or land bigeye tuna caught by longline gear in the Convention Area, except that any bigeye tuna already on board a fishing vessel upon the effective date of the restrictions may be retained on board, transshipped, and landed, provided that they are landed within 14 days of the start of the closure, that is, by September 15, 2017. This 14-day landing requirement does not apply to a vessel that has declared to NMFS, pursuant to 50 CFR 665.803(a), that the current trip type is shallow-setting.

During the effective period of the restrictions, longline-caught bigeye tuna may be retained on board, transshipped, and landed if the fish are caught by a vessel with a valid American Samoa longline permit, or if the fish are landed in the territories. In either case, the following conditions must be met:

(1) The fish is not caught in the U.S. Exclusive Economic Zone (EEZ) around Hawaii;

(2) Other applicable laws and regulations are followed; and

(3) The vessel has a valid permit issued under 50 CFR 660.707 or 665.801.

Bigeye tuna caught by longline gear during the closure may also be retained on board, transshipped, and/or landed if they are caught by a vessel that is included in a valid specified fishing agreement under 50 CFR 665.819(c), in accordance with 50 CFR 300.224(f)(1)(iv).

During the closure, a U.S. vessel is also prohibited from transshipping bigeye tuna caught in the Convention Area by longline gear to any vessel other than a U.S. fishing vessel with a valid permit issued under 50 CFR 660.707 or 665.801.

The catch limit and this closure do not apply to bigeye tuna caught by longline gear outside the Convention Area, such as in the eastern Pacific Ocean. To ensure compliance with the restrictions related to bigeye tuna caught by longline gear in the Convention Area, however, the following requirements apply during the closure period (see 50 CFR 300.224):

(1) Longline fishing both inside and outside the Convention Area is not allowed during the same fishing trip. An exception would be a fishing trip that is in progress on September 1, 2017. In that case, the catch of bigeye tuna must be landed by September 15, 2017; and

(2) If a longline vessel fishes outside the Convention Area and the vessel then enters the Convention Area during the same fishing trip, the fishing gear must be stowed and not readily available for fishing in the Convention Area. Specifically, hooks, branch lines, and floats must be stowed and the mainline hauler must be covered.

The above two additional prohibitions do not apply to the following vessels:

(1) Vessels on declared shallow-setting trips pursuant to 50 CFR 665.803(a); and

(2) Vessels operating in the longline fisheries of the territories. This includes vessels included in a valid specified fishing agreement under 50 CFR 665.819(c), in accordance with 50 CFR 300.224(f)(1)(iv). This group also includes vessels with valid American Samoa longline permits and vessels landing bigeye tuna in one of the territories, as long as the bigeye tuna were not caught in the EEZ around Hawaii, the fishing was compliant with all applicable laws, and the vessel has a valid permit issued under 50 CFR 660.707 or 665.801.

Classification

There is good cause under 5 U.S.C. 553(b)(B) to waive prior notice and the opportunity for public comment on this action, because it would be unnecessary and contrary to the public interest. This rule closes the U.S. longline fishery for bigeye tuna in the western and central Pacific as a result of reaching the applicable bigeye tuna catch limit. The limit is codified in Federal regulations and is based on agreed limits established by the Western and Central Pacific Fisheries Commission. 50 CFR 300.224(e) notifies the public that fishing prohibitions will be placed in effect when the limit is reached. NMFS forecasts that the fishery will reach the 2017 limit by September 1, 2017. Longline fishermen have been subject to longline bigeye tuna limits in the western and central Pacific since 2009. They have received ongoing, updated information about the 2017 catch and progress of the fishery in reaching the Convention Area limit via the NMFS Web site, social media, and other means. This constitutes adequate advance notice of this fishery closure. Additionally, the publication timing of this rule provides longline fishermen with seven days advance notice of the closure date, and allows two weeks to return to port and land their catch of bigeye tuna.

For the reasons stated above, there is also good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in effectiveness for this temporary rule. NMFS must close the fishery as soon as possible to ensure that fishery does not exceed the catch limit. According to NMFS stock-status-determination criteria, bigeye tuna in the Pacific Ocean are currently experiencing overfishing. NMFS implemented the catch limit to reduce the effects of fishing on bigeye tuna and restore the stock to levels capable of producing maximum sustainable yield on a continuing basis. Failure to close the fishery immediately would result in additional fishing pressure on this stock, in violation of Federal law and regulations that implement WCPFC decisions.

This action is required by 50 CFR 300.224 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 6901 *et seq.*

Dated: August 9, 2017.

Emily H. Menashes,

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

[FR Doc. 2017–17164 Filed 8–10–17; 11:15 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 150121066–5717–02]

RIN 0648–XF534

Atlantic Highly Migratory Species; Atlantic Bluefin Tuna Fisheries

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

ACTION: Temporary rule; closure of Angling category northern area trophy fishery.

SUMMARY: NMFS closes the northern area Angling category fishery for large medium and giant (''trophy'' (*i.e.,* measuring 73 inches curved fork length or greater)) Atlantic bluefin tuna (BFT). This action is being taken to prevent

overharvest of the Angling category northern area trophy BFT subquota.

DATES: Effective 11:30 p.m., local time, August 11, 2017, through December 31, 2017.

FOR FURTHER INFORMATION CONTACT: Sarah McLaughlin or Brad McHale, 978–281–9260.

SUPPLEMENTARY INFORMATION: Regulations implemented under the authority of the Atlantic Tunas Convention Act (ATCA; 16 U.S.C. 971 *et seq.*) and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*) governing the harvest of BFT by persons and vessels subject to U.S. jurisdiction are found at 50 CFR part 635. Section 635.27 subdivides the U.S. BFT quota recommended by the International Commission for the Conservation of Atlantic Tunas (ICCAT) among the various domestic fishing categories, per the allocations established in the 2006 Consolidated Atlantic Highly Migratory Species Fishery Management Plan (2006 Consolidated HMS FMP) (71 FR 58058, October 2, 2006) and amendments.

NMFS is required, under § 635.28(a)(1), to file a closure notice with the Office of the Federal Register for publication when a BFT quota is reached or is projected to be reached. On and after the effective date and time of such notification, for the remainder of the fishing year or for a specified period as indicated in the notification, retaining, possessing, or landing BFT under that quota category is prohibited until the opening of the subsequent quota period or until such date as specified in the notice.

Angling Category Large Medium and Giant Northern ''Trophy'' Fishery Closure

The 2017 BFT fishing year, which is managed on a calendar-year basis and subject to an annual calendar-year quota, began January 1, 2017. The Angling category season opened January 1, 2017, and continues through December 31, 2017. The currently codified Angling category quota is 195.2 mt, of which 4.5 mt is allocated for the harvest of large medium and giant (trophy) BFT by vessels fishing under the Angling category quota, with 1.5 mt allocated for each of the following areas: North of 39°18′ N. lat. (off Great Egg Inlet, NJ) (the ''northern area''); south of 39°18′ N. lat. and outside the Gulf of Mexico (the ''southern area''); and in the Gulf of Mexico. Trophy BFT measure 73 inches (185 cm) curved fork length or greater.

Based on reported landings from the NMFS Automated Catch Reporting System, NMFS has determined that the codified Angling category northern area trophy BFT subquota has been reached and that a closure of the northern area trophy BFT fishery is warranted. Therefore, retaining, possessing, or landing large medium or giant BFT north of 39°18′ N. lat. by persons aboard vessels permitted in the HMS Angling category and the HMS Charter/Headboat category (when fishing recreationally) must cease at 11:30 p.m. local time on August 11, 2017. This closure will remain effective through December 31, 2017. This action is intended to prevent overharvest of the Angling category northern area trophy BFT subquota, and is taken consistent with the regulations at § 635.28(a)(1). NMFS previously closed the 2017 trophy BFT fishery in the southern area on March 20, 2017 (82 FR 14162, March 17, 2017) and in the Gulf of Mexico on June 7, 2017 (82 FR 26603, June 8, 2017). Therefore, as of August 11, 2017, the Angling category trophy BFT fishery will be closed in all areas for 2017.

If needed, subsequent Angling category adjustments will be published in the **Federal Register**. Information regarding the Angling category fishery for Atlantic tunas, including daily retention limits for BFT measuring 27 inches (68.5 cm) to less than 73 inches and any further Angling category adjustments, is available at *hmspermits.noaa.gov* or by calling (978) 281–9260. HMS Angling and HMS Charter/Headboat category permit holders may catch and release (or tag and release) BFT of all sizes, subject to the requirements of the catch-and-release and tag-and-release programs at § 635.26. Anglers are also reminded that all BFT that are released must be handled in a manner that will maximize survival, and without removing the fish from the water, consistent with requirements at § 635.21(a)(1). For additional information on safe handling, see the ''Careful Catch and Release'' brochure available at *www.nmfs.noaa.gov/sfa/hms/*.

HMS Charter/Headboat and Angling category vessel owners are required to report the catch of all BFT retained or discarded dead, within 24 hours of the landing(s) or end of each trip, by accessing *hmspermits.noaa.gov* or by using the HMS Catch Reporting App.

Classification

The Assistant Administrator for NMFS (AA) finds that it is impracticable and contrary to the public interest to provide prior notice of, and an opportunity for public comment on, this action for the following reasons:

The regulations implementing the 2006 Consolidated HMS FMP and amendments provide for inseason retention limit adjustments and fishery closures to respond to the unpredictable nature of BFT availability on the fishing grounds, the migratory nature of this species, and the regional variations in the BFT fishery. The closure of the northern area Angling category trophy fishery is necessary to prevent any further overharvest of the northern area trophy fishery subquota. NMFS provides notification of closures by publishing the notice in the **Federal Register**, emailing individuals who have subscribed to the Atlantic HMS News electronic newsletter, and updating the information posted on the Atlantic Tunas Information Line and on *hmspermits.noaa.gov.*

These fisheries are currently underway and delaying this action would be contrary to the public interest as it could result in excessive trophy BFT landings that may result in future potential quota reductions for the Angling category, depending on the magnitude of a potential Angling category overharvest. NMFS must close the northern area trophy BFT fishery before additional landings of these sizes of BFT occur. Therefore, the AA finds good cause under 5 U.S.C. 553(b)(B) to waive prior notice and the opportunity for public comment. For all of the above reasons, there is good cause under 5 U.S.C. 553(d) to waive the 30-day delay in effectiveness.

This action is being taken under 50 CFR 635.28(a)(1), and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 971 *et seq.* and 1801 *et seq.*

Dated: August 9, 2017.

Emily H. Menashes,

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

[FR Doc. 2017–17122 Filed 8–9–17; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 82, No. 155
Monday, August 14, 2017

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

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1051

[Docket No. AO–15–0071; AMS–DA–14–0095]

Proposed California Federal Milk Marketing Order; Documents for Official Notice

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Request for public comments.

SUMMARY: This document announces the intention of the Agricultural Marketing Service (AMS) to take Official Notice of documents related to the California Federal Milk Marketing Order (FMMO) rulemaking proceeding. This document invites interested parties to submit comments on whether the documents are relevant to the material issues of the proceeding.

DATES: Comments are due August 29, 2017.

ADDRESSES: Comments should be submitted at the Federal eRulemaking portal: *www.regulations.gov.* Comments may also be filed with the Hearing Clerk, U.S. Department of Agriculture, Room 1031–S, Washington, DC 20250–9200, Facsimile number (202) 720–9976. All comments should reference the docket number and the date and page number of this issue of the **Federal Register**. All comments will be made available for public inspection in the Office of the Hearing Clerk during regular business hours, or can be viewed at: *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Erin Taylor, Acting Director, Order Formulation and Enforcement Division, USDA/AMS/Dairy Program, STOP 0231, Room 2969–S, 1400 Independence Ave. SW., Washington, DC 20250–0231, telephone: (202) 720–7311, or email address: *erin.taylor@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: The U.S. Department of Agriculture (Department) held a hearing from September 22, 2015, through November 8, 2015, regarding promulgation of a Federal Milk Marketing Order (FMMO) in California. During the hearing, participants requested the Department take Official Notice of several documents and resources relevant to the proceeding. The Administrative Law Judge presiding over the hearing ruled that interested parties could submit requests for Official Notice of documents and resources through their post-hearing briefs, and the Department could then make a determination regarding the requests.

Two parties submitted Official Notice requests in their post-hearing briefs and provided lists and sources for the relevant documents. On February 14, 2017, the Department published in the **Federal Register** a recommended decision on the establishment of a California FMMO (82 FR 10634). After an initial review, the Department took Official Notice of many of the documents in the recommended decision. However, the Department did not make a formal determination regarding others.

Two comments filed in response to the recommended decision took exception to the fact that the Department did not rule upon all documents requested for Official Notice submitted in post-hearing briefs by California Dairies, Inc.; Dairy Farmers of America, Inc.; and Land O'Lakes, Inc. (the Cooperatives); and by the Dairy Institute of California (the Institute).

In response, AMS is considering taking Official Notice of these additional documents. The Code of Federal Regulations (7 CFR 900.8) requires providing interested parties an opportunity to object to taking Official Notice of documents because they are inaccurate or erroneously noticed; for example, if they are not relevant to the material issues of the proceeding. This Notice serves to provide interested parties the opportunity to object to the documents below if they believe that any do not meet the requirements of 7 CFR 900.8.

A complete list of these documents, along with links and sources to access them, is available at *www.ams.usda.gov/caorder.* Comments should focus on whether the documents are relevant to the material issues of the California FMMO proceeding, which are as follows:

1. Whether the handling of milk in the proposed marketing area is in the current of interstate commerce, or directly burdens, obstructs, or affects interstate commerce in milk or its products;
2. Whether economic and marketing conditions in California show a need for a Federal marketing order that would tend to effectuate the declared policy of the Act;
3. If an order is issued, what its provisions should be with respect to:
   a. Handlers to be regulated and milk to be priced and pooled under the order;
   b. Classification of milk, and assignment of receipts to classes of utilization;
   c. Pricing of milk;
   d. Distribution of proceeds to producers; and
   e. Administrative provisions.

The Department will consider any objections filed prior to making a determination in this matter.

The Department compiled the following list after reviewing the documents submitted for Official Notice, verifying or correcting the titles provided, and determining whether publically accessible sources exist. As interested parties did not provide hard copies of the documents they were requesting for Official Notice, those documents for which a source was not provided or that the Department determined to lack a publically accessible source are excluded from Official Notice consideration.

Academic Sources

- Pratt, James E., Phillip M. Bishop, Eric M. Erba, Andrew M. Novakovic, and Mark W. Stephenson: A Description of the Methods and Data Employed in the U.S. Dairy Sector Simulator, Cornell Program on Dairy Markets and Policy, July 1997;
- Pratt, James E., Phillip M. Bishop, Eric M. Erba, Andrew M. Novakovic, and Mark W. Stephenson: Normative Estimates of Class I Prices Across U.S. Milk Markets, Cornell Program on Dairy Markets and Policy, July 1998;
- Class I Surface Maps, March 2014 and September 2014: Mark Stephenson;
- Jacobson, Robert E., et al., Research Bulletin 1105: Pricing Grade A Milk Used in Manufactured Dairy Products, Ohio Agriculture Research and Development Center, December 1978; and

- Baker, Burton A., and Rudolph K. Froker: The Evaporated Milk Industry Under Federal Marketing Agreements, University of Wisconsin, August 1945.

Agricultural Marketing Service (AMS) Data and Publications

- AMS Dairy Market News, weekly reports, January 1, 2015–April 2016;
- AMS Dairy Market Statistics, annual reports, 1997–2015;
- AMS FMMO Marketing and Utilization Summary, annual, 2015;
- AMS FMMO Statistics, annual summaries, 1980–2015;
- AMS Mailbox Milk Prices, monthly, January 2012–February 2016;
- AMS Market Information Branch Publication: Measures of Growth in Federal Milk Orders, September 2016;
- AMS National Dairy Product Sales Reports, weekly, 2012–2016;
- AMS Regulatory Impact Analysis on FMMO Reform, March 1999;
- Letter to Handlers in FMMO 1 regarding temporary dumped milk policy, March 2016;
- Letter to Handlers in FMMO 1 regarding temporary dumped milk policy, December 2015;
- List of Supply Plant Systems: Upper Midwest Marketing Area, annual, 2014–2016;
- Lists of Plants and Handlers: Northeast Marketing Area, monthly, 2014–2016;
- Lists of Plants and Handlers: Pacific Northwest and Arizona Marketing Area, monthly, 2014–2016;
- Lists of Plants, Handlers, and Cooperative Associations: Upper Midwest Marketing Area, monthly, 2014–2016; and
- USDA response to industry request for a national hearing on FMMO program prices, September 17, 2012.

California Department of Food and Agriculture (CDFA) Data and Publications

- CDFA Annual Dairy Data, 2015;
- CDFA Appendix: Glossary of Dairy Terms;
- CDFA California Dairy Plant List, 2015;
- CDFA California Dairy Statistics, annual, 2014 and 2015;
- CDFA California Price Data, weighted average prices received for nonfat dry milk and volumes sold by California processors, weekly and monthly;
- CDFA CME Cheddar Cheese and Butter Prices vs. California Sales, monthly, February 2004–November 2013;
- CDFA Dairy Industry Fact Sheet, 2000;
- CDFA Dairy Manufacturing Cost Surveys (September 18, 2007; November 14, 2013; and December 9, 2015);
- CDFA Dairy Product Data, monthly, 2014–year-to-date;
- CDFA Designated Supply Handlers for Procurement, Regions 1 and 2, 2015–2016;
- CDFA Full Manufacturing Cost Survey, 2014;
- CDFA Hearing Panel Report on Class 4b Pricing, June 2015;
- CDFA Milk Production Cost Data, quarterly, 2013–2016;
- CDFA Milk Production Pooling Data, monthly, 2014;
- CDFA Dairy Review Newsletters, monthly, 2003–2016;
- CDFA Pooling Plan for Market Milk as Amended, June 2013;
- CDFA Stabilization and Marketing Plan for Market Milk as Amended, Northern California Marketing Area, August 2015;
- CDFA Stabilization and Marketing Plan for Market Milk as Amended, Southern California Marketing Area, August 2015;
- CDFA Statistics and Trends Annual Tables and Data, 2014;
- CDFA Statistics and Trends Mid-Year Review, January–June 2015;
- CDFA transcripts from Public Hearing to Consider Amendments to Stabilization and Marketing Plans (Class 4b pricing formula changes), June 2015; and
- CDFA Water Quality Regulations for Dairy Operators in California's Central Valley–Overview and Compliance Cost Analysis, November 2010.

California State Statutes

- California Food and Agriculture Code: Division 21, Part 3, Chapter 1, Sections 61301–61573: Marketing of Milk and Other Dairy Products;
- California Food and Agriculture Code: Division 21, Part 3, Chapter 2, Sections 61801–62402: Stabilization and Marketing of Market Milk;
- California Food and Agriculture Code: Division 21, Part 3, Chapter 2.5, Sections 62500–62667: Milk Producer's Security Fund;
- California Food and Agriculture Code: Division 21, Part 3, Chapter 3, Sections 62700–62731: Equalization Pools; and
- California Food and Agriculture Code: Division 21, Part 3, Chapter 3.5, Sections 62750–62757: Milk Pooling.

Congressional Legislation

- 1965 Farm Bill;
- 1970 Farm Bill;
- 1985 Farm Bill;
- 2008 Farm Bill;
- 2000 Appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies; and
- Milk Regulatory Equity Act of 2005.

Economic Research Service (ERS) Publications

- ERS Dairy Data Spreadsheets: U.S. Dairy Situation at a Glance; Dairy Products Per Capita Consumption; Milk Cows and Production by State and Region; Annual Milk Production and Factors Affecting Supply; Per Capita Consumption of Selected Cheese Varieties (most current spreadsheets);
- ERS Milk Costs of Production: Costs and returns per hundredweight sold by state, annual, 2010–2014;
- ERS Milk Costs of Production: Costs and returns per hundredweight sold by size group, annual, 2014 (data set contains 2010–2014);
- ERS Milk Costs of Production: U.S. dairy costs of production per hundredweight of milk sold, monthly, 2015;
- ERS Publication: Pricing Milk and Dairy Products: Principles, Practices, and Problems, 1971;
- ERS Report to Congress: Report on the United States Department of Agriculture's Reporting Procedures for Nonfat Dry Milk, September 2007;
- ERS Situation and Outlook Reports: Feed Outlook Reports, monthly, 2014–2015; and
- ERS Situation and Outlook Reports: Livestock, Dairy and Poultry Outlook Reports (Dairy Part), monthly, 2014–2016.

National Agricultural Statistics Service (NASS) Data and Publications

- NASS Dairy Products Mandatory Program Web page;
- NASS Dairy Products Prices, weekly, 1998–2012;
- NASS Dairy Products, annual summary, 1997–2015 (data for 1995–2014);
- NASS Dairy Products, monthly, January 2015–April 2016;
- NASS Milk Cows and Production Final Estimates (SB 988), data covers 1998–2002;
- NASS Milk Cows and Production Final Estimates (SB 1022), data covers 2003–2007;
- NASS Milk Cows and Production Final Estimates (SB 1036), data covers 2008–2012;
- NASS Milk Production, Disposition, and Income Annual Summary, 1995–2015;
- NASS Milk Production, monthly reports, January 2015–February 2016;
- NASS Overview of the United States Dairy Industry, September 22, 2010;

• NASS Dairy Products Prices: How Does That Work?; and

• NASS Survey Cheddar Cheese Price Data (May 23, 1997; June 27, 1997; August 1, 1997; September 5, 1997; October 10, 1997; December 19, 1997; December 29, 1997; January 23, 1998; February 20, 1998; March 20, 1998; April 24, 1998; May 29, 1998; June 26, 1998; July 31, 1998; August 28, 1998; and October 2, 1998).

USDA Office of the Chief Economist Publication

• Drought Monitor: Percentage of crops and livestock located in drought, March 2016.

Federal Government Resources

• Census Bureau data on Upper Midwest FMMO, Market Area Population;

• Energy Information Administration Weekly Retail Gasoline and Diesel Prices, January 2011–July 2015;

• Federal Highway Administration Highway Statistics Summary to 1995; and

• Federal Highway Administration Highway Statistics, Annual Issues, 1995–2012.

Federal Register Publications

• 3 FR 1945–1949 regarding the handling of milk in the New York Metropolitan Marketing Area, August 1938;

• 26 FR 7134–7141 regarding amendments to the Chicago marketing order, August 1961;

• 27 FR 799–816 regarding amendments to pricing of milk reserves and excess reserves, January 1962;

• 31 FR 7062 regarding a Puget Sound, Washington, market area expansion and amendments to producer-handler definition, May 1966;

• 39 FR 11567–11571 regarding a partial decision on emergency measures to suspend butter powder prices, March 1974;

• 44 FR 48128–48130 regarding a decision to not promulgate an order in the Southwestern Idaho-Eastern Oregon marketing area, August 1979;

• 50 FR 32716, 32718–32719 regarding a decision to expand two marketing areas and revise location differentials in the Middle Atlantic and New York-New Jersey areas, August 1985;

• 52 FR 15951–15960 regarding termination of proceedings on proposed amendments to the Georgia and certain other marketing areas, May 1987;

• 53 FR 686–731 regarding the merger of two marketing areas in the Great Basin and Lake Mead marketing areas, January 1988;

• 53 FR 36321–36334 regarding a final decision to provide partial credits to handlers hauling surplus milk in the Texas marketing area, September 1988;

• 55 FR 25618–25669 regarding promulgation of a Carolina FMMO, June 1990;

• 56 FR 57850–57864 regarding a decision to adopt multiple component pricing for the Mid-Atlantic FMMO, November 1991;

• 58 FR 58112–58137 regarding amendments to the New England and Certain Other Marketing Areas, October 1993;

• 59 FR 8546–8565 regarding amendments to the Pacific Northwest and Southwestern Idaho-Eastern Oregon Marketing Areas, February 1994;

• 60 FR 7290–7333 regarding amendments to the New England and Other Marketing Areas, February 1995;

• 60 FR 25014–25071 regarding amendments to the Georgia and Certain Other Marketing Areas, May 1995;

• 60 FR 41833–41868 regarding amendments to the Chicago Regional and Other Marketing Areas, August 1995;

• 60 FR 43066–43089 regarding amendments to the Southern Michigan Marketing Area, August 1995;

• 64 Fed Reg. 70868–70912 regarding amendments to the New England and Other Marketing Areas, December 1999;

• 65 FR 76832–76861 regarding amendments to the Northeast and Other Marketing Areas, December 2000;

• 70 FR 74166, 7418 regarding a final decision on amendments to the Pacific Northwest and Arizona-Las Vegas Marketing Areas, December 2005;

• 71 FR 67467–67495 regarding amendments to the Northeast and Other Marketing Areas, November 2006;

• 73 FR 11194–11229 regarding amendments to the Appalachian, Florida, and Southeast Marketing Areas, February 2008;

• 73 FR 35306–35331 regarding amendments to the Northeast and Other Marketing Areas, June 2008;

• 75 FR 33534–33533 regarding amendments to the Northeast and Other Marketing Areas, June 2010; and

• 78 FR 9248 regarding a final decision to adopt changes to the make allowances and butterfat yield factor in Class III and IV price formulas, February 2013.

Authority: 7 U.S.C. 601–608.

Dated: August 8, 2017.

Bruce Summers,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 2017–17100 Filed 8–11–17; 8:45 am]

BILLING CODE 3410–02–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2017–0150; FRL–9965–91–Region 1]

Air Plan Approval; Connecticut; Nonattainment New Source Review Permit Requirements for the 2008 8-Hour Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve the state implementation plan (SIP) revision submitted on March 9, 2017, by the State of Connecticut, through the Connecticut Department of Energy and Environmental Protection (CT DEEP), addressing the nonattainment new source review (NNSR) requirements for the 2008 8-hour ozone National Ambient Air Quality Standards (NAAQS). The SIP revision addresses both of Connecticut's ozone nonattainment areas for the 2008 ozone NAAQS; the Greater Connecticut area and the Connecticut portion of the New York-N. New Jersey-Long Island, NY-NJ-CT area. The Connecticut portion of the New York-N. New Jersey-Long Island, NY-NJ-CT ozone nonattainment area consists of Fairfield, New Haven, and Middlesex counties. The Greater Connecticut nonattainment area includes the rest of the State. This action is being taken pursuant to the Clean Air Act (CAA or Act) and its implementing regulations.

DATES: Written comments must be received on or before September 13, 2017.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R01–OAR–2017–0150 at *https://www.regulations.gov,* or via email to *dahl.donald@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to

make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Donald Dahl, U.S. Environmental Protection Agency, EPA New England Regional Office, Office of Ecosystem Protection, Air Permits, Toxics, and Indoor Programs Unit, 5 Post Office Square—Suite 100, (Mail code OEP05–2), Boston, MA 02109–3912. Mr. Dahl's telephone number is (617) 918–1657; email address: *dahl.donald@epa.gov.*

SUPPLEMENTARY INFORMATION: In the Final Rules Section of this issue of the **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

For additional information, see the direct final rule which is located in the Rules Section of this issue of the **Federal Register**.

Dated: July 24, 2017.

Deborah A. Szaro,

Acting Regional Administrator, EPA New England.

[FR Doc. 2017–17022 Filed 8–11–17; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[CG Docket No. 17–169; FCC 17–91]

Protecting Consumers From Unauthorized Carrier Changes and Related Unauthorized Charges

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Commission proposes to amend its rules to prohibit carriers from misrepresenting themselves when placing telemarketing sales calls to consumers and placing unauthorized charges on their phone bills. The Commission seeks comment on ways to strengthen its rules to protect consumers from slamming and cramming and proposes to codify a rule prohibiting misrepresentations on carrier telemarketing calls to consumers that often precede a carrier switch, and proposes to codify a rule against cramming. The intended effect of this action is to prevent unscrupulous carriers from targeting vulnerable populations from committing fraud either on sales calls or when ''verifying'' a consumer switch.

DATES: Comments are due on or before September 13, 2017, and reply comments are due on or before October 13, 2017.

ADDRESSES: You may submit comments identified by CG Docket No. 17–169 and/or FCC Number 17–91, by any of the following methods:

- *Electronic Filers:* Comments may be filed electronically using the Internet by accessing the Commission's Electronic Comment Filing System (ECFS), through the Commission's Web site: *http://apps.fcc.gov/ecfs/.* Filers should follow the instructions provided on the Web site for submitting comments. For ECFS filers, in completing the transmittal screen, filers should include their full name, U.S. Postal service mailing address, and CG Docket No. 17–169.
- *Mail:* Parties who choose to file by paper must file an original and one copy of each filing. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although the Commission continues to experience delays in receiving U.S. Postal Service mail). All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

For detailed instructions for submitting comments and additional information on the rulemaking process, *see* the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Kimberly A. Wild, Consumer Policy Division, Consumer and Governmental Affairs Bureau (CGB), at (202) 418–1324, email: *Kimberly.Wild@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Rules and Policies Protecting Consumers from Unauthorized Carrier Changes and Related Unauthorized Charges, Notice of Proposed Rulemaking,* document FCC 17–91, adopted on July 13, 2017, released on July 14, 2017. The full text of document FCC 17–91 will be available for public inspection and copying via ECFS, and during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street SW., Room CY–A257, Washington, DC 20554. A copy of document FCC 17–91 and any subsequently filed documents in this matter may also be found by searching ECFS at: *http://apps.fcc.gov/ecfs/* (insert CG Docket No. 17–169 into the Proceeding block).

Pursuant to 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using ECFS. *See* Electronic Filing of Documents in Rulemaking Proceedings, 63 FR 24121 (1998).

- All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th Street SW., Room TW–A325, Washington, DC 20554. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building.
- Commercial Mail sent by overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.
- U.S. Postal Service first-class, Express, and Priority mail should be addressed to 445 12th Street SW., Washington, DC 20554.

Pursuant to § 1.1200 of the Commission's rules, 47 CFR 1.1200, this matter shall be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules. Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentations must contain summaries of the substances of the presentations

and not merely a listing of the subjects discussed. More than a one or two sentence description of the views and arguments presented is generally required. *See* 47 CFR 1.1206(b). Other rules pertaining to oral and written *ex parte* presentations in permit-but-disclose proceedings are set forth in § 1.1206(b) of the Commission's rules, 47 CFR 1.1206(b).

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to: *fcc504@fcc.gov* or call CGB at: (202) 418–0530 (voice), or (202) 418–0432 (TTY). Document FCC 17–91 can also be downloaded in Word or Portable Document Format (PDF) at: *https://www.fcc.gov/document/fcc-proposes-rules-aid-investigation-threatening-calls.*

Initial Paperwork Reduction Act of 1995 Analysis

Document FCC 17–91 seeks comment on proposed rule amendments that may result in modified information collection requirements. If the Commission adopts any modified information collection requirements, the Commission will publish another notice in the **Federal Register** inviting the public to comment on the requirements, as required by the Paperwork Reduction Act (PRA). Public Law 104–13; 44 U.S.C. 3501–3520. In addition, pursuant to the Small Business Paperwork Relief Act of 2002, the Commission seeks comment on how it might further reduce the information collection burden for small business concerns with fewer than 25 employees. Public Law 107–198, 116 Stat. 729; 44 U.S.C. 3506(c)(4).

Synopsis

1. All too often, unscrupulous carriers target Americans, including those within vulnerable populations like the elderly, recent immigrants, small businesses, and non-English speakers, to carry out unauthorized carrier changes, or ''slams.'' These carriers misrepresent who they are and why they are calling, fraudulently verify carrier changes, and add unauthorized charges, or ''crams,'' onto consumers' bills. Some sales agents pretend they are calling from a consumer's existing carrier, others pretend to call about a package delivery to record a consumer saying certain key phrases like their name and ''yes.'' Still others bill for services never rendered or refuse to stop billing for new services even after a consumer terminates service.

2. With document FCC 17–91, the Commission seeks comment on additional steps to protect consumers from slamming and cramming. The Commission seeks to strengthen its ability to take action against slammers and crammers, and deter carriers from slamming and cramming in the first place, without impeding competition or impairing the ability of consumers to switch providers.

Background

Slamming Rules

3. Section 258 of the Communications Act of 1934, as amended (Communications Act or Act), makes it unlawful for any telecommunications carrier to ''submit or execute a change in a subscriber's selection of a provider of telephone exchange service or telephone toll service except in accordance with such verification procedures as the Commission shall prescribe.'' To further protect consumers from slamming and provide them with control over their service providers, the Commission's rules allow consumers to opt in to freeze their choice of carriers. At the same time, the rules do not allow for the executing carrier to verify that the subscriber wants to change carriers, so as to avoid undue delay in authorized switches. Finally, the Commission adopted rules for calculating slamming carrier liability.

Continuing Problem

4. Notwithstanding the Commission's rulemaking and enforcement actions to date, slamming and cramming continue to be a problem. Slammers, or would-be slammers, have also crammed consumers as part of their fraud schemes. The Commission is cognizant that it must balance the benefits of the proposals in document FCC 17–91 against the burden they may place on legitimate carrier changes and third-party charges. The steps the Commission seeks comment on today to strengthen its rules seek to address the evolving practices of bad actors with respect to slamming and cramming, while not impeding competition or impairing the ability of consumers to switch providers.

Notice of Proposed Rulemaking

5. In document FCC 17–91, the Commission seeks comment on ways to strengthen its rules to protect consumers from slamming and cramming. The Commission believes its legal authority stems directly from sections 201(b) and 258 of the Act. The Commission has based slamming and cramming rules on these provisions of the Act in the past. The Commission notes that section 258 of the Act is clear that carriers cannot execute switches unless they do so ''in accordance with such verification procedures as the Commission shall prescribe.'' The Commission believes the anti-slamming steps it proposes here are ''verification procedures'' consistent with the authority specified in section 258 of the Act. Similarly, the Commission has found that both sections 201(b) and 258 of the Act support its truth-in-billing rules, including those to prevent cramming on consumers' bills. The Commission seeks comment on the nature and scope of its authority to adopt the rules it proposes in document FCC 17–91.

Banning Misrepresentation and Unauthorized Charges

6. The Commission's recent enforcement actions reveal that a major source of slamming is deception in the sales calls. The Commission seeks comment on proposed new rules to address sales call abuses and further reduce slamming. The Commission's current rules contain detailed verification procedures, adopted under section 258 of the Act, that specify that carriers shall not submit or execute carrier changes without authorization from the subscriber and verification of that authorization. The Commission has previously held that misrepresentations on sales calls are an unjust and unreasonable practice and unlawful under section 201(b) of the Act. Although the Commission has in place verification rules to prevent slamming, its rules do not expressly ban carrier- or carrier-agent-misrepresentations on the sales calls that typically precede a slam. The Commission thus proposes to codify, pursuant to sections 258 and 201(b) of the Act, a new § 64.1120(a)(1)(i)(A) of its rules banning misrepresentations on the sales calls and stating that any misrepresentation or deception would invalidate any subsequent verification of a carrier change, even where the submitting carrier purports to have evidence of consumer authorization (*e.g.,* a TPV recording). The Commission believes codifying such a ban would provide even greater clarity to carriers and will aid its enforcement efforts. The Commission seeks comment on this proposal. Are there any potential downsides to a codified rule against sales call misrepresentation? The Commission notes that its slamming rules currently do not apply to CMRS, pre-paid wireless, or interconnected Voice over Internet Protocol (VoIP). Are such misrepresentations enough of a problem for CMRS, pre-paid wireless and interconnected VoIP and sufficient to justify extending its proposed rule to cover those services? Would such a rule

impose any burden on legitimate marketing? How should the proposed rule interact with existing State slamming rules?

7. The Commission also proposes to codify a rule against cramming. While cramming has been a long-standing problem and the Commission has adopted truth-in-billing rules to help detect it, the Commission has never codified a rule against cramming. The Commission thus proposes to codify in a new § 64.2401(g) of its rules the existing prohibition against cramming that the Commission has enforced under section 201(b) of the Act. The Commission believes codifying the cramming prohibition for wireline and wireless carriers would act as a deterrent. The Commission believes codifying a ban against cramming would provide even greater clarity to carriers and will aid its enforcement. The Commission seeks comment on this proposal. Are there any potential downsides to such a rule? The Commission's cramming rules currently do not apply to interconnected VoIP, and only some of the cramming rules apply to CMRS. Should the Commission extend this proposed rule to CMRS, pre-paid wireless and interconnected VoIP? Are there limitations on the Commission's ability to adopt the proposed cramming rule? Should this proposed rule be codified under the slamming rules as opposed to the cramming rules? The truth-in-billing rules do not define ''cramming'' or ''telephone bill.'' The Commission seeks comment on whether it should adopt such definitions for clarity of its rules. Many consumers today receive electronic bills and have constant online access to their telephone account showing in near real-time all fees, charges and assessments. If the Commission defines ''telephone bill'' in its rules, should it include the various ways that consumers can keep track of their telephone account activity?

PIC Freezes and Third-Party Billing

Preferred Carrier Freezes by Default

8. The Commission's current rules allow consumers to protect themselves from slamming by ''freezing'' their choice of wireline providers if their local exchange carrier offers that ability. But to do so, a consumer must affirmatively opt in. Given the trend of consumers preferring to buy local and long-distance services together rather than separately, as well as emerging abusive practices in the market for resold local and long-distance services, the Commission seeks comment on making freezes the default so that consumers are automatically afforded additional protection against slamming, rather than requiring them to take extra steps to do so. The Commission believes this would give consumers more control to prevent slamming. Today, carriers must offer freezes for local, intraLATA and interLATA services and get separate authorization from consumers for each of the services the consumer chooses to freeze. A majority of consumers today purchase bundles of services rather than selecting individual services, and the Commission believes most consumers have no reason to distinguish interLATA and intraLATA services. The Commission seeks comment on eliminating the service distinctions for these purposes and having carrier freezes apply to all telephone services a consumer has with no need to seek separate authorization. The Commission believes consumers purchase CMRS and interconnected VoIP as all distance services and thus a default freeze does not make sense for these services. The Commission seeks comment on that view and whether it should consider extending default freezes to those services.

9. If the Commission were to adopt a default freeze rule, should it apply to all local exchange carriers, or only those that currently offer freezes? What effect would the Commission's proposal have on carrier billing systems and sales practices? How should consumers be notified about this change to ensure they are fully aware of the default freeze? Should the Commission change its current requirements for notifying consumers about freezes, or relax those requirements? What procedures should be put in place to lift a default freeze? The Commission seeks comment on whether its freeze proposal would affect number exhaustion by incenting carriers to issue new numbers to consumers while waiting for the freeze to be lifted. The Commission's goals are to ensure that the default freeze is a strong safeguard against slamming while not unduly burdening consumers who may want to opt out of a freeze or giving executing carriers who may be losing the customer an opportunity to behave anti-competitively. The Commission seeks comment on how to achieve these goals along with whether carriers should be able to charge for freezes.

10. What are the costs and benefits of a default freeze? For carriers that already offer consumers a freeze option, the cost to implement a default freeze should be relatively low, essentially changing a field in a preexisting database. For carriers that do not currently offer a preferred carrier freeze to their consumers, the implementation costs would presumably be greater. The benefits of a default freeze may be substantial, because would-be slammers would face significant obstacles to carrying out their intended slams. The Commission seeks comment on these views and ask commenters to provide details on costs and benefits of both implementing a default freeze and procedures to lift a default freeze. Can the Commission mitigate the costs by, for example, extending implementation deadlines and considering additional specific relief for smaller carriers? Could costs be further mitigated by applying a default freeze only to new customers and not existing ones? Should the Commission distinguish between smaller local exchange carriers and larger local exchange carriers in what rules should apply? What would be the cost savings for consumers and carriers in avoiding the expense and inconvenience of restoring service with their original carrier after a slam and seeking a refund for the unauthorized charges?

Blocking Certain Third-Party Billing by Default

11. Today, the Commission's rules do not prohibit carriers from placing third-party charges on consumers' bills without verification by the consumer, a practice that has led to cramming. Consumers who do not have a preferred long-distance provider have been crammed when a third-party carrier adds its long-distance service to the consumer's bill without authorization. Some consumers discover a slam and have their preferred carrier's service reinstated but are still billed by the slamming carrier for local or long-distance service.

12. The Commission seeks comment on requiring wireline carriers to block third-party charges for local and long-distance service—a frequent source of slamming-related cramming—by default, and only bill such charges if a consumer opts in. Do consumers generally expect to be charged for local or long-distance service by third parties? What trends, if any, could inform the Commission's understanding of how consumers make choices in the market for telephone service? How prevalent are such third-party charges? Do the natural reductions in third-party billing as a result of market changes reduce the need for the type of rule the Commission proposes? The Commission notes that the vast majority of complaints and enforcement actions appear to target the billing practices of traditional local exchange carriers, not wireless carriers or interconnected VoIP providers. Is that because wireless

carriers and interconnected VoIP providers generally offer local and long-distance services as a bundle or for some other reason? Notwithstanding the lack of complaints and enforcement actions about CMRS and interconnected VoIP, the Commission seeks comment on whether it should extend its proposal to those services.

13. How exactly should an opt-in process for third-party local and long-distance service work? For example, if a carrier offered its subscribers access to information about their account online, could a simple control be added so that consumers could opt in (or later opt back out) of third-party local and long-distance service billing? What opt-in options should be available for consumers that do not have Internet access? What information, if any, should be presented to consumers before they opt in to such third-party charges? Should opting in last indefinitely, or sunset after some period of time? Or could consumers opt in for only a single service change? How should consumers be made aware of the opt-in option? Should the Commission require providers to notify consumers at the point of sale? Should such notice appear on the provider's Web site and advertising materials or on consumers' bills? The Commission notes that several carriers have committed to blocking certain non-telecommunications third-party charges in the past. The Commission seeks specific comments on the processes they used to inform consumers about these changes.

14. The Commission also seeks comment on several corner cases. For local exchange carriers that do not offer long-distance service, should opt in be required before any third-party long-distance service is charged to the consumer or only any change in third-party long-distance service? For consumers that currently subscribe to a third-party local or long-distance service, should those services be grandfathered? Or should those consumers be considered to have opted in already? And how should the Commission structure any rule to minimize the impact on single-use services—such as placing an international call through a third-party carrier or receiving a collect call—or other legitimate third-party local or long-distance services that haven't been subject to the same pattern of abuse that the Commission has seen in recent slamming and cramming cases?

15. The Commission seeks comment on the costs and benefits of an opt-in process for third-party local and long-distance charges. The Commission believes that blocking such charges would be beneficial to consumers and reduce slamming and cramming significantly. Yet the Commission recognizes that changes to carrier billing systems can be costly. The Commission believes many carriers already have the ability to block third-party charges, and seeks comment on whether this is correct, and whether there would be any challenges, including billing system and notification changes, for carriers arising from adopting an opt-in mechanism for third-party charges. What are the costs of implementing an opt-in mechanism for third-party charges? For those carriers that do not currently offer the option to block third-party charges, what costs would be associated with making that protection available to consumers and how could the Commission craft rules to minimize those costs and burdens? Would the costs to carriers be mitigated if the timeframe to implement the opt-in mechanism was extended or if the opt-in mechanism was phased in, for example, by requiring an opt-in for new customers only? Do small carriers have unique implementation costs or other burdens, and if so, how should the Commission address those issues?

Double-Checking a Switch With the Consumer

16. Rather than requiring an opt in before placing third-party local or long-distance charges on a bill, should the Commission require the executing carrier to confirm or ''double-check'' whether the consumer wants to switch providers before making the change? Requiring the executing carrier to double-check a change request could be a strong anti-slamming safeguard because it gives the consumer a second opportunity to confirm a switch. If the Commission were to adopt such a requirement, the Commission seeks comment on how the Commission could best implement it.

17. Would requiring that the executing carrier obtain the consumer's consent in writing or through the email address of record sufficiently protect consumers? Would mandating that the executing carrier obtain oral consent via a phone call to the consumer at the telephone number of record provide consumers with more protection from slamming? If the Commission requires the executing provider to confirm a switch request, what should the executing carrier be required to ask (*e.g.,* ''the submitting carrier says that you would like to switch to them. Is that correct?'')? Are there First Amendment implications related to prescribing the language to be used by the executing carrier? Should the executing carrier have to follow, for all switch requests, the procedures that are presently only in place when a consumer has activated a preferred carrier freeze? Should the double-check by the executing carrier be strictly limited to certain narrow questions with no opportunity for retention marketing? Should there be a deadline by which the double-check must occur? Should the executing carrier be required to notify the new carrier of the timing and outcome of the double-check? If so, should there be a timeframe within which that notice must occur? Finally, what should the consequences be if an executing carrier fails to meet the deadline? The Commission seeks comment on the effect the proposal would have on carrier billing systems and sales practices. Finally, the Commission seeks comment on whether its proposed double-check would have any effect on number exhaustion by incenting carriers to issue new numbers to consumers while waiting for verification and execution of the carrier change.

18. Currently, unless a consumer has activated a preferred carrier freeze, the slamming rules do not allow the executing carrier to verify whether the subscriber wants to change carriers when it receives a preferred carrier change request because of previous Commission concerns that that approach would be expensive, unnecessary, and duplicative of the submitting carrier's verification. At the time those rules were adopted, the local and long-distance markets had only been recently opened to competition, and there was concern that an executing carrier might intentionally delay the carrier change or attempt to retain the subscriber. Today, the market for wireline communications services is more established and competitive, and consumers have access to a wide variety of providers and technologies to obtain long-distance services and are more likely to purchase bundles of services from the same provider. In addition, slamming has evolved, and the rules the Commission adopted almost two decades ago have not proven effective in preventing slamming. Do market trends involving stand-alone long-distance service impact the need for the type of slamming rules the Commission proposes? Based on the marketplace today, the Commission also seeks comment on the relationship between the ease of switching voice providers and broadband adoption. The Commission seeks to avoid unintended negative consequences of its proposals. For example, would they effectively

''lock'' consumers into bundles of services that may not meet their current broadband needs? Finally, and fundamentally, the Commission seeks comment on the prevalence of incidences of slamming as seen in its enforcement actions versus the number of legitimate carrier changes that occur.

19. Given these changes in the marketplace and the continued and evolving problem of slamming faced by consumers, the Commission seeks comment on whether the Commission's previous concerns about delays and anti-competitive practices that could arise from a double-check requirement are still valid. If the previous concerns are still well-founded, are those concerns now outweighed by other factors, such as ensuring that consumers are not victimized by the new forms of slamming? The Commission seeks comment on whether and how the changed circumstances since 1998 have reduced the danger of anti-competitive behavior, as well as how to structure a double-check mechanism to avoid or limit any competitive harms. Similar to its proposals above, the Commission seeks comment on whether it should extend its proposal to CMRS and interconnected VoIP providers. In the past, the Commission expressed concern that requiring verification by the executing carrier could be a *de facto* preferred carrier freeze without the consumer's consent that would take control away from consumers. The Commission seeks comment on whether the Commission should adopt both a verification by the executing carrier and the default carrier freeze proposed above. Are these processes duplicative and if so, does it make sense to provide consumers with two levels of protection against slamming? Does one option benefit consumers in ways that the other does not? The Commission seeks comment on the costs to consumers, if any, of both options.

20. The Commission also seeks comment on the costs and benefits of requiring some form of secondary verification by the executing carrier before switching a consumer's long-distance provider. The Commission believes the costs of requiring the executing carrier to perform a simple double-check by phone, email or in writing would be fairly modest, yet the consumer benefit in stopping slamming would be substantial. The Commission seeks comment on these views and ask commenters to provide details on costs and benefits. The Commission also seeks comment on how it can further mitigate the costs by, for example, extending implementation deadlines of any rules adopted and considering additional specific relief for smaller carriers.

21. *Section 222(b) of the Act.* When it previously determined that executing carriers should not verify carrier changes, the Commission expressed concern that such verification would violate section 222(b) of the Act. Section 222(b) of the Act states that a carrier that ''receives or obtains proprietary information from another carrier for purposes of providing any telecommunications service shall use such information only for such purpose, and shall not use such information for its own marketing efforts.'' The Commission found that the information contained in a submitting carrier's change request is proprietary because the submitting carrier must provide information regarding the consumer's choice of long-distance providers to the executing carrier, to which the executing carrier would otherwise not have access, to obtain provisioning of service for the new subscriber. Thus, under the Commission's current rules the executing carrier can only use the information to provide service to the submitting carrier, *i.e.,* changing the subscriber's carrier, and may not attempt to verify that subscriber's decision to change carriers.

22. The Commission notes that section 222(d)(2) of the Act provides an exception allowing the carrier to use the customer *information* ''to protect users of those services and other carriers from fraudulent, abusive, or unlawful use of, or subscription to such services.'' The Commission tentatively concludes that this exception supports its proposals to allow the executing carrier to use the customer information to re-verify that the consumer wants to change providers. The Commission seeks comment on this interpretation. The Commission also seeks comment on whether a carrier indeed is using the ''proprietary information'' received from a submitting carrier only for ''purposes of providing any telecommunications service'' if it uses that information to verify a carrier switch without conducting any additional marketing. The Commission seeks comment on whether double-checking by the executing provider could be permissive, rather than required, and whether permissive double-checking would fulfill the Commission's policy goals of deterring slamming.

23. If the Commission determines that section 222 of the Act supports requiring executing carriers to confirm a switching request, it is important to note that the exceptions in section 222(d) of the Act that allow the carrier to use the consumer information for a specific purpose would not allow the re-verification process to be used for retention marketing, and any rule the Commission adopts would bar the executing carrier from using the confirmation process for marketing or anticompetitive purposes. The Commission seeks comment on this view, and on how its rules could best implement such a bar.

Other Measures

Recording Sales Calls

24. The Commission's current verification rules provide that carriers shall not submit or execute carrier changes without authorization from the subscriber and verification of that authorization. The Commission seeks comment on whether submitting carriers that rely on TPVs should be required to record the entire sales call that precedes a switch. The Commission seeks comment on how to define a sales call. The Commission believes that a requirement to record all sales calls would deter misrepresentation and aid enforcement if misrepresentation does occur. The Commission seeks comment on this view.

25. If the Commission requires that sales calls be recorded, should the Commission require the same two-year retention of the recordings as it currently does for TPV calls? Should the Commission also require that sales representatives give the consumer specific information to help them understand the call's purpose, for example: (1) The identity of the company that is calling or on whose behalf the call is being made; (2) that the sales representative is not affiliated with the consumer's current long-distance, international, or other toll carrier (if true); and (3) the purpose of the call is to inquire whether the consumer is authorized to make a change to and wishes to change his or her long-distance, international, or other toll service from his or her current preferred carrier to the calling carrier. Should the Commission's rules also prohibit the sales representative from (1) making any false or misleading statements to the consumer regarding the third-party verifier or the role of the verifier, and (2) instructing the consumer in how he or she should respond to the verifier's questions? In the alternative, the Commission seeks comment on whether recording the sales call should be voluntary as opposed to being required and whether a valid recording should serve as an affirmative defense if a slamming complaint was filed against the carrier. Further, are there First

Amendment implications related to prescribing specific notifications?

26. The Commission does not believe that requiring the disclosures discussed above, as well as recording and preserving the sales call, would be costly for providers. At the same time, based on evidence from recent consumer complaints and enforcement actions indicating that sales call misrepresentations are a significant source of slamming, the Commission believes the benefits to consumers are material. The Commission seeks comment on these views and asks commenters to provide details on costs and benefits of its proposals. The Commission also seeks comment on how it can further mitigate the costs by, for example, extending implementation deadlines and considering additional specific relief for smaller carriers.

Third-Party Verifications

27. The Commission seeks comment on whether TPVs are an effective means of providing evidence that a consumer wishes to switch carriers. Would eliminating TPVs as a verification mechanism be effective in preventing slamming and provide substantial benefits to consumers? How would the elimination of TPVs affect legitimate providers' sales efforts? If the TPV is eliminated, are there other mechanisms the Commission should put in place to verify authorization of a carrier change? Should consumers have the option to sign up for service online after the sales call has ended, or to call a designated customer service number to confirm their desire to switch long distance or other toll services? The Commission seeks comment on the impact of these or other verification mechanisms on competition. The Commission seeks comment on the costs and benefits of elimination of the TPV option. The Commission also seeks comment on how it can further mitigate any costs to providers by, for example, extending implementation deadlines and considering additional specific relief for smaller carriers.

28. If the Commission decides to retain TPVs as evidence of a consumer's wish to switch providers, how might it make them more difficult to falsify? The Commission's rules require that TPVs elicit certain information, including the subscriber's identity, that the person on the call is authorized and wishes to make the switch, and the telephone numbers to be switched. Should the Commission update the TPV requirements to require that consumers affirmatively state all telephone numbers to be switched, rather than, as is currently permitted, to allow the third-party verifier to read off the numbers to be switched? Because the third-party verifier must already obtain specific information during the TPV, the Commission does not believe adding this requirement represents a significant additional cost. But the Commission believes it would benefit consumers by making it more difficult to falsify TPVs.

29. Are there other ways to ensure the validity of the TPV? For example, should the Commission require certification of third-party verifiers by either carriers or the Commission? Does the Commission have authority to require such certification? The Commission also seeks comment on whether there are any current provisions in its verification requirements that it could update to make the rules clearer and easier to follow. Should the Commission eliminate the requirement that verifiers must get confirmation of each individual service sold (*e.g.,* intraLATA and interLATA service)? Does this requirement make sense in today's bundle-oriented marketplace? The Commission asks commenters to provide details on costs and benefits of implementing these potential rule changes. The Commission also seeks comment on how it can further mitigate the costs by, for example, extending implementation deadlines and considering additional specific relief for smaller carriers.

Initial Regulatory Flexibility Act Analysis

30. As required by the Regulatory Flexibility Act of 1980, as amended, (RFA), the Commission has prepared the Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on a substantial number of small entities by the policies and rules proposed in document FCC 17–91. Written public comments are requested on the IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments on document FCC 17–91 provided on the first page of document FCC 17–91. The Commission will send a copy of document FCC 17–91, including the IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA).

Need for, and Objectives of, the Proposed Rules

30. Document FCC 17–91 contains proposals regarding how to strengthen the Commission's rules to prevent slamming and cramming. Slamming is the unauthorized change of a consumer's preferred interexchange telecommunications service provider and cramming is the placement of unauthorized charges on a consumer's telephone bill. Despite detailed slamming rules and truth-in-billing rules, thousands of consumers are still being slammed and billed for unauthorized charges. Since, 2010, the Commission's Enforcement Bureau has brought multiple actions against carriers for slamming and cramming violations. These actions have resulted in over $80 million dollars in fines and proposed forfeitures. The Commission believes that adopting the proposals in document FCC 17–91 will provide consumers with the additional safeguards they need to protect themselves from this risk.

31. Specifically, document FCC 17–91 seeks comment on whether and, if so, how: (1) The Commission should codify in a rule the prohibition against deceptive marketing and misrepresentations on the sales call; (2) the Commission should codify in a rule the prohibition against placing unauthorized charges on a consumer's telephone bill; (3) the Commission should make preferred carrier freezes the default rather than something the consumer must initiate; (4) the Commission should require consumers to opt in to third-party billing; (5) the Commission should require executing carriers to make contact with consumers to verify preferred carrier change requests prior to execution; (6) the Commission should require recording and retention of the sales call; and (7) the Commission should modify the verification rules relating to preferred carrier changes to require the consumer to affirmatively list the telephone numbers to be switched in a TPV, or update the TPV requirements to eliminate the requirement to list all services being changed, or eliminate the TPV altogether as an option to verify authorization of a carrier switch.

Legal Basis

32. The legal basis for any action that may be taken pursuant to document FCC 17–91 is contained in sections 1–4, 201(b), and 258 of the Communications Act of 1934, as amended, 47 U.S.C. 151–154, 201(b), 258.

Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply

33. The RFA directs agencies to provide a description of, and where feasible, an estimate of the number of small entities that will be affected by the proposed rules, if adopted. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small

organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act. Under the Small Business Act, a ''small business concern'' is one that: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) meets any additional criteria established by the Small Business Administration.

Wireline Carriers

34. *Incumbent Local Exchange Carriers (Incumbent LECs).* Neither the Commission nor the SBA has developed a small business size standard specifically for incumbent local exchange services. The closest applicable size standard under SBA rules is for the category Wired Telecommunications Carriers. The U.S. Census Bureau defines this industry as ''establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired communications networks. Transmission facilities may be based on a single technology or a combination of technologies. Establishments in this industry use the wired telecommunications network facilities that they operate to provide a variety of services, such as wired telephony services, including VoIP services, wired (cable) audio and video programming distribution, and wired broadband internet services. By exception, establishments providing satellite television distribution services using facilities and infrastructure that they operate are included in this industry.'' Under that size standard, such a business is small if it has 1,500 or fewer employees. Census data for 2012 show that there were 3,117 firms that operated that year. Of this total, 3,083 operated with fewer than 1,000 employees. Consequently, the Commission estimates that most providers of incumbent local exchange service are small businesses.

35. *Competitive Local Exchange Carriers (Competitive LECs), Competitive Access Providers (CAPs), Shared-Tenant Service Providers, and Other Local Service Providers.* Neither the Commission nor the SBA has developed a small business size standard specifically for these service providers. The appropriate size standard under SBA rules is for the category Wired Telecommunications Carriers. The U.S. Census Bureau defines this industry as ''establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired communications networks. Transmission facilities may be based on a single technology or a combination of technologies. Establishments in this industry use the wired telecommunications network facilities that they operate to provide a variety of services, such as wired telephony services, including VoIP services, wired (cable) audio and video programming distribution, and wired broadband internet services. By exception, establishments providing satellite television distribution services using facilities and infrastructure that they operate are included in this industry.'' Under that size standard, such a business is small if it has 1,500 or fewer employees. Census data for 2012 show that there were 3,117 firms that operated that year. Of this total, 3,083 operated with fewer than 1,000 employees. Consequently, the Commission estimates that most providers of competitive local exchange service, competitive access providers, Shared-Tenant Service Providers, and other local service providers are small entities.

36. The Commission has included small incumbent LECs in this present RFA analysis. As noted above, a ''small business'' under the RFA is one that, inter alia, meets the pertinent small business size standard (*e.g.,* a telephone communications business having 1,500 or fewer employees), and ''is not dominant in its field of operation.'' The SBA's Office of Advocacy contends that, for RFA purposes, small incumbent LECs are not dominant in their field of operation because any such dominance is not ''national'' in scope. The Commission has therefore included small incumbent LECs in this RFA analysis, although it emphasizes that the RFA action has no effect on Commission analyses and determinations in other, non-RFA contexts.

37. *Interexchange Carriers (IXCs).* Neither the Commission nor the SBA has developed a small business size standard specifically for providers of interexchange services. The appropriate size standard under SBA rules is for the category Wired Telecommunications Carriers. The U.S. Census Bureau defines this industry as ''establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired communications networks. Transmission facilities may be based on a single technology or a combination of technologies. Establishments in this industry use the wired telecommunications network facilities that they operate to provide a variety of services, such as wired telephony services, including VoIP services, wired (cable) audio and video programming distribution, and wired broadband internet services. By exception, establishments providing satellite television distribution services using facilities and infrastructure that they operate are included in this industry.'' Under that size standard, such a business is small if it has 1,500 or fewer employees. Census data for 2012 show that there were 3,117 firms that operated that year. Of this total, 3,083 operated with fewer than 1,000 employees. Consequently, the Commission estimates that the majority of IXCs are small entities.

38. *Other Toll Carriers.* Neither the Commission nor the SBA has developed a size standard for small businesses specifically applicable to Other Toll Carriers. This category includes toll carriers that do not fall within the categories of interexchange carriers, operator service providers, pre-paid calling card providers, satellite service carriers, or toll resellers. The closest applicable size standard under SBA rules is for Wired Telecommunications Carriers. The U.S. Census Bureau defines this industry as ''establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired communications networks. Transmission facilities may be based on a single technology or a combination of technologies. Establishments in this industry use the wired telecommunications network facilities that they operate to provide a variety of services, such as wired telephony services, including VoIP services, wired (cable) audio and video programming distribution, and wired broadband internet services. By exception, establishments providing satellite television distribution services using facilities and infrastructure that they operate are included in this industry.'' Under that size standard, such a business is small if it has 1,500 or fewer employees. Census data for 2012 show that there were 3,117 firms that operated that year. Of this total, 3,083 operated with fewer than 1,000 employees. Thus, under this category and the associated small business size standard, the majority of Other Toll Carriers can be considered small.

Wireless Carriers

39. *Wireless Telecommunications Carriers (except Satellite).* Since 2007, the Census Bureau has placed wireless firms within this new, broad, economic census category. Under the present and prior categories, the SBA has deemed a wireless business to be small if it has 1,500 or fewer employees. For the category of Wireless Telecommunications Carriers (except Satellite), Census data for 2012 show that there were 967 firms that operated for the entire year. Of this total, 955 firms had fewer than 1,000 employees. Thus under this category and the associated size standard, the Commission estimates that the majority of wireless telecommunications carriers (except satellite) are small entities. Similarly, according to internally developed Commission data, 413 carriers reported that they were engaged in the provision of wireless telephony, including cellular service, Personal Communications Service PCS, and Specialized Mobile Radio SMR services. Of this total, an estimated 261 have 1,500 or fewer employees. Thus, using available data, the Commission estimates that the majority of wireless firms can be considered small.

Resellers

40. *Local Resellers.* The SBA has developed a small business size standard for the category of Telecommunications Resellers. Under that size standard, such a business is small if it has 1,500 or fewer employees. Census data for 2012 show that 1,341 firms provided resale services during that year. Of that number, all operated with fewer than 1,000 employees. Thus, under this category and the associated small business size standard, the majority of these pre-paid calling card providers can be considered small entities.

41. *Toll Resellers.* The SBA has developed a small business size standard for the category of Telecommunications Resellers. Under that size standard, such a business is small if it has 1,500 or fewer employees. Census data for 2012 show that 1,341 firms provided resale services during that year. Of that number, all operated with fewer than 1,000 employees. Thus, under this category and the associated small business size standard, the majority of these pre-paid calling card providers can be considered small entities.

Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities

42. Document FCC 17–91 contains proposals regarding how to strengthen the Commission's rules to prevent slamming and cramming. Until the proposed rules are defined in full, it is not possible to predict with certainty whether the costs of compliance will be proportionate between small and large providers. The Commission seeks to minimize the burden associated with reporting, recordkeeping, and other compliance requirements for the proposed rules.

43. The proposals under consideration could result in additional costs to regulated entities. These proposals may necessitate that some carriers create new processes or make changes to their existing processes which would impose some additional costs to carriers. Document FCC 17–91 proposes to require: Reverification by the executing carrier; a default carrier freeze and procedures to lift the freeze; recording of sales calls and retention of such recordings for two years; certain information be conveyed during the sales call; implementation of new marketing methods; and an explicit opt-in decision for third-party billing. These proposals may require changes to certain carrier processes. However, some carriers may already be in compliance with some of these requirements and therefore, no additional compliance efforts will be required.

Steps Taken To Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

44. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.

45. The Commission proposes rules to eliminate slamming and cramming on consumers' bills. The Commission believes that any economic burden these proposed rules may have on carriers is outweighed by the considerable benefits to consumers. Consumers are currently being charged for services they never authorized and in some instances never received. In addition, consumers must expend significant time and energy trying to recoup these costs and get back to the provider of their choice. In document FCC 17–91 the Commission specifically asks how to minimize the economic impact of its proposals on small entities. For instance, the Commission seeks comment on the specific costs of the measures it discusses in document FCC 17–91, and ways it might mitigate any implementation costs, including by extending implementation deadlines for small carriers. It also particularly asks whether smaller carriers face unique implementation costs and, if so, how the Commission might address those concerns. In addition, for example, it seeks comment on alternatives for how a carrier should obtain a consumer's decision to opt in to third-party charges, if the Commission decides to adopt an ''opt-in'' approach. Finally, the Commission seeks comment on the overall economic impact these proposed rules may have on carriers because the Commission seeks to minimize all costs associated with these proposed rules.

46. The Commission expects to consider the economic impact on small entities, as identified in comments filed in response to document FCC 17–91 and the IRFA, in reaching its final conclusions and taking action in this proceeding.

Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rules

47. None.

List of Subjects in 47 CFR Part 64

Claims, Communications common carriers, Computer technology, Credit, Foreign relations, Individuals with disabilities, Political candidates, Radio, Reporting and recordkeeping requirements, Telecommunications, Telegraph, Telephone.

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison Officer, Office of the Secretary.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 64 as follows:

PART 64—MISCELLANEOUS RULES RELATING TO COMMON CARRIERS

■ 1. The authority citation for part 64 continues to read as follows:

Authority: 47 U.S.C. 154, 225, 254(k), 403(b)(2)(B), (c), 715, Pub. L. 104–104, 110

Stat. 56. Interpret or apply 47 U.S.C. 201, 218, 222, 225, 226, 227, 228, 254(k), 616, 620, and the Middle Class Tax Relief and Job Creation Act of 2012, Pub. L. 112–96, unless otherwise noted.

■ 2. Amend § 64.1120 by revising paragraph (a)(1)(i) to read as follows:

§ 64.1120 Verification of orders for telecommunications services.

(a) * * *

(1) * * *

(i) Authorization from the subscriber, subject to the following:

(A) Misrepresentation and/or deception on the sales call is prohibited. Authorization is not valid if there is any misrepresentation and/or deception when making the sales call.

(B) [Reserved]

* * * * *

■ 3. Amend § 64.2401 by adding paragraph (g) to read as follows:

§ 64.2401 Truth-in Billing Requirements.

* * * * *

(g) Prohibition against unauthorized charges. Carriers shall not place or cause to be placed on any telephone bill charges that have not been authorized by the subscriber. For purposes of this subsection, telephone bill means any bill that contains charges for an interstate telecommunications service.

[FR Doc. 2017–16961 Filed 8–11–17; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register
Vol. 82, No. 155
Monday, August 14, 2017

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

DEPARTMENT OF COMMERCE

U.S. Census Bureau

Proposed Information Collection; Comment Request; Participant Statistical Areas Program

AGENCY: U.S. Census Bureau, Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: To ensure consideration, submit written comments, on or before October 13, 2017.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the internet at *PRAcomments@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information or copies of the information collection instrument(s) and instructions to Robin A. Pennington, U.S. Census Bureau, 4600 Silver Hill Road, Washington, DC 20233 (or via the internet at *robin.a.pennington@census.gov*).

SUPPLEMENTARY INFORMATION:

I. Abstract

Following Census Bureau guidelines, the Participant Statistical Areas Program (PSAP) allows participants to review and suggest modifications to the boundaries for block groups, census tracts, census county divisions (CCDs), and census designated places (CDPs). Additionally, tribal government designees can review or propose changes for tribal statistical areas, which include: Tribal block groups (TBGs), tribal census tracts (TCTs), CDPs, tribal designated statistical areas (TDSAs), state designated tribal statistical areas (SDTSAs), state reservations,[1] Alaska Native village statistical areas (ANVSAs), Oklahoma tribal statistical areas (OTSA), and OTSA tribal subdivisions. Participants, usually geographers or planners, are representatives from tribal, state, county, or local governments, and planning agencies. The Census Bureau contacts participants from the 2010 PSAP and invites tribal, state, county, or local governments, and planning agencies to the 2020 PSAP. The statistical boundaries delineated in PSAP reflect localized knowledge, meet Census Bureau-established criteria and guidelines, and are intended to better meet data user needs. These standard or tribal statistical geographies are reviewed and refined once every ten years in advance of each decennial census.

The PSAP geographies represent statistical units for the tabulation and dissemination of small area data from the decennial census, the American Community Survey (ACS), and other Census Bureau programs and surveys. While legal boundaries, such as cities and counties, allow the Census Bureau to publish data by those areas, local governments often need data for planning by smaller units, such as neighborhoods. PSAP is a unique program initiated and executed by the Census Bureau to allow local and regional governments to break larger geographic areas into smaller units so that they can receive 2020 Census and ACS data by these smaller units and better plan local services. PSAP occurs between March 2018 and October 2020 and has three primary components:

1. PSAP Internal Review.
2. PSAP Delineation.
3. PSAP Verification.

The primary participants are tribal governments, regional planning agencies, and councils of governments. Individual counties and incorporated places may participate in the program if they have the resources or better local knowledge of their geography. State agencies may also act on behalf of non-tribal, local governments that lack the resources to participate in the program.

1—PSAP Internal Review

From March 2018 through May 2018, Census Bureau staff will contact 2010 Census PSAP participants to solicit participation in the 2020 Census PSAP. During this time, Census Bureau staff will also research and identify contacts where the Census Bureau has no 2010 Census PSAP participant contact information. Census Bureau staff will encourage designated 2020 Census PSAP contacts to reach out to tribal, state, county and local contacts, as well as planning organizations to ensure additional stakeholders have the opportunity to be involved in the 2020 Census PSAP.

In July 2018, all tribal, state, county, or local governments, and planning agencies receive an official invitation package by mail. The participant receives a Contact Update Form that they fill out and return to the Census Bureau. The Census Bureau then sends reminder packages to governments that do not respond in the time period mentioned on the Contact Update Form. Census Bureau staff perform an internal review of PSAP entities prior to the distribution of materials to the partners. This internal review ensures each of the statistical areas meets the criteria as defined. Partners will have an option to start with statistical areas from 2010 or the Census Bureau proposed areas for 2020.

2—Program Delineation

In December 2018, the Census Bureau notifies program participants of the start of the delineation phase. The Census Bureau conducts delineation of the 2020 PSAP boundaries using the web-based Geographic Update Partnership Software (GUPS), a customized geographic information system (GIS) based on an open-source platform. Participants can either download the materials and software online from the Census Bureau's Web site or have them shipped on DVDs. Tribal participants have the additional option to use Census Bureau-provided paper maps for the delineation. Participants have a maximum of 120 days from the date of receipt of materials to complete and submit statistical geography updates to the Census Bureau. The delineation phase occurs between December 2018

[1] State reservations are not statistical areas, but they are included in PSAP for administrative reasons.

and July 2019. Then, in July 2019, the Census Bureau sends follow-up letters to inform participants when the verification phase will start.

3—Program Verification

The verification phase allows participants to review the proposed edits from Census Bureau geographers. The Census Bureau sends a prepaid postcard to participants asking them to verify, accept, or reject the final version of the proposed plan, which is available online or by paper maps for tribal participants. Participants have 90 calendar days to review updates. Census Bureau staff contacts non-respondents through a follow-up mail-out and follow-up telephone calls. Once the Census Bureau receives the postcard with the participants' approval or acceptance of the final verification plan, the Census Bureau finalizes the 2020 statistical boundaries. This phase occurs between December 2019 and April 2020.

II. Method of Collection

The Census Bureau offers two methods of collection for the 2020 Census PSAP: GUPS submission (electronic) and paper map submission. The Census Bureau uses several formats to collect information and updates for statistical boundaries during the internal review, delineation, and verification phases. The Census Bureau collects updated contact information from participants who choose to participate in the program online, by email, and by telephone. The Census Bureau-provided software, GUPS, is the only method of response for state and local governments. Some tribal participants only have the option to use the paper map submission (TDSAs, ANVSAs, STDSAs, OTSAs, and OTSA tribal subdivisions).

GUPS Submission

The Census Bureau developed GUPS to provide (1) a free digital update option to those participants lacking an existing GIS and (2) standardized tools and functions enabling participants to navigate quickly and accurately through the update process. In addition, the standardized GUPS submissions enable Census Bureau staff to review, process, and incorporate submissions quickly and accurately into its database. Participants can download GUPS materials via the Web site or request DVDs of the materials via mail.

Participants use GUPS to review their updated standard or tribal statistical geographies already delineated by the Census Bureau. The Census Bureau designs two types of packages: One for GUPS participants who are delineating or reviewing standard statistical geographies, and one for tribal statistical geography review.

A. The 2020 Census PSAP package for standard statistical geographies contains:

(1) Cover letter from the Director of the Census Bureau.

(2) 2020 Census Participant Statistical Areas Program (PSAP) Information Guide.

(3) 2020 Census Participant Statistical Areas Program (PSAP) Geographic Update Partnership Software (GUPS) Respondent Guide.

(4) Quick reference guides for county and local governments. A one-page document providing criteria for each statistical geography eligible for updates as part of PSAP:

(a) Overview.

(b) Block groups.

(c) Census tracts.

(d) Census county divisions (CCDs).

(e) Census designated places (CDPs).

(5) GUPS Quick Start Online Download.

(6) GUPS Quick Start DVD Download.

(7) DVD for GUPS and DVD for Spatial Data.

(8) Postage-paid envelope to submit boundary changes.

(9) Delineation and verification prepaid postage postcards.

B. The typical PSAP package for tribal statistical geographies contains:

(1) Cover letter from the Director of the Census Bureau.

(2) 2020 Census Participant Statistical Areas Program (PSAP) Tribal Information Guide.

(3) 2020 Census Participant Statistical Areas Program (PSAP) Geographic Update Partnership Software (GUPS) Tribal Respondent Guide.

(4) Quick reference guides for tribal governments. A one-page document providing criteria for each statistical geography eligible for updates as part of PSAP:

(a) Overview.

(b) Census designated places (CDPs).

(c) Census county divisions (CCDs).

(d) Tribal block groups (TBGs).

(e) Tribal census tracts (TCTs).

(f) Tribal designated statistical areas (TDSAs).

(g) State designated tribal statistical areas (SDTSAs).

(h) Alaska Native village statistical areas (ANVSAs).

(i) Oklahoma tribal statistical areas (OTSAs).

(j) OTSA tribal subdivisions.

(5) GUPS Quick Start Online Download.

(6) GUPS Quick Start DVD Download.

(7) DVD for GUPS and DVD for Spatial Data.

(8) Postage-paid envelope to submit boundary changes.

(9) Delineation and verification prepaid postage postcards.

Paper Map Submission Only

Submission using paper maps is the only option offered to tribal governments and state tribal liaisons whose spatial data are not available in GUPS. The participant receives a large paper map and draws the boundary updates on the maps using pencils provided in the package. The participant uses the postage-paid envelope to submit the annotated map to the Census Bureau and then Census Bureau digitizes the map. The typical PSAP paper map submission package contains:

(1) *Cover letter from the Director of the Census Bureau.*

(2) *2020 Census Participant Statistical Areas Program (PSAP) Tribal Paper Respondent Guide.*

(3) Quick reference guides for tribal governments. A one-page document providing criteria for each statistical geography eligible for updates as part of PSAP:

(a) Overview.

(b) Census designated places (CDPs).

(c) Census county divisions (CCDs).

(d) Tribal block groups (TBGs).

(e) Tribal census tracts (TCTs).

(f) Tribal designated statistical areas (TDSAs).

(g) State designated tribal statistical areas (SDTSAs).

(h) Alaska Natives village statistical areas (ANVSAs).

(i) Oklahoma tribal statistical areas (OTSAs).

(j) OTSA tribal subdivisions.

(4) Set of maps of their statistical geographic entities.

(5) Supplies for updating paper maps.

(6) Postage-paid envelope to submit boundary changes.

(7) Delineation and verification prepaid postage postcards.

III. Data

OMB Control Number

Form Number: 20PSAP–F–500—State Recognized Tribes Update Form. 20PSAP–F–510—Contact Update Form. 20PSAP–F–511—Product Preference Form. 20PSAP–F–520—State Tribal Liaison Contact Update Form. 20PSAP–F–530—Federally Recognized Tribe Contact Update Form. 20PSAP–F–540—Federally Recognized Tribe Product Preference Form.

Type of Review: Regular submission.

Affected Public: All Federally or state recognized Indian tribes and Alaska Natives in the United States, states,

counties, local governments, and planning agencies.

Estimated Number of Respondents: 3,801.

Estimated Time per Response: Between 7 and 606 hours, estimated average 40 hours.

Estimated Total Burden Hours: 152,040.

Estimated Total Annual Cost to Public: $4,523,190.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C. Section 6.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Summarization of comments submitted in response to this notice will be included in the request for OMB approval of this information collection. Comments will also become a matter of public record.

Sheleen Dumas,

PRA Department Lead, Office of the Chief Information Officer.

[FR Doc. 2017–17033 Filed 8–11–17; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–75–2017]

Approval of Subzone Status; Universal Metal Products, Inc.; Pharr, Texas

On May 10, 2017, the Executive Secretary of the Foreign-Trade Zones (FTZ) Board docketed an application submitted by McAllen Foreign Trade Zone, Inc., grantee of FTZ 12, requesting subzone status subject to the existing activation limit of FTZ 12, on behalf of Universal Metal Products, Inc., in Pharr, Texas.

The application was processed in accordance with the FTZ Act and Regulations, including notice in the **Federal Register** inviting public comment (82 FR 25240, June 1, 2017). The FTZ staff examiner reviewed the application and determined that it meets the criteria for approval. Pursuant to the authority delegated to the FTZ Board Executive Secretary (15 CFR Sec. 400.36(f)), the application to establish Subzone 12B was approved on July 14, 2017, subject to the FTZ Act and the Board's regulations, including Section 400.13, and further subject to FTZ 12's 873.5-acre activation limit.

Dated: August 8, 2017.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2017–17120 Filed 8–11–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–351–851]

Silicon Metal From Brazil: Preliminary Affirmative Countervailing Duty Determination, and Alignment of Final Determination With Final Antidumping Duty Determination

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

SUMMARY: The Department of Commerce (the Department) preliminarily determines that countervailable subsidies are being provided to producers and exporters of silicon metal from Brazil. The period of investigation is January 1, 2016, through December 31, 2016.

DATES: Effective August 14, 2017.

FOR FURTHER INFORMATION CONTACT: Robert Palmer or George Ayache, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–9068 or (202) 482–2623, respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 703(b) of the Tariff Act of 1930, as amended (the Act). The Department published the notice of initiation of this investigation on April 4, 2017.[1] On May 16, 2017, the Department postponed the preliminary determination of this investigation and the revised deadline is now August 7, 2017.[2] For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[3] A list of topics discussed in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov,* and is available to all parties in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed and electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Investigation

The product covered by this investigation is silicon metal from Brazil. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the preamble to the Department's regulations,[4] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage, (*i.e.,* scope).[5] Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice.* For a summary of the product coverage comments and rebuttal responses submitted to the record for this preliminary determination, and accompanying discussion and analysis of all comments timely received, *see* the Preliminary Scope Decision Memorandum.[6] The Department preliminarily is not modifying the scope language as it appeared in the *Initiation Notice. See* Appendix I.

[1] *See Silicon Metal from Australia, Brazil, and Kazakhstan: Initiation of Countervailing Duty Investigations,* 82 FR 16356 (April 4, 2017) (*Initiation Notice).*

[2] *See Silicon Metal from Australia, Brazil and Kazakhstan: Notice of Postponement of Preliminary Determinations of Antidumping Duty Investigations,* 82 FR 22490 (May 16, 2017).

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Determination: Countervailing Duty Investigation of Silicon Metal from Brazil,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[5] *See Initiation Notice.*

[6] *See* Memorandum, ''Silicon Metal from Australia, Brazil, Kazakhstan, and Norway: Scope Comments Decision Memorandum for the Preliminary Determinations,'' dated June 27, 2017 (Preliminary Scope Decision Memorandum).

Methodology

The Department is conducting this investigation in accordance with section 701 of the Act. For each of the subsidy programs found countervailable, the Department preliminarily determines that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient, and that the subsidy is specific.[7]

In making these findings, the Department relied, in part, on facts available and, because it finds that one or more respondents did not act to the best of their ability to respond to the Department's requests for information, it drew an adverse inference where appropriate in selecting from among the facts otherwise available.[8] For further information, *see* ''Use of Facts Otherwise Available and Adverse Inferences'' in the Preliminary Decision Memorandum.

Alignment

On March 28, 2017, the Department initiated this countervailing duty (CVD) investigation of silicon metal from Brazil.[9] On the same day, the Department also initiated antidumping duty (AD) investigations of silicon metal from Australia, Brazil, and Norway.[10] This CVD investigation and the AD investigations of Australia, Brazil, and Norway cover the same class or kind of merchandise.

As noted in the Preliminary Decision Memorandum, in accordance with section 705(a)(1) of the Act and 19 CFR 351.210(b)(4), the Department is aligning the final CVD determination in this investigation with the final determinations in the companion AD investigations of silicon metal from Australia, Brazil, and Norway, based on a request made by the petitioner.[11] Consequently, the final CVD determination will be issued on the same date as the final AD determinations, which are currently scheduled to be issued no later than December 18, 2017, unless postponed.

All-Others Rate

Sections 703(d) and 705(c)(5)(A) of the Act provide that in the preliminary determination, the Department shall determine an estimated all-others rate for companies not individually examined. This rate shall be an amount equal to the weighted average of the estimated subsidy rates established for those companies individually examined, excluding any zero and *de minimis* rates and any rates based entirely under section 776 of the Act.

In this investigation, the Department preliminarily assigned a rate based entirely on facts available to Ligas de Aluminio S.A.—LIASA (LIASA). Therefore, the only rate for an individually-examined respondent that is not zero, *de minimis* or based entirely on facts otherwise available is the rate calculated for Dow Corning Silicio do Brasil Indústria e Comércio Ltda. (DC Silicio). Consequently, the rate calculated for DC Silicio is also assigned as the rate for all-other producers and exporters, pursuant to section 705(c)(5)(A)(i) of the Act.

Preliminary Determination

The Department preliminarily determines that the following estimated countervailable subsidy rates exist:

Company	Subsidy rate (percent)
Dow Corning Silicio do Brasil Indústria e Comércio Ltda[12]	3.69
Ligas de Aluminio S.A.—LIASA	52.07
All-Others	3.69

Suspension of Liquidation

In accordance with section 703(d)(1)(B) and (d)(2) of the Act, the Department will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise as described in the scope of the investigation section entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. Further, pursuant to 19 CFR 351.205(d), the Department will instruct CBP to require a cash deposit equal to the rates indicated above.

Disclosure

The Department intends to disclose to interested parties its calculations and analysis performed in this preliminary determination within five days of its public announcement, or if there is no public announcement, within five days of the publication date of this notice in accordance with 19 CFR 351.224(b).

Verification

As provided in section 782(i)(1) of the Act, the Department intends to verify the information relied upon in making its final determination.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last verification report is issued in this investigation. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.[13] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this investigation are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, the Department intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230, at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

International Trade Commission Notification

In accordance with section 703(f) of the Act, the Department will notify the International Trade Commission (ITC) of its determination. If the final determination is affirmative, the ITC will make its final injury determination before the later of 120 days after the date of this preliminary determination or 45 days after the final determination.

[7] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[8] *See* sections 776(a) and (b) of the Act.

[9] *See Initiation Notice,* 82 FR 16356.

[10] *See Silicon Metal from Australia, Brazil, and Norway: Initiation of Less-Than-Fair-Value Investigations,* 82 FR 16352 (April 4, 2017).

[11] *See* Letter from the petitioner, ''Silicon Metal from Australia, Brazil, and Kazakhstan; Countervailing Duty Investigations; Request for Alignment of Final Determinations,'' dated July 10, 2017.

[12] As discussed in the Preliminary Decision Memorandum, the Department has found the following companies to be cross-owned with Dow Corning Silicio do Brasil Indústria e Comércio Ltda.: Palmyra Recursos Naturais Exploração e Comércio Ltda. and Dow Corning Metais do Pará IND.

[13] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

Notification to Interested Parties

This determination is issued and published pursuant to sections 703(f) and 777(i) of the Act and 19 CFR 351.205(c).

Dated: August 7, 2017.

Carole Showers,

Executive Director, Office of Policy, performing the duties of Deputy Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The scope of this investigation covers all forms and sizes of silicon metal, including silicon metal powder. Silicon metal contains at least 85.00 percent but less than 99.99 percent silicon, and less than 4.00 percent iron, by actual weight. Semiconductor grade silicon (merchandise containing at least 99.99 percent silicon by actual weight and classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheading 2804.61.0000) is excluded from the scope of these investigations.

Silicon metal is currently classifiable under subheadings 2804.69.1000 and 2804.69.5000 of the HTSUS. While HTSUS numbers are provided for convenience and customs purposes, the written description of the scope remains dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope Comments
IV. Alignment
V. Injury Test
VI. Use of Facts Otherwise Available
VII. Subsidies Valuation
VIII. Analysis of Programs
IX. Conclusion

[FR Doc. 2017–17117 Filed 8–11–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–602–811]

Silicon Metal From Australia: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Determination With Final Antidumping Duty Determination

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

SUMMARY: The Department of Commerce (the Department) preliminarily determines that countervailable subsidies are being provided to a producer/exporter of silicon metal from Australia. The period of investigation is January 1, 2016 through December 31, 2016.

DATES: Effective August 14, 2017.

FOR FURTHER INFORMATION CONTACT: Katherine Johnson or John Anwesen, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–4929 or (202) 482–0131, respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 703(b) of the Tariff Act of 1930, as amended (the Act). The Department published the notice of initiation of this investigation on April 4, 2017.[1] On May 16, 2017, the Department postponed the preliminary determination of this investigation and the revised deadline is now August 7, 2017.[2] For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[3] A list of topics discussed in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov,* and is available to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed and electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Investigation

The product covered by this investigation is silicon metal from Australia. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the preamble to the Department's regulations,[4] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage, (*i.e.,* scope).[5] Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice.* For a summary of the product coverage comments and rebuttal responses submitted to the record for this preliminary determination, and accompanying discussion and analysis of all comments timely received, *see* the Preliminary Scope Decision Memorandum.[6] The Department preliminarily is not modifying the scope language as it appeared in the *Initiation Notice. See* Appendix I.

Methodology

The Department is conducting this investigation in accordance with section 701 of the Act. For each of the subsidy programs found countervailable, the Department preliminarily determines that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient, and that the subsidy is specific.[7]

Alignment

On March 28, 2017, the Department initiated this countervailing duty (CVD) investigation of silicon metal from Australia.[8] On the same day, the Department also initiated antidumping duty (AD) investigations of silicon metal from Australia, Brazil, and Norway.[9] This CVD investigation and the AD investigations of Australia, Brazil, and Norway cover the same class or kind of merchandise.

As noted in the Preliminary Decision Memorandum, in accordance with section 705(a)(1) of the Act and 19 CFR 351.210(b)(4), the Department is aligning the final CVD determination in this investigation with the final determinations in the companion AD investigations of silicon metal from Australia, Brazil, and Norway based on

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[1] *See Silicon Metal from Australia, Brazil, and Kazakhstan: Initiation of Countervailing Duty Investigations,* 82 FR 16356 (April 4, 2017) (*Initiation Notice*).

[2] *See Silicon Metal from Australia, Brazil, and Kazakhstan: Postponement of Preliminary Determinations of Countervailing Duty Investigations,* 82 FR 22490 (May 16, 2017).

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Determination in the Countervailing Duty Investigation of Silicon Metal from Australia,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[5] *See Initiation Notice.*

[6] *See* Memorandum, ''Silicon Metal from Australia, Brazil, Kazakhstan, and Norway: Scope Comments Decision Memorandum for the Preliminary Determinations,'' dated June 27, 2017 (Preliminary Scope Decision Memorandum).

[7] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[8] *See Initiation Notice.*

[9] *See Silicon Metal from Australia, Brazil and Norway: Initiation of Less-Than-Fair-Value Investigations,* 82 FR 16352 (April 4, 2017).

a request made by the petitioner.[10] Consequently, the final CVD determination will be issued on the same date as the final AD determinations for Australia, Brazil, and Norway, which are currently scheduled to be issued no later than December 18, 2017, unless postponed.

All-Others Rate

Sections 703(d) and 705(c)(5)(A) of the Act provide that in the preliminary determination, the Department shall determine an estimated all-others rate for companies not individually examined. This rate shall be an amount equal to the weighted average of the estimated subsidy rates established for those companies individually examined, excluding any zero and *de minimis* rates and any rates based entirely under section 776 of the Act.

The Department calculated an individual estimated countervailable subsidy rate for Simcoa Operations Pty. Ltd. (Simcoa), the only individually examined producer/exporter in this investigation. Because the only individually calculated rate is not zero, *de minimis,* or based entirely on facts otherwise available, the estimated weighted-average rate calculated for Simcoa is the rate assigned to all-other producers and exporters, pursuant to section 705(c)(5)(A)(i) of the Act.

Preliminary Determination

The Department preliminarily determines that the following estimated countervailable subsidy rates exist:

Company	Subsidy rate (percent)
Simcoa Operations Pty Ltd [11]	16.23
All-Others	16.23

Suspension of Liquidation

In accordance with section 703(d)(1)(B) and (d)(2) of the Act, the Department will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise as described in the scope of the investigation section entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. Further, pursuant to 19 CFR 351.205(d), the Department will instruct CBP to require a cash deposit equal to the rates indicated above.

Disclosure

The Department intends to disclose to interested parties its calculations and analysis performed in this preliminary determination within five days of its public announcement, or if there is no public announcement, within five days of the publication date of this notice in accordance with 19 CFR 351.224(b).

Verification

As provided in section 782(i)(1) of the Act, the Department intends to verify the information relied upon in making its final determination.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance at a date to be determined. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.[12] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this investigation are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, the Department intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230, at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

International Trade Commission Notification

In accordance with section 703(f) of the Act, the Department will notify the International Trade Commission (ITC) of its determination. If the final determination is affirmative, the ITC will make its final injury determination before the later of 120 days after the date of this preliminary determination or 45 days after the final determination.

Notification to Interested Parties

This determination is issued and published pursuant to sections 703(f) and 777(i) of the Act and 19 CFR 351.205(c).

Dated: August 7, 2017.

Carole Showers,

Executive Director, Office of Policy, performing the duties of Deputy Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The scope of these investigation covers all forms and sizes of silicon metal, including silicon metal powder. Silicon metal contains at least 85.00 percent but less than 99.99 percent silicon, and less than 4.00 percent iron, by actual weight. Semiconductor grade silicon (merchandise containing at least 99.99 percent silicon by actual weight and classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheading 2804.61.0000) is excluded from the scope of these investigations.

Silicon metal is currently classifiable under subheadings 2804.69.1000 and 2804.69.5000 of the HTSUS. While HTSUS numbers are provided for convenience and customs purposes, the written description of the scope remains dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope Comments
IV. Alignment
V. Injury Test
VI. Subsidies Valuation
VII. Analysis of Programs
VIII. Conclusion

[FR Doc. 2017–17116 Filed 8–11–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–054]

Certain Aluminum Foil From the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination

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

SUMMARY: The Department of Commerce (the Department) preliminarily determines that countervailable subsidies are being provided to

[10] *See* Letter from the petitioner, ''Silicon Metal from Australia, Brazil, and Kazakhstan; Countervailing Duty Investigations; Request for Alignment of Final Determinations,'' dated July 10, 2017.

[11] As discussed in the Preliminary Decision Memorandum, the Department has found the following companies to be cross-owned with Simcoa: Silicon Metal Company of Australia Pty Ltd., Microsilica Pty Ltd., and Simcoa International Pty Ltd.

[12] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

producers and exporters of certain aluminum foil (aluminum foil) from the People's Republic of China (PRC). The period of investigation is January 1, 2016, through December 31, 2016.

DATES: August 14, 2017.

FOR FURTHER INFORMATION CONTACT: John Corrigan at (202) 482–7438, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 703(b) of the Tariff Act of 1930, as amended (the Act). The Department published the notice of initiation of this investigation on March 30, 2017.[1] On May 17, 2017, the Department postponed the preliminary determination of this investigation and the revised deadline is now August 7, 2017.[2] For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[3] A list of topics discussed in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically *via* Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov,* and is available to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/*. The signed and electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Investigation

The product covered by this investigation is aluminum foil from the PRC. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the preamble to the Department's regulations,[4] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage, (*i.e.,* scope).[5] Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice* as well as additional language proposed by the Department. The Department intends to issue its preliminary decision regarding comments concerning the scope of the antidumping duty (AD) and countervailing duty (CVD) investigations in the preliminary determination of the companion AD investigation.

Methodology

The Department is conducting this investigation in accordance with section 701 of the Act. For each of the subsidy programs found countervailable, the Department preliminarily determines that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient, and that the subsidy is specific.[6]

The Department notes that, in making these findings, it relied, in part, on facts available and, because it finds that one or more respondents did not act to the best of their ability to respond to the Department's requests for information, it drew an adverse inference where appropriate in selecting from among the facts otherwise available.[7] For further information, *see* ''Use of Facts Otherwise Available and Adverse Inferences'' in the Preliminary Decision Memorandum.

All-Others Rate

Sections 703(d) and 705(c)(5)(A) of the Act provide that in the preliminary determination, the Department shall determine an estimated all-others rate for companies not individually examined. This rate shall be an amount equal to the weighted average of the estimated subsidy rates established for those companies individually examined, excluding any zero and *de minimis* rates and any rates based entirely under section 776 of the Act. In this investigation, the Department preliminarily assigned rates based entirely on facts available to Loften Aluminum (Hong Kong) Limited (Loften HK), as well as Manakin Industries, LLC (Manakin Industries). Therefore, the only rates that are not zero, *de minimis,* or based entirely on facts otherwise available, are the rates calculated for Dingsheng Aluminum Industries (Hong Kong) Trading Co., Ltd. (Dingsheng HK) and Jiangsu Zhongji Lamination Materials Co., Ltd. (Zhongji). Consequently, a simple average of the rates calculated for Dingsehng HK and Zhongji is also assigned as the rate for all-other producers and exporters.

Preliminary Determination

The Department preliminarily determines that the following estimated countervailable subsidy rates exist:

Company	Subsidy rate (percent)
Dingsheng Aluminum Industries (Hong Kong) Trading Co., Ltd[8]	28.33
Jiangsu Zhongji Lamination Materials Co., Ltd[9]	16.56
Loften Aluminum (Hong Kong) Limited	80.97
Manakin Industries, LLC[10]	80.97
All-Others	22.45

Suspension of Liquidation

In accordance with section 703(d)(1)(B) and (d)(2) of the Act, the Department will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise as described in the scope of the investigation section entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal**

[1] *See Certain Aluminum Foil from the People's Republic of China: Initiation of Countervailing Duty Investigation,* 82 FR 15688 (March 30, 2017) (*Initiation Notice*).

[2] *See Certain Aluminum Foil from the People's Republic of China: Postponement of Preliminary Determination in the Countervailing Duty Investigation,* 82 FR 22646 (May 17, 2017).

[3] *See* Decision Memorandum for the Preliminary Affirmative Determination: Countervailing Duty Investigation of Certain Aluminum Foil from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[5] *See Initiation Notice.*

[6] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[7] *See* sections 776(a) and (b) of the Act.

[8] As discussed in the Preliminary Decision Memorandum, the Department has found the following companies to be cross-owned with Dingsheng HK: Jiangsu Dingsheng New Materials Joint-Stock Co., Ltd.; Hangzhou Teemful Aluminum Co., Ltd.; Hangzhou Five Star Aluminum Co., Ltd.; Hangzhou DingCheng Aluminum Co., Ltd.; Luoyang Longding Aluminum Co., Ltd.; Hangzhou Dingsheng Industrial Group Co., Ltd.; Hangzhou Dingsheng Import & Export Co., Ltd.; and Walson (HK) Trading Co., Limited.

[9] As discussed in the Preliminary Decision Memorandum, the Department has found the following companies to be cross-owned with Zhongji: Shantou Wanshun Package Material Stock Co., Ltd.; Jiangsu Huafeng Aluminum Industry Co., Ltd.; and Jiangsu Zhongji Lamination Materials Co., (HK) Ltd.

[10] As discussed in the Preliminary Decision Memorandum, the Department preliminarily finds that Manakin Industries and Suzhou Manakin Aluminum Processing Technology Co., Ltd., effectively function by joint operation as a trading company. Therefore, the rate for Manakin Industries also applies to Suzhou Manakin Aluminum Processing Technology Co., Ltd. For additional information, *see* Preliminary Decision Memorandum.

Register. Further, pursuant to 19 CFR 351.205(d), the Department will instruct CBP to require a cash deposit equal to the rates indicated above.

Disclosure

The Department intends to disclose its calculations and analysis performed to interested parties in this preliminary determination within five days of its public announcement, or if there is no public announcement, within five days of the date of this notice in accordance with 19 CFR 351.224(b).

Verification

As provided in section 782(i)(1) of the Act, the Department intends to verify the information relied upon in making its final determination.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last verification report is issued in this investigation. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.[11] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this investigation are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, and a list of the issues to be discussed. If a request for a hearing is made, the Department intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230, at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

International Trade Commission Notification

In accordance with section 703(f) of the Act, the Department will notify the International Trade Commission (ITC) of its determination. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination.

Notification to Interested Parties

This determination is issued and published pursuant to sections 703(f) and 777(i) of the Act and 19 CFR 351.205(c).

Dated: August 7, 2017.

Carole Showers,

Executive Director, Office of Policy, performing the duties of Deputy Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by this investigation is aluminum foil having a thickness of 0.2 mm or less, in reels exceeding 25 pounds, regardless of width. Aluminum foil is made from an aluminum alloy that contains more than 92 percent aluminum. Aluminum foil may be made to ASTM specification ASTM B479, but can also be made to other specifications. Regardless of specification, however, all aluminum foil meeting the scope description is included in the scope.

Excluded from the scope of this investigation is aluminum foil that is backed with paper, paperboard, plastics, or similar backing materials on only one side of the aluminum foil, as well as etched capacitor foil and aluminum foil that is cut to shape.

Where the nominal and actual measurements vary, a product is within the scope if application of either the nominal or actual measurement would place it within the scope based on the definitions set forth above. The products under investigation are currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheadings 7607.11.3000, 7607.11.6000, 7607.11.9030, 7607.11.9060, 7607.11.9090, and 7607.19.6000. Further, merchandise that falls within the scope of this proceeding may also be entered into the United States under HTSUS subheadings 7606.11.3060, 7606.11.6000, 7606.12.3045, 7606.12.3055, 7606.12.3090, 7606.12.6000, 7606.91.3090, 7606.91.6080, 7606.92.3090, and 7606.92.6080. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this proceeding is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope Comments
IV. Scope of the Investigation
V. Injury Test
VI. Application of the CVD Law to Imports From the PRC
VII. Subsidies Valuation
VIII. Benchamrks and Interest Rates
IX. Use of Facts Otherwise Available and Adverse Inferences
X. Analysis of Programs
XI. ITC Notification
XII. Disclosure and Public Comment
XIII. Verification
XIV. Conclusion

[FR Doc. 2017–17113 Filed 8–11–17; 8:45 am]

BILLING CODE 3510–DS–P

[11] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Antidumping and Countervailing Duty Administrative Reviews

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

FOR FURTHER INFORMATION CONTACT: Marcia E. Short, Office of AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230, telephone: (202) 482–1560.

SUPPLEMENTARY INFORMATION:

Background

On August 1, 2017, the Department of Commerce (the Department) published the June *Initiation Notice*[1] in which the Department inadvertently initiated an antidumping duty administrative review of Polyester Staple Fiber from Taiwan (A–583–833) covering the period May 1, 2016, through April 30, 2017. The Department did not intend to initiate a review with respect to this order. Instead, the Department intended to correct the May *Initiation Notice*[2] in which the Department inadvertently included TFM North America, Inc. in the initiation notice with respect to the antidumping duty administrative review of Certain Stillbenic Optical Brightening Agents (A–583–848) covering the period May 1, 2016 through April 30, 2017. The Department only intended to initiate a review with respect to Teh Fong Min International Co. Ltd. In addition, in the June *Initiation Notice* the Department misspelt Teh Fong Min International Co. Ltd. as The Fong Min International Co. Ltd.[3] This notice serves as a correction to the June *Initiation Notice.*

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews; 82 FR 35749 (August 2, 2017) (June Initiation Notice).*

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews; 82 FR 31292 (June 6, 2016) (May Initiation Notice).*

[3] *See June Initiation Notice, 82 FR at 35749.*

Dated: August 9, 2017.

James Maeder,

Senior Director, perfoming the Duties of Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2017–17114 Filed 8–11–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–834–808]

Silicon Metal From the Republic of Kazakhstan: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Determination With Final Antidumping Duty Determination

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

SUMMARY: The Department of Commerce (the Department) preliminarily determines that countervailable subsidies are being provided to producers and exporters of silicon metal from the Republic of Kazakhstan (Kazakhstan). The period of investigation is January 1, 2016, through December 31, 2016.

DATES: Effective August 14, 2017.

FOR FURTHER INFORMATION CONTACT: Terre Keaton Stefanova or Rebecca Janz, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–1280 or (202) 482–2972, respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 703(b) of the Tariff Act of 1930, as amended (the Act). The Department published the notice of initiation of this investigation on April 4, 2017.[1] On May 16, 2017, the Department postponed the preliminary determination of this investigation and the revised deadline is now August 7, 2017.[2] For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[3] Tau-Ken Temir LLP (Tau-Ken Temir), a producer and exporter of silicon metal from Kazakhstan, is the sole mandatory respondent for which we have determined there were exports during the period of investigation to the United States. A list of topics discussed in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov,* and is available to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/*. The signed and electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Investigation

The product covered by this investigation is silicon metal from Kazakhstan. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the preamble to the Department's regulations,[4] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.,* scope).[5] Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice.* For a summary of the product coverage comments and rebuttal responses submitted to the record for this preliminary determination, and accompanying discussion and analysis of all comments timely received, *see* the Preliminary Scope Decision Memorandum.[6] The Department preliminarily is not modifying the scope language as it appeared in the *Initiation Notice. See* Appendix I.

Methodology

The Department is conducting this investigation in accordance with section 701 of the Act. For each of the subsidy programs found countervailable, the Department preliminarily determines that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient, and that the subsidy is specific.[7]

In its questionnaire responses, Tau-Ken Temir refused to provide the Department with requested information or analyze whether its cross-owned companies received countervailable subsidies.[8] Furthermore, the Government of Kazakhstan's (GOK)'s initial questionnaire response was wholly deficient with respect to an allegation that electricity was sold to Tau-Ken Temir for less than adequate remuneration, and its supplemental response regarding this allegation was untimely filed.[9] Thus, the Department has relied on facts available as part of its analysis. Additionally, because we find that Tau-Ken Temir and the GOK did not act to the best of their abilities to respond to the Department's requests for information and, therefore, impeded this investigation, we drew an adverse inference where appropriate in selecting from among the facts otherwise available.[10] For further information, *see* ''Use of Facts Otherwise Available and Adverse Inferences'' in the Preliminary Decision Memorandum.

Alignment

On March 28, 2017, the Department initiated this countervailing duty (CVD) investigation of silicon metal from Kazakhstan.[11] On the same day, the Department also initiated antidumping duty (AD) investigations of silicon metal from Australia, Brazil, and Norway.[12] This CVD investigation and the AD investigations of Australia, Brazil, and Norway cover the same class or kind of merchandise.

As noted in the Preliminary Decision Memorandum, in accordance with section 705(a)(1) of the Act and 19 CFR 351.210(b)(4), the Department is aligning the final CVD determination in this investigation with the final determinations in the companion AD investigations of silicon metal from Australia, Brazil, and Norway based on

[1] *See Silicon Metal from Australia, Brazil, and Kazakhstan: Initiation of Countervailing Duty Investigations,* 82 FR 16356 (April 4, 2017) (*Initiation Notice*).

[2] *See Silicon Metal From Australia, Brazil, and Kazakhstan: Postponement of Preliminary Determinations of Countervailing Duty Investigations,* 82 FR 22490 (May 16, 2017).

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Determination of the Countervailing Duty Investigation of Silicon Metal from the Republic of Kazakhstan,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[5] *See Initiation Notice.*

[6] *See* Memorandum, ''Silicon Metal from Australia, Brazil, Kazakhstan, and Norway: Scope Comments Decision Memorandum for the Preliminary Determinations,'' dated June 27, 2017 (Preliminary Scope Decision Memorandum).

[7] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[8] *See* Tau-Ken Temir's Supplemental Affiliation Response, dated May 15, 2017 (Tau-Ken Temir May 15, 2017 SAFFR).

[9] *See* GOK's June 1, 2017 Initial Questionnaire Response (GOK June 1, 2017 IQR).

[10] *See* sections 776(a) and (b) of the Act.

[11] *See Initiation Notice,* 82 FR 16356.

[12] *See Silicon Metal from Australia, Brazil, and Norway: Initiation of Less-Than-Fair-Value Investigations,* 82 FR 16352 (April 4, 2017).

a request made by the petitioner.[13] Consequently, the final CVD determination will be issued on the same date as the final AD determinations for Australia, Brazil, and Norway, which are currently scheduled to be issued no later than December 18, 2017, unless postponed.

All-Others Rate

Sections 703(d) and 705(c)(5)(A) of the Act provide that in the preliminary determination, the Department shall determine an estimated all-others rate for companies not individually examined. This rate shall be an amount equal to the weighted average of the estimated subsidy rates established for those companies individually examined, excluding any zero or *de minimis* rates and any rates based entirely under section 776 of the Act. Pursuant to section 705(c)(5)(A)(ii) of the Act, if the individual estimated countervailable subsidy rates established for all exporters and producers individually examined are zero, *de minimis,* or determined based entirely on facts otherwise available, the Department may use any reasonable method to establish the estimated subsidy rate for all-other producers or exporters.

In this investigation, the Department preliminarily assigned a rate based entirely on facts available to Tau-Ken Temir. Accordingly, we are using ''any reasonable method'' to establish the all-others rate. We find that it is reasonable to rely on the rate established for Tau-Ken Temir as the all-others rate, particularly because there is no other information on the record that can be used to determine an all-others rate.[14]

Preliminary Determination

The Department preliminarily determines that the following estimated countervailable subsidy rates exist:

Company	Subsidy rate (percent)
Tau-Ken Temir LLP [15]	120.00
All-Others	120.00

Suspension of Liquidation

In accordance with section 703(d)(1)(B) and (d)(2) of the Act, the Department will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise as described in the scope of the investigation section entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. Further, pursuant to 19 CFR 351.205(d), the Department will instruct CBP to require a cash deposit equal to the rates indicated above.

Disclosure

Normally, the Department discloses to interested parties the calculations performed in connection with a preliminary determination within five days of the public announcement of, where there is no public announcement, within five days of the date of publication of the notice of preliminary determination in the **Federal Register**, in accordance with 19 CFR 351.224(b). However, because the Department preliminarily applied facts available with an adverse inference to the individually examined company Tau-Ken Temir in this investigation in accordance with section 776 of the Act, and the applied facts available rate is based solely on the corporate income tax rate in Kazakhstan, there are no calculations to disclose.

Verification

Because both Tau-Ken Temir and the GOK did not provide information requested by the Department, and the Department preliminarily determines that Tau-Ken Temir and the GOK have been uncooperative, we do not intend to conduct verification.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than 30 days after the date of publication of the preliminary determination. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.[16] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this investigation are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, the Department intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230, at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

International Trade Commission Notification

In accordance with section 703(f) of the Act, the Department will notify the International Trade Commission (ITC) of its determination. If the final determination is affirmative, the ITC will make its final injury determination before the later of 120 days after the date of this preliminary determination or 45 days after the final determination.

Notification to Interested Parties

This determination is issued and published pursuant to sections 703(f) and 777(i) of the Act and 19 CFR 351.205(c).

Dated: August 7, 2017.

Carole Showers,

Executive Director, Office of Policy performing the duties of Deputy Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The scope of this investigation covers all forms and sizes of silicon metal, including silicon metal powder. Silicon metal contains at least 85.00 percent but less than 99.99 percent silicon, and less than 4.00 percent iron, by actual weight. Semiconductor grade silicon (merchandise containing at least 99.99 percent silicon by actual weight and classifiable under Harmonized Tariff Schedule of the United States (HTSUS)

[13] *See* Letter from the petitioner, ''Silicon Metal from Australia, Brazil, and Kazakhstan; Countervailing Duty Investigations; Request for Alignment of Final Determinations,'' dated July 10, 2017.

[14] *See, e.g., Grain-Oriented Electrical Steel from the People's Republic of China: Final Affirmative Countervailing Duty Determination,* 79 FR 59221 (October 1, 2014), and accompanying Issues and Decision Memorandum at Comment 1; *Circular Welded Carbon-Quality Steel Pipe from India: Final Affirmative Countervailing Duty Determination,* 77 FR 64468, 64470 (October 22, 2012); and *Certain Potassium Phosphate Salts from the People's Republic of China: Final Affirmative Countervailing Duty Determination and Termination of Critical Circumstances Inquiry,* 75 FR 30375 (June 1, 2010).

[15] As discussed in the Preliminary Decision Memorandum, the Department has found the following companies to be cross-owned with Tau-Ken Temir LLP: JSC NMC Tau-Ken Samruk and LLP Silicon Mining.

[16] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

subheading 2804.61.0000) is excluded from the scope of this investigation.

Silicon metal is currently classifiable under subheadings 2804.69.1000 and 2804.69.5000 of the HTSUS. While HTSUS numbers are provided for convenience and customs purposes, the written description of the scope remains dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Period of Investigation
IV. Scope Comments
V. Respondent Selection
VI. Injury Test
VII. Use of Facts Otherwise Available and Adverse Inferences
VIII. Calculation of the All-Others Rate
IX. Conclusion

[FR Doc. 2017–17112 Filed 8–11–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF604

Permanent Advisory Committee To Advise the U.S. Commissioners to the Western and Central Pacific Fisheries Commission; Meeting Announcement

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

ACTION: Notice of public meeting.

SUMMARY: NMFS announces a public meeting of the Permanent Advisory Committee (PAC) to advise the U.S. Commissioners to the Commission for the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean (WCPFC) on September 12, 2017.

DATES: The meeting of the PAC will be held via conference call on September 12, 2017, from 11 a.m. to 1 p.m. HST (or until business is concluded). Members of the public may submit written comments; comments must be received by September 7, 2017.

ADDRESSES: The public meeting will be conducted via conference call. For details on how to call in to the conference line or to submit comments, please contact Emily Crigler, NMFS Pacific Islands Regional Office; telephone: 808–725–5036; email: *emily.crigler@noaa.gov.* Documents to be considered by the PAC will be sent out via email in advance of the conference call. Please submit contact information to Emily Crigler (telephone: 808–725–5036; email: *emily.crigler@noaa.gov)* at least 3 days in advance of the call to receive documents via email.

FOR FURTHER INFORMATION CONTACT: Emily Crigler, NMFS Pacific Islands Regional Office; 1845 Wasp Blvd., Bldg. 176, Honolulu, HI 96818; telephone: 808–725–5036; facsimile: 808–725–5215; email: *emily.crigler@noaa.gov.*

SUPPLEMENTARY INFORMATION: In accordance with the Western and Central Pacific Fisheries Convention Implementation Act (16 U.S.C. 6901 *et seq.*), the Permanent Advisory Committee, or PAC, has been formed to advise the U.S. Commissioners to the WCPFC. Members of the PAC have been appointed by the Secretary of Commerce in consultation with the U.S. Commissioners to the WCPFC. The PAC supports the work of the U.S. National Section to the WCPFC in an advisory capacity. The U.S. National Section is made up of the U.S. Commissioners and the Department of State. NMFS Pacific Islands Regional Office provides administrative and technical support to the PAC in cooperation with the Department of State. More information on the WCPFC, established under the Convention on the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean, can be found on the WCPFC Web site: *http://wcpfc.int/.*

Meeting Topics

The purpose of the September 12, 2017, conference call is to discuss outcomes of: The 2017 regular session of the WCPFC Scientific Committee (SC13), the 2017 regular session of the WCPFC Northern Committee (NC13), and the Intersessional Meeting to progress the draft Bridging CMM on Tropical Tuna. There will also be a discussion on topics relevant to the subsequent regular session of the Technical and Compliance Committee (TCC13).

Special Accommodations

The conference call is accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Emily Crigler at 808–725–5036 at least ten working days prior to the meeting.

Authority: 16 U.S.C. 6902 *et seq.*

Dated: August 9, 2017.

Emily H. Menashes,

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

[FR Doc. 2017–17121 Filed 8–11–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF431

Endangered Species; File No. 21516

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

ACTION: Notice of availability; request for public comments.

SUMMARY: We, NMFS, have received an application from Virginia Electric and Power Company, D.B.A. Dominion Virginia Power (Dominion) for an incidental take permit, pursuant to the Endangered Species Act (ESA) of 1973, as amended, for activities associated with the otherwise lawful continued operation and maintenance of the Dominion Chesterfield Power Station (CPS) in Chesterfield, VA. We are considering issuing a 10-year permit to the applicant that would authorize take of ESA-listed Atlantic sturgeon (*Acipenser oxyrinchus oxyrinchus*) from the Chesapeake Bay Distinct Population Segment (DPS) incidental to otherwise lawful activities associated with the withdrawal of cooling water from the James River and entrainment and impingement sampling required by the Clean Water Act. Pursuant to the ESA and the National Environmental Policy Act (NEPA), we announce the availability of Dominion's ITP application and draft habitat conservation plan (HCP), as well as our draft environmental assessment (EA), for public review and comment. We provide this notice to seek comments from the public and Federal, Tribal, State, and local governments.

DATES: To allow for timely processing of the permit application, we must receive your comments no later than September 13, 2017.

ADDRESSES: The application is available for download and review at *http://www.nmfs.noaa.gov/pr/permits/esa_review.htm* under the section heading ESA section 10(a)(1)(B) Permits and Applications and at *http://www.regulations.gov.* The application is also available upon written request or by appointment in the following office: Protected Resources Division, NMFS Greater Atlantic Regional Fisheries Office, 55 Great Republic Drive, Gloucester, MA 01930; phone (978) 281–9328.

Submit your comments by including NOAA–NMFS–2017–0051, by either of the following methods:

• *Electronic Submissions:* Submit all electronic public comments via the Federal e-Rulemaking Portal.

1. Go to *www.regulations.gov/!docketDetail;D=NOAA-NMFS-2017-0051,*

2. Click the ''Comment Now!'' icon, complete the required fields

3. Enter or attach your comments.

• *Mail:* Submit written information to Julie Crocker, NMFS, Greater Atlantic Regional Fisheries Office, Protected Resources Division, 55 Great Republic Drive, Gloucester, MA 01930.

Instructions: We may not consider comments if they are sent by any other method, to any other address or individual, or received after the end of the specified period. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.) confidential business information, or otherwise sensitive or protected information submitted voluntarily by the sender is publicly accessible. We will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). We will accept attachments to electronic comments in Microsoft Word or Excel, WordPerfect, or Adobe PDF file formats, only.

FOR FURTHER INFORMATION CONTACT: Julie Crocker, (978) 282–8480.

SUPPLEMENTARY INFORMATION: We received an initial draft application from Dominion in December 2016 and a complete application on April 10, 2017, for an ITP to take federally listed Atlantic sturgeon over a 10-year period. The ITP would authorize take resulting from continued operations of the facility, including impingement and entrainment in the cooling water intake system and collection during studies and sampling required by section 316(b) of the Clean Water Act. A conservation program to minimize and mitigate for the impacts of the incidental take would be implemented by Dominion as described in the draft HCP.

To comply with the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) (NEPA), we prepared an EA that describes the proposed action, issuance of an ITP to Dominion, and possible alternatives and analyzes the effects of the proposed action and alternatives on the human environment. We will evaluate whether the EA's analysis is adequate to support a Finding of No Significant Impact.

Background

Section 9 of the ESA and Federal regulations prohibit the ''take'' of species listed as endangered or threatened. The ESA defines ''take'' to mean harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct. However, under section 10(a)(1)(B) of the ESA, we may issue permits to authorize incidental take of listed species. ''Incidental take'' is defined by the ESA as take that is incidental to, and not the purpose of, carrying out an otherwise lawful activity. Section 10(a)(2)(A) of the ESA requires an ITP applicant to submit an HCP that specifies the steps the applicant will take to minimize and mitigate the impacts of the taking. Regulations governing ITPs for threatened and endangered species are found at 50 CFR 222.307.

The CPS is a coal-fueled power station in Chesterfield, Virginia in the upper tidal portion, approximately river mile 82 (river kilometer, rkm, 132), of the James River. It has been in operation since 1945. It operates pursuant to a permit issued by the Virginia Department of Environmental Quality under section 402 of the Clean Water Act (the National Pollutant Discharge Elimination System program). CPS has a design intake flow of approximately 1,090 million gallons per day (MGD), at least 25 percent of which is used exclusively for cooling purposes, and is therefore subject to the Clean Water Act section 316(b) existing facility rule (79 FR 48300, August 15, 2014).

Dominion is seeking a permit for the incidental take of Atlantic sturgeon for a term of 10-years. Incidental take may occur as a result of operation of the cooling water intakes and performance of studies required to comply with Clean Water Act 316(b). Additional activities considered, but for which take is not expected include, dredging, constituent discharge, thermal discharge, vessel movements, and shoreline and structure maintenance. The permit application includes Dominion's consideration of the potential effects to shortnose sturgeon (*Acipenser brevirostrum*). However, Dominion does not anticipate incidental take of shortnose sturgeon because shortnose sturgeon rarely occur in the James River.

Dominion estimates the take of up to 846 Atlantic sturgeon larvae per year from the Chesapeake Bay DPS due to entrainment in the Dominion CPS cooling water intakes. Dominion estimates the take of up to two juvenile, subadult or adult Atlantic sturgeon from the Chesapeake Bay DPS over a ten-year period as a result of impingement at the Dominion CPS intakes.

Conservation Plan

Section 10(a)(1)(B) of the ESA specifies that no permit may be issued unless an applicant submits an adequate HCP. Dominion's proposed HCP describes measures designed to minimize, monitor, and mitigate the incidental take of Atlantic sturgeon. Dominion's proposed HCP includes support for two research initiatives to increase knowledge of Atlantic sturgeon in the James River. The first would build on the existing knowledge of the genetic structure of cohorts spawning in the James River. The second would characterize Atlantic sturgeon spatial and temporal use of the upper tidal portion of the James River. The HCP also includes monitoring of incidental take. Other monitoring and mitigation actions will be undertaken as required.

The proposed action is the issuance of an ITP and implementation of the proposed HCP. Dominion considered two alternatives to the proposed action in its HCP: (1) No change to existing operations, studies and maintenance at CPS, and (2) avoiding and minimizing permitted activities (*e.g.,* modifying water withdrawals; modifying the cooling water intake structure; not conducting or not continuing the planned CWA 316(b) studies; not dredging and/or dredging less frequently; not using barges or vessels for the shipment or delivery of bulk materials; not performing or reducing shoreline and structure maintenance activities at CPS).

National Environmental Policy Act

In compliance with NEPA, we analyzed the impacts of the proposed issuance of an ITP and implementation of the HCP, and alternatives. Based on this analysis and any new information resulting from public comment, we will determine if there are any significant impacts caused by the proposed action. We have prepared a draft EA on the proposed action and have made it available for public inspection online or in person at the Greater Atlantic Regional Fisheries Office (see Availability of Documents).

This notice is provided pursuant to section 10(c) of the ESA and the National Environmental Policy Act regulations (40 CFR 1506.6). We will evaluate the application, associated documents, and submitted comments received to determine whether the application meets the requirements of section 10 of the ESA (16 U.S.C. 1531 *et seq.*). We will also evaluate whether issuance of a section 10(a)(1)(B) permit would comply with section 7 of the ESA by conducting an intra-Service section 7

consultation. We will use the results of this consultation, in combination with the above findings, in our final analysis to determine whether to issue a permit. If the requirements are met, we will issue the permit to the applicant.

We will publish a record of our final action in the **Federal Register**.

Authority: This notice is provided pursuant to section 10(c) of the ESA (16 U.S.C. 1531 *et seq.*) and NEPA regulations (40 CFR 1506.6).

Dated: August 9, 2017.

Angela Somma,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2017–17105 Filed 8–11–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF561

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to the U.S. Navy Training and Testing Activities in the Atlantic Fleet Training and Testing Study Area

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

ACTION: Notice; receipt of application for letter of authorization; request for comments and information.

SUMMARY: NMFS has received a request from the U.S. Navy (Navy) for authorization to take marine mammals incidental to the training and testing activities conducted in the Atlantic Fleet Training and Testing (AFTT) Study Area from October 2018 through October 2023. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is announcing our receipt of the Navy's request for the development and implementation of regulations governing the incidental taking of marine mammals and inviting information, suggestions, and comments on the Navy's application and request.

DATES: Comments and information must be received no later than September 13, 2017.

ADDRESSES: Comments on the application should be addressed to Jolie Harrison, Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910–3225. The mailbox address for providing email comments is *ITP.Egger@noaa.gov.* NMFS is not responsible for email comments sent to addresses other than the one provided here. Comments sent via email, including all attachments, must not exceed a 10-megabyte file size.

Instructions: All comments received are a part of the public record and will generally be posted to *www.nmfs.noaa.gov/pr/permits/incidental.htm#applications* without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Stephanie Egger, Office of Protected Resources, NMFS; phone: (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Availability

An electronic copy of the Navy's application may be obtained online at: *www.nmfs.noaa.gov/pr/permits/incidental.htm#applications.* The Navy released a draft Environmental Impact Statement (EIS)/Overseas EIS (OEIS) for the on June 30, 2017. A copy of the draft EIS, which would also support NMFS' proposed rulemaking under the MMPA, is available at *www.aftteis.com.*

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (Secretary) to allow, upon request, the incidental, but not intentional taking of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) if certain findings are made and regulations are issued or, if the taking is limited to harassment, notice of a proposed authorization is provided to the public for review.

Incidental take authorizations shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such taking are set forth.

NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.''

With respect to military readiness activities, the MMPA defines ''harassment'' as any act that injures or has the significant potential to injure a marine mammal or marine mammal stock in the wild (Level A Harassment); or (ii) any act that disturbs or is likely to disturb a marine mammal or marine mammal stock in the wild by causing disruption of natural behavioral patterns, including, but not limited to, migration, surfacing, nursing, breeding, feeding, or sheltering, to a point where such behavioral patterns are abandoned or significantly altered (Level B Harassment).

Summary of Request

On June 16, 2017, NMFS received an application from the Navy requesting authorization to take individuals of 39 marine mammal species by Level A and B (behavioral) harassment incidental to training, testing, and routine military operations (all categorized as military readiness activities) from the use of sonar and other transducers, in-water detonations, air guns, and impact pile driving/vibratory extraction. In addition, the Navy is requesting nine mortalities of four marine mammal species during ship shock trials, and three takes (not to exceed two from any individual stock) by injury or mortality from vessel strikes over the five-year period. One marine mammal species, the North Atlantic right whale (*Eubalaena glacialis*), has designated critical habitat in the AFTT Study Area. The Navy's training and testing activities would occur over five years beginning October 2018. On August 4, 2017, the Navy sent an amendment to its application and Navy's application was considered final and complete.

This will be NMFS' third rule making for AFTT activities under the MMPA. NMFS published the first rule effective from January 22, 2009 through January 22, 2014 on January 27, 2009 (74 FR 4844) and the second rule effective from November 14, 2013 through November 13, 2018 on December 4, 2013 (78 FR 73009). For this third rule making, the Navy is proposing to conduct similar sonar activities in the proposed rulemaking as they have conducted over the past nine years in the previous two rule makings.

Description of the Specified Activity

The Navy's training and testing activities to be conducted within the AFTT Study Area (includes areas of the western Atlantic Ocean along the east coast of North America, portions of the Caribbean Sea, and the Gulf of Mexico, covering approximately 2.6 million square nautical miles of ocean area,

oriented from the mean high tide line along the U.S. coast and extends east to the 45-degree west longitude line, north to the 65-degree north latitude line, and south to approximately the 20-degree north latitude line) over the course of 5 years. Please refer to the application, specifically Figure 1.1–1 for a map of the Study Area and Figures 2.2–1 through Figure 2.2–3 for additional maps of the range complexes and testing ranges. The following types of training and testing, which are classified as military readiness activities pursuant to the MMPA, as amended by the National Defense Authorization Act, would be covered under the LOAs (if authorized): amphibious warfare (in-water detonations), anti-submarine warfare (sonar and other transducers, in-water detonations), expeditionary warfare (in-water detonations), surface warfare (in-water detonations), mine warfare (sonar and other transducers, in-water detonations), and other (sonar and other transducers, impact pile driving/vibratory extraction, air guns).

The Navy has proposed a suite of mitigation measures for marine mammals that could be implemented during training and testing activities in the AFTT Study Area. Procedural mitigation generally involves: (1) The use of one or more trained Lookouts to diligently observe for specific biological resources within a mitigation zone, (2) requirements for Lookouts to immediately communicate sightings of specific biological resources to the appropriate watch station for information dissemination, and (3) requirements for the watch station to implement mitigation (*e.g.,* halt an activity) until certain recommencement conditions have been met. Mitigation measures are also conducted in specific mitigation zones and can consist of a variety of measures including, but not limited to: Conducting a certain number of major training exercise per year, not planning or avoid planning major training exercises, minimizing or not conducting active sonar, conducting a certain amount of hull-mounted mid-frequency active sonar per year, not expending explosive or non-explosive ordnance, and implementing vessel speed reductions.

The Navy also proposes to undertake monitoring and reporting efforts to track compliance with take authorizations and to help investigate the effectiveness of implemented mitigation measures in the AFTT Study Area. This can include Adaptive Management, the Integrated Comprehensive Monitoring Program, the Strategic Planning Process, and Annual Monitoring and Exercise and Testing Reports. As an example, under the Integrated Comprehensive Monitoring Program, the monitoring relating to the effects of Navy training and testing activities on protected marine species are designed to increase in the understanding of the likely occurrence of marine mammals in the vicinity of the action (*i.e.,* presence, abundance, distribution, and density of species) and to increase the understanding of the nature, scope, or context of the likely exposure of marine mammals to any of the potential stressors associated with the action. Please refer to Chapter 13 of the Navy's application for full details on monitoring and reporting proposed by the Navy.

Information Solicited

Interested persons may submit information, suggestions, and comments concerning the Navy's request (see **ADDRESSES**). NMFS will consider all information, suggestions, and comments related to the Navy's request and NMFS' potential development and implementation of regulations governing the incidental taking of marine mammals by the Navy's testing and training activities for the AFTT Study Area.

Dated: August 8, 2017.

Donna S. Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2017–17061 Filed 8–11–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP10–996–000.
Applicants: Dominion Cove Point LNG, LP.
Description: Dominion Energy Cove Point LNG, LP submits tariff filing per: DECP—2017 Report of Operational Sales and Purchases of Gas.
Filed Date: 07/31/2017.
Accession Number: 20170731–5099.
Comment Date: 5:00 p.m. Eastern Time on Monday, August 14, 2017.

Docket Numbers: RP17–961–000.
Applicants: Transcontinental Gas Pipe Line Company.
Description: Transcontinental Gas Pipe Line Company, LLC submits tariff filing per 154.204: Update List of Non-Conforming Service Agreements (Dalton) to be effective 8/1/2017.
Filed Date: 08/03/2017.
Accession Number: 20170803–5115.
Comment Date: 5:00 p.m. Eastern Time on Tuesday, August 15, 2017.

Docket Numbers: RP17–962–000.
Applicants: Cameron Interstate Pipeline, LLC.
Description: Cameron Interstate Pipeline, LLC submits tariff filing per 154.204: Filing of Tenaska Capacity Release Umbrella Agreement to be effective 8/1/2017.
Filed Date: 08/03/2017.
Accession Number: 20170803–5156.
Comment Date: 5:00 p.m. Eastern Time on Tuesday, August 15, 2017.

Docket Numbers: RP17–920–001.
Applicants: Gulf South Pipeline Company, LP.
Description: Gulf South Pipeline Company, LP submits tariff filing per 154.205(b): Amendment to Filing in Docket No. RP17–920–000 to be effective 8/1/2017.
Filed Date: 08/04/2017.
Accession Number: 20170804–5077.
Comment Date: 5:00 p.m. Eastern Time on Wednesday, August 16, 2017.

Docket Numbers: RP17–963–000.
Applicants: NJR Energy Services Company, Talen Energy Marketing, LLC.
Description: Joint Petition for Temporary Waiver of Capacity Release of NJR Energy Services Company, et al.
Filed Date: 08/04/2017.
Accession Number: 20170804–5088.
Comment Date: 5:00 p.m. Eastern Time on Friday, August 11, 2017.

Docket Numbers: RP17–964–000.
Applicants: Texas Eastern Transmission, LP.
Description: Joint Settlement Extension Agreement (Phase II/PCBs, RP88–67, et. al.) of Texas Eastern Transmission, LP.
Filed Date: 08/04/2017.
Accession Number: 20170804–5166.
Comment Date: 5:00 p.m. Eastern Time on Wednesday, August 16, 2017.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests,

service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated August 7, 2017.

Nathaniel J. Davis, Sr.

Deputy Secretary

[FR Doc. 2017–17093 Filed 8–11–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC17–155–000.

Applicants: Bayshore Solar C, LLC.

Description: Application for Authorization Under Section 203 of the Federal Power Act, Request for Expedited Consideration and Confidential Treatment of Bayshore Solar C, LLC.

Filed Date: 8/8/17.

Accession Number: 20170808–5071.

Comments Due: 5 p.m. ET 8/29/17.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER12–162–018; ER10–2611–020; ER11–2044–023; ER11–3876–022; ER13–1266–015; ER15–2211–012.

Applicants: Bishop Hill Energy II LLC, CalEnergy, LLC, Cordova Energy Company LLC, MidAmerican Energy Company, MidAmerican Energy Services, LLC, Saranac Power Partners, L.P.

Description: Notice of Non-Material Change in Status of Bishop Hill Energy II LLC, et al.

Filed Date: 8/8/17.

Accession Number: 20170808–5089.

Comments Due: 5 p.m. ET 8/29/17.

Docket Numbers: ER17–2260–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2017–08–08_SA# 1927 IPL–ITCMW 3rd Revised LGIA (P001) to be effective 8/2/2017.

Filed Date: 8/8/17.

Accession Number: 20170808–5069.

Comments Due: 5 p.m. ET 8/29/17.

Docket Numbers: ER17–2261–000.

Applicants: Southern California Edison Company.

Description: § 205(d) Rate Filing: LGIA Antelope Expansion 2 LLC Antelope Solar 2 Project SA No. 195 TOT762 to be effective 8/9/2017.

Filed Date: 8/8/17.

Accession Number: 20170808–5084.

Comments Due: 5 p.m. ET 8/29/17.

Docket Numbers: ER17–2262–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Cancellation: Notice of Cancellation of Original Service Agreement No. 4097, Queue No. AA1–019 to be effective 9/25/2017.

Filed Date: 8/8/17.

Accession Number: 20170808–5108.

Comments Due: 5 p.m. ET 8/29/17.

Docket Numbers: ER17–2263–000.

Applicants: California Independent System Operator Corporation.

Description: Compliance filing: 2017–08–08 Petition for Tariff Waiver—Availability Assessment of Hours 2018 to be effective N/A.

Filed Date: 8/8/17.

Accession Number: 20170808–5142.

Comments Due: 5 p.m. ET 8/29/17.

Take notice that the Commission received the following qualifying facility filings:

Docket Numbers: QF17–1274–000.

Applicants: Shaw Industries Group, Inc.

Description: Form 556 of Shaw Industries Group, Inc.

Filed Date: 8/7/17.

Accession Number: 20170807–5122.

Comments Due: None Applicable.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 8, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–17088 Filed 8–11–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Records Governing Off-the-Record Communications; Public Notice

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt of prohibited and exempt off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive a prohibited or exempt off-the-record communication relevant to the merits of a contested proceeding, to deliver to the Secretary of the Commission, a copy of the communication, if written, or a summary of the substance of any oral communication.

Prohibited communications are included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication, and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications are included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of off-the-record communications recently received by the Secretary of the Commission. The communications listed are grouped by docket numbers in ascending order. These filings are available for electronic review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the eLibrary link.

Enter the docket number, excluding the last three digits, in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

Docket No.	File date	Presenter or requester
Prohibited:		
1. CP15–554–000	7–25–2017	Mass Mailing [1]
2. CP15–554–000	7–25–2017	William Alexander
3. CP15–554–000	7–26–2017	Mass Mailing [2]
4. CP15–554–000	7–27–2017	Mass Mailing [3]
5. CP15–554–000	7–31–2017	Gwendolyn Wilkins
6. CP15–554–000	8–4–2017	John Wagner
Exempt:		
1. CP17–40–000	7–28–2017	FERC Staff [4]
2. CP17–40–000	7–31–2017	FERC Staff [5]
3. P–1494–000	8–1–2017	Oklahoma Department of Wildlife Conservation
4. P–1494–000	8–1–2017	U.S. Congress Members [6]
5. CP15–554–000	8–1–2017	U.S. House Representative Bob Goodlatte
6. CP15–93–000	8–3–2017	U.S. Congress Members [7]
7. P–1494–000	8–3–2017	Oklahoma Office of the Secretary of Energy & Environment

[1] Six letters have been sent to FERC Commissioners and staff under this docket number.
[2] Three letters have been sent to FERC Commissioners and staff under this docket number.
[3] Three letters have been sent to FERC Commissioners and staff under this docket number.
[4] Agency Conference Call Summary for call on July 27, 2017 with United States Army Corps of Engineers, United States Fish and Wildlife Service, and Illinois Department of Agriculture.
[5] Agency Project Conference Call Summary for call on July 27, 2017 with Spire STl Pipeline L.L.C.
[6] Senators James M. Inhofe and James Lankford. House Representatives Markwayne Mullin and Jim Bridenstine.
[7] Representative Frank Pallone, Jr. and Senator Maria Cantwell.

Dated: August 8, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–17091 Filed 8–11–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Number: PR17–55–000.
Applicants: Columbia Gas of Ohio, Inc.
Description: Tariff filing per 284.123(b),(e)/: COH Rates effective 7–31–2017 to be effective 7/31/2017; Filing Type: 980.
Filed Date: 8/2/17.
Accession Number: 201708025059.
Comments/Protests Due: 5 p.m. ET 8/23/17.

Docket Numbers: RP17–960–000.
Applicants: Texas Eastern Transmission, LP.
Description: Texas Eastern Transmission, LP submits tariff filing per 154.204: Negotiated Rates—Eco-Energy 8946929 to be effective 8/2/2017 under RP17–960 Filing Type: 570.
Filed Date: 08/02/2017.
Accession Number: 20170802–5091.
Comment Date: 5:00 p.m. Eastern Time on Monday, August 14, 2017.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated August 3, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–17092 Filed 8–11–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 739–034]

Appalachian Power Company; Notice of Application Accepted for Filing and Soliciting Comments, Motions to Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Shoreline Management Plan Update.
b. *Project No:* 739–034.
c. *Date Filed:* June 14, 2017.
d. *Applicant:* Appalachian Power Company.
e. *Name of Project:* Claytor Hydroelectric Project.
f. *Location:* The project is located on the New River, in Pulaski County, Virginia.
g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.
h. *Applicant Contact:* Elizabeth Parcell, Process Supervisor Senior; Appalachian Power Company, 40 Franklin Road SW., P.O. Box 2021, Roanoke, VA 24011–2121; (540) 985–2441.
i. *FERC Contact:* Krista Sakallaris; (202) 502–6302; *Krista.Sakallaris@ferc.gov.*
j. *Deadline for filing comments, motions to intervene, and protests:* September 6, 2017.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–739–034. Comments emailed to Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Request:* The licensee filed an update to the Claytor Project's Shoreline Management Plan (SMP), pursuant to Section 3.5 of the current SMP and Article 414 of the project's license. The revised SMP includes minor revisions and updates throughout the plan, including formatting changes and updates to existing tables to reflect current data. Other notable changes include: Clarification of terms used (*i.e.,* steep slope, automatic boat cover, high-density multi-use, etc.); amending vegetation removal regulations; adding permitting exceptions; and incorporating various changes requested by agencies during the consultation process.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above. Agencies may obtain copies of the application directly from the applicant.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions To Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

Dated: August 8, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–17089 Filed 8–11–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC17–153–000.
Applicants: Bayshore Solar B, LLC.
Description: Application for Authorization Under Section 203 of the Federal Power Act, Request for Expedited Consideration and Confidential Treatment of Bayshore Solar B, LLC.
Filed Date: 8/7/17.
Accession Number: 20170807–5184.
Comments Due: 5 p.m. ET 8/28/17.

Docket Numbers: EC17–154–000.
Applicants: Sagebrush, a California partnership, Sagebrush Asset Holdings, LLC, Sky River LLC.
Description: Application For Authorization for Disposition of Jurisdictional Facilities and Request for Expedited Action of Sky River LLC, et. al.
Filed Date: 8/7/17.
Accession Number: 20170807–5190.
Comments Due: 5 p.m. ET 8/28/17.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER14–2144–007; ER10–3308–026; ER11–2005–024; ER11–2007–021; ER11–2009–024; ER11–2011–024; ER11–2013–024; ER11–2014–024; ER11–2016–021; ER11–3989–020; ER12–1223–021; ER12–1829–016; ER12–2201–015; ER12–2311–015; ER12–2528–014; ER14–2145–007; ER16–2363–003.
Applicants: Beebe 1B Renewable Energy, LLC, Beebe Renewable Energy, LLC, Bluestem Wind Energy, LLC, Cassia Gulch Wind Park, LLC, Cow Branch Wind Power, LLC, CR Clearing, LLC, Criterion Power Partners, LLC, Fourmile Wind Energy, LLC, Harvest WindFarm, LLC, Harvest II Windfarm, LLC, High Mesa Energy, LLC, Michigan Wind 1, LLC, Michigan Wind 2, LLC, Shooting Star Wind Project, LLC, Tuana Springs Energy, LLC, Wildcat Wind, LLC, Wind Capital Holdings, LLC.
Description: Notice of Change in Status of the Exelon Sellers.
Filed Date: 8/7/17.
Accession Number: 20170807–5199.
Comments Due: 5 p.m. ET 8/28/17.

Docket Numbers: ER17–795–002.
Applicants: ISO New England Inc.
Description: Tariff Amendment: ISO–NE Filing to Re-Establish Statutory Action Date to be effective 3/15/2017.

Filed Date: 8/8/17.
Accession Number: 20170808–5034.
Comments Due: 5 p.m. ET 8/29/17.
Docket Numbers: ER17–2256–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: Cost Allocation for Brookline and Morgan Transmission Projects (Part 1 of 2) to be effective 10/6/2017.
Filed Date: 8/7/17.
Accession Number: 20170807–5173.
Comments Due: 5 p.m. ET 8/28/17.
Docket Numbers: ER17–2257–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: Cost Allocation for Brookline and Morgan Transmission Projects (Part 2 of 2) to be effective 10/6/2017.
Filed Date: 8/7/17.
Accession Number: 20170807–5175.
Comments Due: 5 p.m. ET 8/28/17.
Docket Numbers: ER17–2258–000.
Applicants: Rock Falls Wind Farm LLC.
Description: Baseline eTariff Filing: Rock Falls Wind Farm Initial Market-Based Rate Application Filing to be effective 10/7/2017.
Filed Date: 8/7/17.
Accession Number: 20170807–5180.
Comments Due: 5 p.m. ET 8/28/17.
Docket Numbers: ER17–2259–000.
Applicants: Seville Solar One LLC.
Description: § 205(d) Rate Filing: Revised SLA Rate Schedule No. 2 to be effective 8/8/2017.
Filed Date: 8/7/17.
Accession Number: 20170807–5181.
Comments Due: 5 p.m. ET 8/28/17.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 8, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–17087 Filed 8–11–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2809–034]

KEI (Maine) Power Management (III); Notice Soliciting Scoping Comments

Take notice that the following hydroelectric license application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Subsequent Minor License.

b. *Project No.:* P–2809–034.

c. *Date filed:* April 28, 2017.

d. *Applicant:* KEI (Maine) Power Management (III) LLC (KEI Power).

e. *Name of Project:* American Tissue Hydroelectric Project.

f. *Location:* On Cobbosseecontee Stream, in the Town of Gardiner, Kennebec County, Maine. There are no Federal or tribal lands within the project boundary.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Lewis C. Loon, Operations and Maintenance Manager, USA, KEI (Maine) Power Management (III) LLC, 423 Brunswick Avenue, Gardiner, ME 04345; (207) 203–3026.

i. *FERC Contact:* John Baummer, 202–502–6837, or *john.baummer@ferc.gov.*

j. *Deadline for filing scoping comments:* September 7, 2017.

The Commission strongly encourages electronic filing. Please file scoping comments using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–2809–034.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application is not ready for environmental analysis at this time.

l. *The existing American Tissue Project consists of:* (1) A 256-foot-long, 23-foot-high cut granite, stone and brick masonry dam that includes a 61-foot-long west abutment section, a 100-foot-long spillway section with 12-inch-high flashboards and a crest elevation of 122.3 feet mean sea level (msl), and a 95-foot-long east abutment section with an intake structure that includes: (a) Trashracks with 2-inch clear spacing, (b) a manually-operated headgate that controls flow to the penstock, and (c) three low level outlets at an elevation of about 100 feet msl for releasing minimum flows to the bypassed reach; (2) an approximately 5.5-acre, 1,000-foot-long impoundment with a normal maximum water surface elevation of 123.3 feet msl; (3) a 280-foot-long, 7-foot-diameter underground steel penstock; (4) a 37-foot-long, 34-foot-wide concrete and wooden powerhouse containing a single 1.0-MW turbine-generator unit; (5) a 250-foot-long, 12-kilovolt transmission line; (6) a tailrace; and (7) appurtenant facilities.

KEI Power operates the project in a run-of-river mode with an average annual generation of 5,430 megawatt-hours. KEI Power proposes to release year-round minimum flows of 10 cubic feet per second (cfs) (or inflow to the impoundment, whichever is less), to the bypassed reach to enhance habitat for aquatic organisms and provide downstream passage for alewives. KEI Power also proposes to release a minimum flow of 52 cfs (or inflow, whichever is less) to the tailrace to protect aquatic resources in the downstream reach. In addition, KEI Power proposes to upgrade the existing downstream fish passage facility, construct and operate a new upstream passage facility for American eel, and release 40 cfs through the low level gates of the dam from September 1 to November 15 to facilitate downstream eel passage.

m. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to address the document. For assistance, contact FERC Online Support. A copy is available for inspection and reproduction at the address in item (h) above.

n. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects.

For assistance, contact FERC Online Support.

o. *Scoping Process:* The Commission staff intends to prepare a single Environmental Assessment (EA) for the American Tissue Hydroelectric Project in accordance with the National Environmental Policy Act. The EA will consider both site-specific and cumulative environmental impacts and reasonable alternatives to the proposed action.

Commission staff does not propose to conduct any on-site scoping meetings at this time. Instead, we are soliciting comments, recommendations, and information, on Scoping Document 1 (SD1) issued on August 8, 2017.

Copies of SD1 outlining the subject areas to be addressed in the EA were distributed to the parties on the Commission's mailing list and the applicant's distribution list. Copies of SD1 may be viewed on the web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, call 1–866–208–3676 or for TTY, (202) 502–8659.

Dated: August 8, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–17090 Filed 8–11–17; 8:45 am]

BILLING CODE 6717–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meetings

AGENCY: Federal Election Commission

DATE AND TIME: Thursday, August 17, 2017 at 10:00 a.m.

PLACE: 999 E Street NW., Washington, DC. (Ninth floor).

STATUS: This meeting will be open to the public.

ITEMS TO BE DISCUSSED:

Audit Division Recommendation Memorandum on the Illinois Republican Party (IRP) (A13–09)

Draft Advisory Opinion 2017–06: Stein and Gottlieb

Management and Administrative Matters

Individuals who plan to attend and require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Dayna C. Brown, Secretary and Clerk, at (202) 694–1040, at least 72 hours prior to the meeting date.

PERSON TO CONTACT FOR INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Laura E. Sinram,

Acting Deputy Secretary of the Commission.

[FR Doc. 2017–17237 Filed 8–10–17; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on the agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within twelve days of the date this notice appears in the **Federal Register**. A copy of the agreement is available through the Commission's Web site (*www.fmc.gov*) or by contacting the Office of Agreements at (202)–523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 012108–006.

Title: The World Liner Data Agreement.

Parties: Maersk Line A/S; CMA CGM S.A.; COSCO Shipping Lines Co., Ltd.; Hamburg-Sud; Hapag-Lloyd AG; Mediterranean Shipping Company S.A.; Orient Overseas Container Line Ltd.; United Arab Shipping Company S.A.G.; Hyundai Merchant Marine Co., Ltd.; Evergreen Line Joint Service Agreement; Nile Dutch Africa Line B.V.; Zim Integrated Shipping Services Limited; and Independent Container Line Ltd.

Filing Party: Wayne Rohde, Esq.; Cozen O'Connor; 1200 Nineteenth Street NW.; Washington, DC 20036.

Synopsis: The amendment deletes ANL and Hanjin as parties and adds COSCO and Nile Dutch as parties to the Agreement.

Agreement No.: 012300–001.

Title: The COSCO Shipping/KL/YMUK/ELJSA Slot Allocation and Sailing Agreement.

Parties: COSCO Shipping Lines Co., Ltd., Limited; Kawasaki Kisen Kaisha, Ltd.; Yang Ming (UK) Ltd.; Hanjin Shipping Co., Ltd.; and the Evergreen Line Joint Service Agreement.

Filing Party: Eric. C. Jeffrey, Esq.; Nixon Peabody LLP; 799 9th Street NW., Suite 500; Washington, DC 20001.

Synopsis: The amendment deletes Hanjin Shipping as a member of the agreement, changes the name of the agreement accordingly, and updates the name of COSCO Shipping.

Agreement No.: 012439–001.

Title: THE Alliance Agreement.

Parties: Hapag-Lloyd AG and Hapag-Lloyd USA LLC (acting as one party); Kawasaki Kisen Kaisha, Ltd.; Mitsui O.S.K. Lines, Ltd.; Nippon Yusen Kaisha; and Yang Ming Marine Transport Corp.

Filing Party: David F. Smith, Esq.; Cozen O'Conner; 1200 Nineteenth Street NW.; Washington, DC 20036.

Synopsis: The amendment authorizes the Parties to the Agreement to form, contribute funds to, develop rules for, and administer a contingency fund designed to protect against the effects of one of the parties experiencing financial distress or an insolvency event. The parties have requested expedited review.

By Order of the Federal Maritime Commission.

Dated: August 9, 2017.

JoAnne D. O' Bryant,

Program Analyst.

[FR Doc. 2017–17126 Filed 8–11–17; 8:45 am]

BILLING CODE 6731–AA–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than August 29, 2017.

A. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *Deborah Viergutz, Ellenton, Florida; Lisa A. Verzani, Helena, Montana; Donald Verzani and Patricia L. Verzani, both of Portland, Oregon; and Jenny Wilcynski and Mike Wilcynski, both of Big Sky, Montana;* to retain or acquire voting shares of First State Bancorp, Inc., Randolph, Nebraska, and for approval as members of the Viergutz Family Group to control voting shares of First State Bancorp,

Inc., and thereby own shares of First State Bank, both of Randolph, Nebraska.

Board of Governors of the Federal Reserve System, August 9, 2017.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2017–17109 Filed 8–11–17; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than September 7, 2017.

A. Federal Reserve Bank of Boston (Prabal Chakrabarti, Senior Vice President) 600 Atlantic Avenue, Boston, Massachusetts 02210–2204. Comments can also be sent electronically to *BOS.SRC.Applications.Comments@bos.frb.org:*

1. *Mascoma Mutual Financial Services Corporation,* Lebanon, New Hampshire; to become a bank holding company by acquiring voting shares of Macsoma Savings Bank, Lebanon, New Hampshire.

Board of Governors of the Federal Reserve System, August 9, 2017.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2017–17110 Filed 8–11–17; 8:45 am]

BILLING CODE 6210–01–P

OFFICE OF GOVERNMENT ETHICS

Solicitation of Input From Stakeholders Regarding the U.S. Office of Government Ethics Strategic Plan (FY 2018–2022)

AGENCY: Office of Government Ethics (OGE).

ACTION: Notice of request for public comment.

SUMMARY: The U.S. Office of Government Ethics (OGE) is providing notice of request for public comment on its draft Strategic Plan (Plan). The Plan describes OGE's priorities for the next five years. OGE will consider all comments received by the deadline. You may access the Plan at *https://www.oge.gov/web/OGE.nsf/News+Releases/B0EE73EF1ADC7AF38525816F0075CB6F?opendocument,* or you may obtain a copy of the plan by sending an email request to *OGEStrategicPlan@oge.gov.*

DATES: All comments must be received by August 25, 2017.

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

Email: OGEStrategicPlan@oge.gov.

Mail, Hand Delivery/Courier: U.S. Office of Government Ethics, Suite 500, 1201 New York Avenue NW., Washington, DC 20005–3917, Attention: Nicole Stein, OGE Strategic Plan.

Instructions: All submissions must include OGE's agency name and the words ''Strategic Plan.'' All comments, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. Comments may be posted on OGE's Web site, *www.oge.gov.* Sensitive personal information, such as account numbers or Social Security numbers, should not be included. Comments generally will not be edited to remove any identifying or contact information.

FOR FURTHER INFORMATION CONTACT: Nicole Stein, Chief, Agency Assistance Branch, U.S. Office of Government Ethics, Suite 500, 1201 New York Avenue NW., Washington, DC 20005–3917; Telephone (202) 482–9255; TTY: 800–877–8339; Email: *nicole.stein@oge.gov.*

Dated: August 8, 2017.

David J. Apol,

Acting Director, U.S. Office of Government Ethics.

[FR Doc. 2017–17032 Filed 8–11–17; 8:45 am]

BILLING CODE 6345–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number: NIOSH 278]

Board of Scientific Counselors, National Institute for Occupational Safety and Health

ACTION: Notice of meeting.

SUMMARY: In accordance with section 10(a)(2) of the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned committee. This meeting is open to the public. The public comment period is from 12:30 p.m. to 12:45 p.m. Please note that the public comment period ends at the time indicated above or following the last call for comments, whichever is earlier. Each commenter will be provided up to five minutes for comment. A limited number of time slots are available and will be assigned on a first come-first served basis. Written comments will also be accepted from those unable to attend the public session via an on-line form at the following Web site: *http://www.cdc.gov/niosh/bsc/contact.html.*

This meeting is open to the public, limited only by the space available. The meeting room accommodates approximately 33 people. The meeting is also open to the public via webcast. If you wish to attend in person or by webcast, please see the NIOSH Web site to register (*http://www.cdc.gov/niosh/bsc/*) or call (404–498–2539) at least five business days in advance of the meeting. Teleconference is available toll-free; please dial (888) 397–9578, Participant Pass Code 63257516. Adobe Connect webcast will be available at *https://odniosh.adobeconnect.com/nioshbsc/* for participants wanting to connect remotely.

DATES: The meeting will be held on September 26, 2017, 8:30 a.m.–2:30 p.m., EDT.

ADDRESSES: Patriots Plaza I, 395 E Street SW., Room 9000, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Alberto Garcia, M.S., Executive Secretary, BSC, NIOSH, CDC, 1090

Tusculum Avenue, MS–R5, Cincinnati, OH 45226, telephone (513) 841–4596, fax (513) 841–4506.

SUPPLEMENTARY INFORMATION:

Purpose: The Secretary, the Assistant Secretary for Health, and by delegation the Director, Centers for Disease Control and Prevention, are authorized under Sections 301 and 308 of the Public Health Service Act to conduct directly or by grants or contracts, research, experiments, and demonstrations relating to occupational safety and health and to mine health. The Board of Scientific Counselors provides guidance to the Director, National Institute for Occupational Safety and Health on research and prevention programs. Specifically, the Board provides guidance on the Institute's research activities related to developing and evaluating hypotheses, systematically documenting findings and disseminating results. The Board evaluates the degree to which the activities of the National Institute for Occupational Safety and Health: (1) Conform to appropriate scientific standards, (2) address current, relevant needs, and (3) produce intended results.

Matters for Discussion: The agenda for the meeting addresses occupational safety and health issues related to: Stockpiled surgical gowns & respirators; the increased use and complexity of robots; NIOSH's disaster science responder research; and fentanyl exposures to emergency responders.

Agenda items are subject to change as priorities dictate.

An agenda is also posted on the NIOSH Web site (*http://www.cdc.gov/niosh/bsc/*). Members of the public who wish to address the NIOSH BSC are requested to contact the Executive Secretary for scheduling purposes (see contact information below). Alternatively, written comments to the BSC may be submitted via an on-line form at the following Web site: *http://www.cdc.gov/niosh/bsc/contact.html.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2017–17128 Filed 8–11–17; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Meeting of Board of Scientific Counselors BSC National Center for Injury Prevention

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned committee. This meeting is open to the public. The public is also welcome to listen to the meeting by joining the teleconference at the USA toll-free, dial-in number, 1–877–492–3517 and the passcode is 2576415. The phone line has 75 ports available for teleconference participants. The meeting room will only accommodate 50 people. There will be 15 minutes allotted on Wednesday, September 27, 2017 from 11:30 a.m.–11:45 a.m. for public comments. The public is welcome to submit written comment in advance of the meeting, to the contact person listed below. Written comments received in advance of the meeting will be included in the official record of the meeting.

DATES: The meeting will be held on September 26, 2017, 9:00 a.m. to 4:40 p.m., EDT, and September 27, 2017, 9:30 a.m.–12:00 p.m., EDT.

ADDRESSES: Crown Plaza Atlanta Perimeter at Ravinia, 4355 Ashford Dunwoody Road NE., Atlanta, 30346 and via Teleconference: Dial-In Number: 1–877–492–3517, Participant Code: 2576415.

FOR FURTHER INFORMATION CONTACT: Gwendolyn H. Cattledge, Ph.D., M.S.E.H., Deputy Associate Director for Science, NCIPC, CDC, 4770 Buford Highway NE., Mailstop F–63, Atlanta, GA 30341, Telephone (770) 488–1430. Email address: *GCattledge@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: The Board will: (1) Conduct, encourage, cooperate with, and assist other appropriate public health authorities, scientific institutions, and scientists in the conduct of research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases, and other impairments; (2) assist States and their political subdivisions in preventing and suppressing communicable and non-communicable diseases and other preventable conditions and in promoting health and well-being; and (3) conduct and assist in research and control activities related to injury.

The Board of Scientific Counselors makes recommendations regarding policies, strategies, objectives, and priorities; and reviews progress toward injury prevention goals and provides evidence in injury prevention-related research and programs. The Board also provides advice on the appropriate balance of intramural and extramural research, the structure, progress and performance of intramural programs. The Board is designed to provide guidance on extramural scientific program matters, including the: (1) Review of extramural research concepts for funding opportunity announcements; (2) conduct of Secondary Peer Review of extramural research grants, cooperative agreements, and contracts applications received in response to the funding opportunity announcements as it relates to the Center's programmatic balance and mission; (3) submission of secondary review recommendations to the Center Director of applications to be considered for funding support; (4) review of research portfolios, and (5) review of program proposals.

Matters To Be Considered: The Board of Scientific Counselors Agenda for the two-day meeting will be: September 26, 2017—Will discuss science matters to include research strategies needed to guide the Center's focus, as well as updates on the NCIPC extramural research program, the National Intimate and Sexual Violence Workgroup, and the Pediatric Mild-Traumatic Injury Workgroup. September 27, 2017—Will discuss science matters to include the Essentials for Childhood Workgroup Portfolio Review, the Suicide Strategic Plan, and Opioid Overdose CDC Coordination/Strategic Directions. Agenda items are subject to change as priorities dictate.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and

Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2017–17129 Filed 8–11–17; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–17–17NS]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Assessing the Infrastructure for Public Sexually Transmitted Disease (STD) Prevention Services—NEW—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Annually, there are nearly 20 million cases of sexually transmitted diseases (STD) in the United States (US) causing an estimated $15.6 billion in direct medical costs. A significant percentage of reported cases of STDs are diagnosed in publicly funded clinics, such as STD clinics that are operated by state health departments (SHDs) and local health departments (LHDs). Additionally, state and local health departments also engage in other essential STD prevention activities such as partner services and disease surveillance. Therefore, it is important to periodically assess the current level of publicly-funded STD prevention services that are offered by health departments in the US.

The STD infrastructure survey will aid CDC in understanding the scope of the delivery of timely public STD preventive and clinical services that are provided to reduce the number of newly acquired STDs and prevent STD-related sequelae. There is no national data available that focuses on detailed STD prevention activities conducted by state and local health departments.

The purpose of this survey is to periodically, (*i.e.,* every three years) examine STD prevention services provided by local and state health departments. The survey will include all state health departments and a nationally representative sample of local health departments in the US. The local health department sample will allow for estimates by jurisdiction population size and US Census region.

The survey contains sections on STD program structure within the health department, STD-related clinical services (local health departments only), partner and other prevention services, and workforce and impacts of any budget reductions.

CDC will administer the STD infrastructure survey to all 50 state health departments and a random sample of 668 local health departments from a list of local health departments maintained by the National Association of City and County Health Officials (NACCHO). Using a web-based survey, multiple reminders will be sent to non-responders in order to reach the target of 44 completed state and 334 completed local surveys for each data collection (different respondents per data collection). The total estimated annual burden hours are 238. There is no cost to respondents other than their time.

ESTIMATED ANNUAL BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
STD program director, LHDs	LHD survey	668	1	15/60
STD program director, SHDs	SHD survey	50	1	85/60

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2017–17025 Filed 8–11–17; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Board on Radiation and Worker Health (ABRWH or the Advisory Board), Subcommittee for Dose Reconstruction Reviews (SDRR), National Institute for Occupational Safety and Health (NIOSH)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC), announces the following meeting for the aforementioned subcommittee. This meeting is open to the public, but without a public comment period. The public is welcome to submit written comments in advance of the meeting, to the contact person below. Written comments received in advance of the meeting will be included in the official record of the meeting. The public is also welcome to listen to the meeting by joining the teleconference at the USA toll-free, dial-in number at 1–866–659–0537 and the pass code is 9933701. The conference line has 150 ports for callers.

DATES: The meeting will be held on September 28, 2017, 10:30 a.m.–5:00 p.m., EDT.

ADDRESSES: Audio Conference Call via FTS Conferencing. The USA toll-free dial-in number is 1–866–659–0537 and the pass code is 9933701.

FOR FURTHER INFORMATION CONTACT: Theodore Katz, MPA, Designated Federal Officer, NIOSH, CDC, 1600 Clifton Road, Mailstop E–20, Atlanta, Georgia 30333, Telephone (513) 533–6800, Toll Free 1 (800) CDC–INFO, Email *ocas@cdc.gov.*

SUPPLEMENTARY INFORMATION: *Background:* The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines, which have been promulgated by the Department of Health and Human Services (HHS) as a final rule; advice on methods of dose reconstruction, which have also been promulgated by HHS as a final rule; advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program; and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, rechartered on March 22, 2016 pursuant to Executive Order 13708, and will expire on September 30, 2017.

Purpose: The Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class. The Subcommittee for Dose Reconstruction Reviews was established to aid the Advisory Board in carrying out its duty to advise the Secretary, HHS, on dose reconstruction.

Matters To Be Considered: The agenda for the Subcommittee meeting includes the following dose reconstruction program quality management and assurance activities: Dose reconstruction cases under review from Sets 14–23, including the Oak Ridge sites (Y–12, K–25, Oak Ridge National Laboratory), Hanford, Feed Materials Production Center (''Fernald''), Lawrence Livermore National Laboratory, Mound Plant, Rocky Flats Plant, Nevada Test Site, Idaho National Laboratory, Savannah River Site, Brookhaven National Laboratory, Westinghouse, W.R. Grace, Uranium Mill in Monticello, Ventron Corporation, Weldon Springs Plant, and other Department of Energy and ''Atomic Weapons Employer'' facilities. The agenda is subject to change as priorities dictate.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2017–17130 Filed 8–11–17; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Numbers: 93.581, 93.587, 93.612]

Request for Public Comment on the Proposed Adoption of Administration for Native Americans Program Policies and Procedures

AGENCY: Administration for Native Americans, ACF, HHS.

ACTION: Notice for public comment.

SUMMARY: Pursuant to Section 814 of the Native American Programs Act of 1974 (NAPA), as amended, the Administration for Native Americans (ANA) is required to provide members of the public an opportunity to comment on proposed changes in interpretive rules and general statements of policy and to give notice of the final adoption of such changes no less than 30 days before such changes become effective. In accordance with notice requirements of NAPA, ANA herein describes proposed interpretive rules and general statements of policy that relate to ANA's funding opportunities beginning in Fiscal Year (FY) 2018. Changes to FY 2018 Funding Opportunity Announcements (FOAs) will be based on the following previously published programs: Environmental Regulatory Enhancement (ERE) HHS–2017–ACF–ANA–NR–1221, Native American Language Preservation and Maintenance-Esther Martinez Immersion (EMI) HHS–2017–ACF–ANA–NB–1226, Native American Language Preservation and Maintenance (P&M) HHS–2017–ACF–ANA–NL–1235, Social and Economic Development Strategies (SEDS) HHS–2017–ACF–ANA–NA–1236, Social and Economic Development Strategies-Alaska (SEDS–AK) HHS–2015–ACF–ANA–NK–0960,

and Native Youth Initiative for Leadership, Empowerment, and Development (ILEAD) HHS–2017–ACF–ANA–NC–1263. This notice of public comment also provides additional information about ANA's plan for administering grant programs.

DATES: The deadline for receipt of comments is 30 days from the date of publication in the **Federal Register**. No FOA will be published prior to 30 days from publication of this Notice.

ADDRESSES: Comments in response to this notice should be addressed to Carmelia Strickland, Director of Program Operations, Administration for Native Americans, 330 C Street SW., Washington, DC 20201. Delays may occur in mail delivery to federal offices; therefore, a copy of comments should be emailed to *ANAComments@acf.hhs.gov.* Comments will be available for inspection by members of the public at the Administration for Native Americans, 330 C Street SW., Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Carmelia Strickland, Director, Division of Program Operations, Administration for Native Americans (877) 922–9262.

SUPPLEMENTARY INFORMATION: Section 814 of NAPA, as amended, incorporates provisions of the Administrative Procedure Act (APA) that require ANA to provide notice of its proposed interpretive rules and statements of policy and to seek public comment on such proposals. This notice serves to fulfill the statutory notice and public comment requirement. ANA has also chosen to provide notice of its proposed rules of agency practice and procedure. The proposed interpretive rules, statements of policy, and rules of ANA practice and procedure reflected in clarifications, modifications, and new text will appear in the six FY 2018 FOAs: Environmental Regulatory Enhancement (ERE), Native American Language Preservation and Maintenance-Esther Martinez Immersion (EMI), Native American Language Preservation and Maintenance (P&M), Social and Economic Development Strategies (SEDS), Social and Economic Development Strategies-Alaska (SEDS–AK), and Native Youth Initiative for Leadership, Empowerment, and Development (ILEAD). This notice also reflects ANA's elimination of the Sustainable Employment and Economic Strategies (SEEDS) FOA.

For information on the types of projects funded by ANA, please refer to the following for information on current and previously funded ANA grants at *https://www.acf.hhs.gov/ana/grants.*

Pre-publication information on ANA's FOAs is available at *https://www.grants.gov/web/grants/search-grants.html* by clicking on 'Forecasted' under Opportunity Status and 'Administration for Children and Families—ANA [HHS–ACF–ANA]' on the left side of the page. ANA's FOAs can be accessed at: *http://www.acf.hhs.gov/grants/open/foa/office/ana* or *http://www.acf.hhs.gov/grants/open/foa/.* Synopses and application forms will be available on *https://www.grants.gov/.*

A. Interpretive rules, statements of policy, procedures, and practice. The proposals below reflect ANA's proposed changes in rules, policy, or procedure which will take effect in the FY 2018 FOAs.

1. Application periods. ANA proposes to provide an open application period of no less than 90 days to respond to FOAs. ANA is increasing the open application period to provide applicants with additional time to review proposed changes that are actualized in the FY 2018 FOAs, and to develop their applications according to FOA requirements. ANA intends to maintain the 90 day open application period for subsequent years.

2. Two-File Upload Requirement. ANA proposes to include the grant application submission requirement established by the Administration for Children and Families (ACF), which specifies ''applicants submitting their applications electronically are required to upload only two electronic files. No more than two files will be accepted for the review and additional files will be removed. Standard Forms will not be considered as additional files.'' ANA requested to deviate from this policy in order to provide rural communities and lower capacity organizations an opportunity to adjust to any technological, or bandwidth requirements that go along with transfer and upload of large files. The policy has now been in existence for several years for other ACF Programs, therefore ANA will no longer request a deviation from this standard ACF policy.

3. Reduced project period for ILEAD. ANA proposes to maintain the reduced maximum project period for awards made under the ILEAD FOA from four years (four 12- month budget periods) to three years (three 12-month budget periods). The reduced project period was made in FY 2017 FOAs to align the program with ANA's Social and Economic Development Strategies (SEDS) program, which is published under the same CFDA number as ILEAD.

4. FY 2018 FOA—Project Description. ANA proposes to modify the information requested in the project description for FY 2018 application submissions. Modifications are being proposed to reflect a shift away from a deficit approach, towards a strength-based approach to defining projects and addressing long-term community goals, and to align the application request for information with common terminology related to program evaluation. The following is applicable to project description requests, and evaluation criterion for all ANA FOAs published beginning in FY 2018:

(a) ANA will no longer require the ''Problem Statement'' or include the section titled ''Objectives and Need for Assistance''. Instead, ANA proposes to focus on long term community goals, the community condition, and how the project outcomes relate to the community condition. Information will be requested under the Expected Outcomes section of the Project Description request.

(b) To shift terms included in the FOA towards commonly used evaluation terminology, objectives will no longer be referred to as Specific, Measureable, Achievable, Relevant, and Time-bound (SMART). ANA proposes to define objectives with population, targets, indicators, and timelines. In addition the terms ''results'' and ''benefits'' will be replaced with ''outcomes'' and ''outputs.''

(c) ANA proposes to require information that addresses elements of a ''Project Framework''. The project framework will include the following elements: Long-term community goal, current community condition, outcomes; project goal, objectives, indicators, and outputs. The project framework includes elements previously requested in ANA FOAs, in combination with new elements, to fully identify the project in relation to overall community goals; identify project outcomes related to the enhancement of a current community condition; and establish a framework for monitoring changes and identifying tangible results from the project.

(d) ANA will no longer require the identification of impact or an impact indicator; instead, ANA proposes the requirement of an outcome tracking strategy. The outcome tracking strategy will require applicants to identify an indicator and outcome for each objective; a means for measuring change to the indicator, which includes data points and establishes targets to be met throughout project implementation; and a list of project outputs related to each project objective. Within the FY 2018

FOAs, ANA intends to include a suggested format for organizing the information included in the outcome tracking strategy, similar to the suggestion included in the FY 2017 FOAs for organizing impact indicators.

(e) To prioritize community based projects, ANA proposes to require information to identify a community-based strategy for project implementation. The requirement will include information to describe how the proposed project relates to community based priorities, how the community was involved in project development, and how the community will be involved in implementation and sustainability.

(f) The ANA Objective Work Plan (OWP) [current OMB form 0970–0452] will be modified. The terms ''results'' and ''benefits'' will no longer be used; instead, applicants will be required to identify outcomes and outputs. Key project activities will be included separately from administrative activities. Requirements for key activities will include alignment to outputs that are created by project implementation and a maximum of 25 key activities per objective during each year of implementation.

(a) To accommodate modifications to ANA's application information request, ANA proposes the following evaluation criteria headings and scoring values: Outcomes Expected (0–25 points), Outcome Tracking Strategy (0–10 points), Approach (0–25 points), Organizational Capacity (0–15 points), OWP (0–15 points), and Budget (0–10 points).

(b) A scoring table will be included in all FOAs to provide additional guidance to panel reviewers regarding the allocation of points in relation to the quality of information provided in the application.

5. ANA Administrative Policies. The following modifications are applicable to the ANA Administrative Policies included in all FY 2018 FOAs:

(a) ANA proposes to add an administrative policy to prioritize the award of funds to applicant organizations that are local, community based organizations. In the case of national, regional, or non-local based organizations, ANA may provide support to organizations that have provided information to justify they are the appropriate applicant organization to administer the proposed project in support of the community and project beneficiaries being served. The policy is proposed as follows:

Prioritized Funding for Local, Native American Community Based Organizations:

ANA reserves the right to prioritize funding to local Native American community-based organizations serving their local communities and populations. Applications from national and regional organizations that propose projects that are performed in a different geographic location must clearly demonstrate how the target community was selected. They must also demonstrate a need for the project, explain how the project originated, discuss the community-based delivery strategy of the project, identify and describe the intended beneficiaries, describe and relate the actual project benefits to the community and organization, and describe a community-based delivery system. National and regional organizations must describe their membership, define how the organization operates and demonstrate Native community and/or Tribal government involvement in the development of the project and support for the project. The type of community to be served will determine the type of documentation necessary to support the project.

This proposed administrative policy is based on the priority for self-sufficiency for Native American communities, and follows the premise that self-sufficiency is best obtained when local organizations are leading efforts to achieve community goals. The policy will state ANA's priority for community local, community based organizations, and describe information requirements for national, regional, or non-local based organizations.

(b) Limitation on Number of Awards Based on Two Consecutively Funded Projects: ANA proposes to edit language for this policy to clarify that a no cost extension (NCE) will be included as a period of project implementation, towards consecutively funded projects. The policy is proposed as follows:

Limitation on Number of Awards Based on Two Consecutively Funded Projects:

ANA will maximize the reach of its limited funding. Therefore, applicants that have implemented at least two consecutive projects within one CFDA number may not be funded for a third consecutive project within the same CFDA number if other applicants who have not received ANA funding in the past 3 years are within the scoring range to be funded. Project implementation periods are comprised of newly awarded first year project periods, Non Competing Continuation (NCC) periods, and any No Cost Extensions (NCE) periods.

Therefore grantees that have been approved for a NCE must complete a year after the end of the NCE period without implementing an ANA project under the same CFDA number before they are considered to be exempt from this policy. This specific issue has raised several questions during the implementation period for ANA projects. Editing the policy is meant to clarify its application prior to the start of an award.

6. Ineligible Activities. ANA proposes to revise language describing ineligible third party training and technical assistance, which is included in the list of Projects Ineligible for Funding in all FY 2018 FOAs. The revision will remove the statement that describes third party training and technical assistance as activities that duplicate training and technical assistance provided by ANA T/TA providers, and the language will directly align the ineligible activity with language in Subchapter D—The Administration for Native Americans, Native American programs, 45 CFR 1336.33(b).

Ineligible Third Party Training and Technical Assistance activities will be stated in the FOAs as follows:

Projects for which a grantee will provide training and technical assistance to other tribes or Native American organizations or to non-members of the grantee organization (third party training or technical assistance).

7. Disqualification Factors. ANA proposes the following edits to the ANA Disqualification Factors included in all FY 2018 FOAs:

(a) ANA will include language to clarify that Tribal Colleges and public agencies serving native peoples from Guam, American Samoa, or the Commonwealth of the Northern Mariana Islands, are required to submit Assurance of Community Representation and Governing Body Documentation from the governing body of the Tribal College. Documentation from the governing body of the Tribe will not fulfill the requirements for this documentation. This clarification is proposed to reduce the number of applications that are disqualified due to misunderstanding the requirements.

(b) ANA will revise the categories for community representation, as described under the Assurance of Community Representation on Board of Directors. ANA proposes to remove the second category of affiliation/relationship to the community being served. This category was listed as: ''persons eligible to be a participant in, or beneficiary of the project.'' The Assurance of Community Representation is included to ensure ANA funds are awarded to organizations that directly represent the Native American community that will be served (See 45 CFR 1336.33). However, ANA does not limit project participants or beneficiaries to individuals that represent the community being served. Therefore ANA has determined that the inclusion of this category does not support the intention of this policy.

The revised policy is proposed as follows:

Assurance of Community Representation on Board of Directors

Applicants other than tribes or Alaska Native Villages applying for funding must show that a majority of board members are representative of a Native American community to be served. Applicants must submit documentation that identifies each board member by name and indicates his/her affiliation or relationship to at least one of ANA's three categories of community representation, which include: (1) Members of federally or state-recognized tribes; (2) persons who are recognized by members of the eligible Native American community to be served as having a cultural relationship with that community; or (3) persons considered to be Native American as defined in 45 CFR 1336.10 and Native American Pacific Islanders as defined in Section 815 of the Native American Programs Act. Applicants that do not include this documentation will be considered non-responsive, and the application will not be considered for competition. See Section IV.2. Project Description, Additional Eligibility Documentation.

Public agencies serving native peoples from Guam, American Samoa, or the Commonwealth of the Northern Mariana Islands, and Tribal Colleges governed by a board that is separate from the governing body of a tribe, must include Assurance of Community Representation from the governing body of the Tribal College, and not from the governing body of the Tribe. If the documentation is not included by the submission deadline, the application will be considered unresponsive and will be disqualified from the competition.

8. Review and Selection Process. ANA will modify the implementation of the Review and Selection process, as stated in all FY 2018 FOAs as follows:

(a) ANA's commissioner has the discretion to make all final funding decisions. In exercising this discretion, the commissioner includes a list in Section V.2. Review and Selection Process of projects that may not be chosen for funding. For the FY 2018 FOAs, ANA proposes the following:

Additions:

- Projects that have not demonstrated a community-based strategy as described in Section I. Program Description, Key Project Features.
- Projects proposed by national, regional, and non-local organization that have not justified their position as the best applicant organization to address long term community goals for a local community. Please see Section I. Administrative Policies, Prioritized Funding for Local, Native American Community Based Organizations.
- Projects proposing activities that were previously implemented without Federal Assistance.

Because ANA funding is limited, ANA proposes adding these items to the list in order to align with new language emphasizing community-based strategies, and to highlight the priority for funding these projects. ANA also wants to ensure that its limited funding is being used for projects that are not able to secure other sources of funding for activities that were being previously implemented without support from the Federal Government.

Deletion:

- Projects that provide couples or family counseling activities that are medically-based.

ANA has stated in other administrative policies that it will not fund human research, or projects that may cause unintended harm to project participants. Outside of these limitations, and in an effort to support the Native American community's ability to determine if these activities are actually beneficially to achievement of their long-term goals, ANA will no longer limit the proposal of projects that include medically-based couples or family counseling activities.

9. Native American Preservation and Maintenance Program. The following modifications are being proposed to the ''Native American Languages Preservation and Maintenance,'' and ''Native American Languages Preservation and Maintenance Esther Martinez Immersion'' FOAs only:

(a) ANA proposes the identification of language specific outcomes that relate to one of the following categories: Language fluency, increased community member use of language learning resources; certified language teachers; or increased capacity to implement a language program. The categories are being proposed in order to further define the outcomes for ANA language projects, and to support the monitoring and evaluation of ANA's language and preservation program.

(b) ANA will include language in the FY 2018 FOAs to restate application requirements included in Section 803C(c)(5–6) of the Native American Programs Act (NAPA) of 1974. The requirements are as follows:

(5) if appropriate, an identification of opportunities for the replication of such project or the modification of such project for use by other Native Americans; and

(6) a plan for the preservation of the products of the Native American language project for the benefit of future generations of Native Americans and other interested persons''

This language will be added directly as stated in ANA's authorizing legislation to ensure that applications meet the requirements of NAPA.

Statutory Authority: Section 814 of the Native American Programs Act of 1974 (NAPA), as amended.

Kimberly Romaine,

Deputy Commissioner, Administration for Native Americans.

[FR Doc. 2017–17099 Filed 8–11–17; 8:45 am]

BILLING CODE 4184–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Social Services Block Grant (SSBG) Post-Expenditure Report.

OMB No.: 0970–0234.

Description: The purpose of this is to request approval to: (1) Reinstate and extend the collection of post-expenditure data using the current OMB approved Post-Expenditure Reporting form (OMB No. 0970–0234) with modification past the current expiration date of November 30, 2017; (2) propose 8 minor additions to the current Post-Expenditure Reporting form; and (3) to request that grantees continue to voluntarily submit estimated pre-expenditure data using the Post-Expenditure Reporting form, as part of the required annual Intended Use Plan.

The Social Services Block Grant (SSBG) is authorized under Title XX of the Social Security Act, as amended, and is codified at 42 U.S.C § 1397 through § 1397e. SSBG provides funds to States, the District of Columbia, Puerto Rico, American Samoa, Guam, the Virgin Islands, and the Commonwealth of the Northern Mariana Islands (hereinafter referred to as States and Territories or grantees) to assist in delivering critical services to vulnerable older adults, persons with disabilities, at-risk adolescents and young adults, and children and families. SSBG funds are distributed to each State and the District of Columbia based on each State's population relative to all other States. Distributions are made to Puerto Rico, Guam, American Samoa, the Virgin Islands, and the Commonwealth of the Northern Mariana Islands based on the same ratio allotted to them in 1981 as compared to the total 1981 appropriation.

Each State or Territory is responsible for designing and implementing its own use of SSBG funds to meet the specialized needs of their most vulnerable populations. States and Territories may determine what services will be provided, who will be eligible,

and how funds will be distributed among the various services. State or local SSBG agencies (*i.e.,* county, city, regional offices) may provide the services or grantees may purchase services from qualified agencies, organizations, or individuals. States and Territories must administer the SSBG according to their accepted Intended Use Plan, along with amendments, and in conformance with their own implementing rules and policies. The Office of Community Services (OCS), Administration for Children and Families administers the SSBG.

Annually, grantees are required to submit a Pre-Expenditure Report and Intended Use Plan as a prerequisite to receiving SSBG funds. The Pre-Expenditure Report must include information on the types of services to be supported and the characteristics of individuals to be served. This report is to be submitted 30 days prior to the start of the Fiscal Year (June 1 if the State operates on a July–June Fiscal Year, or September 1 if the State operates on a Federal Fiscal Year). No specific format is required for the Intended Use Plan. Grantees are required to submit a revised Intended Use Plan and Pre-Expenditure Report if the planned use of SSBG funds changes during the year (42 U.S.C. 1397c).

In order to provide a more accurate analysis of the extent to which funds are spent ''in a manner consistent'' with each of the grantees' plan for their use, as required by 42 U.S.C. 1397e (a), OCS continues to request that States voluntarily use the format of the Post-Expenditure Reporting form to create their Pre-Expenditure Report, which provides estimates of the amount of expenditures and the number of recipients, by service category, and is submitted as part of the grantees' Intended Use Plan. Most of the States and Territories are currently using the format of the Post-Expenditure Reporting form to report estimated expenditures and recipients (the Pre-Expenditure Report), by service category, as part of their Intended Use Plan.

On an annual basis, States and Territories are also required to submit a Post-Expenditure Report that details their use of SSBG funds in each of 29 service categories. Grantees are required to submit their Post-Expenditure Report within six months of the end of the period covered by the report. The Post-Expenditure Report must address (1) The number of individuals (including number of children and number of adults) who receive services paid for, in whole or in part, with Federal funds under the SSBG; (2) The amount of SSBG funds spent in providing each service; (3) The total amount of Federal, State, and Local funds spent in providing each service, including SSBG funds; (4) The method(s) by which each service is provided, showing separately the services provided by public and private agencies; and (5) the criteria applied in determining eligibility for each service such as income eligibility guidelines, sliding scale fees, the effect of public assistance benefits, and any requirements for enrollment in school or training programs (45 CFR 96.74a). The Post-Expenditure Report must also; (1) indicate if recipient totals are actual or if the total reported is based on estimates and/or sampled data; and (2) use its own definition of child and adult in reporting the required data (45 CFR 96.74b).

This request seeks approval to reinstate and continue the use of the current OMB approved Post-Expenditure Reporting form (OMB No. 0970–0234) with modification, for estimating expenditures and recipients as part of States'/Territories' Pre-Expenditure Reports and for annual Post-Expenditure Reporting. The proposed modifications seek to consolidate information that would be stored or transmitted elsewhere into the singular reporting form to allow OCS to better analyze and provide guidance to improve States efficiency in grant administration. These modifications address the regulations 42 U.S.C. 1397e and 45 CFR 96.74 cited above by providing space on the Post-Expenditure form to indicate the required information.

Beginning in 2013, States completed the current reporting form on the SSBG Portal. The SSBG Portal is a secure web-based data portal. The SSBG Portal allows for more efficient data submission without increasing the overall burden on States. Until recently, Territories reported the data on the Post-Expenditure Reporting form in Microsoft Excel and submitted it to ACF, via email or posted mail. In 2017, Territories can complete the current reporting form on the SSBG Portal. The SSBG Portal provides a user-friendly means for States and Territories to submit and access their Pre-Expenditure and Post-Expenditure and Recipient Data.

Information collected in the Post-Expenditure Reports submitted by States and Territories is analyzed and described in an annual report on SSBG expenditures and recipients produced by the Office of Community Services (OCS), Administration for Children and Families (ACF). The information contained in this report is used for grant planning and management. The data establishes how SSBG funding is used for the provision of services in each State or Territory.

The data is also analyzed to determine the performance of States and Territories in meeting the SSBG performance measures developed to meet the requirements of the Government Performance and Results Act of 1993 (GPRA), as amended by the GPRA Modernization Act of 2010 [Pub. L. 11–352; 31 U.S.C 1115(b)(10)]. GPRA requires all Federal agencies to develop measurable performance goals.

The SSBG currently has an administrative costs efficiency measure which is intended to decrease the percentage of SSBG funds identified as administrative costs in the Post-Expenditure Reports [U.S. Department of Health and Human Services, Administration for Children and Families, Office of Community Services. (2007, June). *Implementing a new performance measure to enhance efficiency* (Information Memorandum Transmittal No. 04–2007). Available from *https://www.acf.hhs.gov/ocs/resource/implementing-a-new-performance-measure-to-enhance-efficiency*]. The SSBG also implements a performance measure designed to ensure that SSBG funds are spent effectively and efficiently while maintaining the intrinsic flexibility of the SSBG as a block grant. The performance measure assesses the degree to which States and Territories spend SSBG funds in a manner consistent with their intended use, as required by Federal law [42 U.S.C. 1397e(a); U.S. Department of Health and Human Services, Administration for Children and Families, Office of Community Services. (2012, February). *Implementation of a new performance measure* (Information Memorandum Transmittal No. 01–2012). Available from *https://www.acf.hhs.gov/ocs/resource/implementation-of-a-new-performance-measure*]. It will be used to determine how well grantees are doing overall in minimizing variance between projected and actual expenditures of SSBG funds. This program measure began implementation with FY 2013 data and remains ongoing.

Respondents: The Post-Expenditure Reporting form and Pre-Expenditure Report are completed once annually by a representative of the agency that administers the Social Services Block Grant at the State or Territory level. Respondents include the 50 States, the District of Columbia, and Puerto Rico, as well as the territories of American Samoa, Guam, the Virgin Islands, and

the Commonwealth of Northern Mariana Islands.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Post-Expenditure Reporting Form	56	1	110	6,160
Use of Post-Expenditure Reporting Form as Part of the Intended Use Plan	56	1	2	112

Estimated Total Annual Burden Hours: 6,272.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2017–17098 Filed 8–11–17; 8:45 am]

BILLING CODE 4184–24–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–4515]

International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Ocfentanil, Carfentanil, Pregabalin, Tramadol, Cannabidiol, Ketamine, and Eleven Other Substances; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting interested persons to submit comments concerning abuse potential, actual abuse, medical usefulness, trafficking, and impact of scheduling changes on availability for medical use of 17 drug substances. These comments will be considered in preparing a response from the United States to the World Health Organization (WHO) regarding the abuse liability and diversion of these drugs. WHO will use this information to consider whether to recommend that certain international restrictions be placed on these drugs. This notice requesting comments is required by the Controlled Substances Act (the CSA).

DATES: Submit either electronic or written comments by September 13, 2017.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 13, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of September 13, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for Written/Paper Submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–N–4515 for ''International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Ocfentanil; Furanyl fentanyl (Fu-F); Acryloylfentanyl (Acrylfentanyl); Carfentanil; 4-fluoroisobutyrfentanyl (4–FIBF); Tetrahydrofuranylfentanyl (THF–F); 4-fluoroamphetamine (4–FA); AB–PINACA; AB–CHMINACA; 5F–PB–22; UR–144; 5F–ADB; Etizolam; Pregabalin; Tramadol; Cannabidiol; Ketamine; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential

with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

James R. Hunter, Center for Drug Evaluation and Research, Controlled Substance Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5150, Silver Spring, MD 20993–0002, 301–796–3156, email: *james.hunter@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The United States is a party to the 1971 Convention on Psychotropic Substances (Psychotropic Convention). Article 2 of the Psychotropic Convention provides that if a party to the convention or WHO has information about a substance, which in its opinion may require international control or change in such control, it shall so notify the Secretary-General of the United Nations (the U.N. Secretary-General) and provide the U.N. Secretary-General with information in support of its opinion.

Section 201 of the CSA (21 U.S.C. 811) (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970) provides that when WHO notifies the United States under Article 2 of the Psychotropic Convention that it has information that may justify adding a drug or other substances to one of the schedules of the Psychotropic Convention, transferring a drug or substance from one schedule to another, or deleting it from the schedules, the Secretary of State must transmit the notice to the Secretary of Health and Human Services (Secretary of HHS). The Secretary of HHS must then publish the notice in the **Federal Register** and provide opportunity for interested persons to submit comments that will be considered by HHS in its preparation of the scientific and medical evaluations of the drug or substance.

II. WHO Notification

The Secretary of HHS received the following notice from WHO (non-relevant text removed):

Ref.: C.L.xx.2017

The World Health Organization (WHO) presents its compliments to Member States and Associate Members and has the pleasure of informing that the Thirty-ninth Expert Committee on Drug Dependence (ECDD) will meet in Geneva from 6 to 10 November 2017 to review a number of substances with potential for dependence, abuse and harm to health, and will make recommendations to the U.N. Secretary-General, on the need for and level of international control of these substances.

At its 126th session in January 2010, the Executive Board approved the publication ''Guidance on the WHO review of psychoactive substances for international control'' (EB126/2010/REC1, Annex 6) which requires the Secretariat to request relevant information from Ministers of Health in Member States to prepare a report for submission to the ECDD. For this purpose, a questionnaire was designed to gather information on the legitimate use, harmful use, status of national control and potential impact of international control for each substance under evaluation. Member States are invited to collaborate, as in the past, in this process by providing pertinent information as requested in the questionnaire and concerning substances under review.

It would be appreciated if a person from the Ministry of Health could be designated as the focal point responsible for coordinating and answering the questionnaire. (non relevant information from letter not shown, see letter for text not shown here) The designated focal point, and only this person, should access and complete the questionnaires:

1. Ocfentanil
2. Furanyl fentanyl (Fu-F)
3. Acryloylfentanyl (Acrylfentanyl)
4. Carfentanil
5. 4-fluoroisobutyrfentanyl (4–FIBF)
6. Tetrahydrofuranylfentanyl (THF–F)
7. 4-fluoroamphetamine (4–FA)
8. AB–PINACA
9. AB–CHMINACA
10. 5F–PB–22
11. UR–144
12. 5F–ADB
13. Etizolam
14. Pregabalin
15. Tramadol
16. Cannabidiol
17. Ketamine

PDF versions of the questionnaire in English, French and Spanish may be downloaded from the link *http://www.who.int/medicines/access/controlled-substances/ecdd/en/.* Please note that these versions are for reference only and all questionnaires must be answered through the online system. Further clarification regarding the questionnaire may be obtained from the Secretariat by emailing: *ecddsecretariat@who.int.*

Replies to the questionnaire must reach the Secretariat by 30 September 2017 in order to facilitate analyses and preparation of the report before the planned meeting. Where there is a competent National Authority under the International Drug Control Treaties, it is kindly requested that the questionnaire be completed in collaboration with such body.

The summary information from the questionnaire will be published online as part of the report on the Web site for the Thirty-ninth ECDD linked to the Department of Essential Medicines and Health Products (EMP). The provisional agenda of the Thirty-ninth ECDD and the list of psychoactive substances under review are also published on Thirty-ninth ECDD Web page: *http://www.who.int/medicines/access/controlled-substances/ecdd/en/.*

Member States are also encouraged to provide any additional relevant information (unpublished or published) that is available on these substances to: *ecddsecretariat@who.int.* This information will be an invaluable contribution to the ECDD and all submissions will be treated as confidential.

The World Health Organization takes this opportunity to renew to Member States and Associate Members the assurance of its highest consideration.

GENEVA, 7 July 2017

FDA has verified the Web site addresses contained in the WHO notice, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

III. Substances Under WHO Review

Ocfentanil is a synthetically produced opioid that is structurally related to fentanyl and approximately equipotent in effect. Reported risks associated with use of ocfentanil include development of opioid use disorder, overdose, and fatal overdose. It has no approved medical use in the United States and is not a controlled substance in the United States under the CSA.

Furanyl fentanyl (Fu-F) is a potent clandestinely produced synthetic opioid that is an analog of fentanyl. Evidence suggests that the pattern of abuse of fentanyl analogues, including furanyl fentanyl, parallels that of heroin and

prescription opioid analgesics. Fu-F produces the typical opioid effects that include respiratory depression and loss of consciousness. Seizures of Fu-F have been encountered in powder form. Fu-F has been connected to fatal overdoses, in which intravenous routes of administration are documented. It has no approved medical use in the United States. On November 29, 2016, the Drug Enforcement Administration (DEA) issued a final order to temporarily schedule Fu-F and its isomers, esters, ethers, salts and salts of isomers, esters and ethers, into Schedule I pursuant to the temporary scheduling provisions of the CSA.

Acryloylfentanyl (Acrylfentanyl) belongs to the 4-anilidopiperidine class of synthetic opioids and is similar in structure to fentanyl. Acryloylfentanyl is a clandestinely produced analog of fentanyl and sold illegally as a research chemical on several Web sites. Acryloylfentanyl has also been associated with adverse events typically associated with opioid use such as respiratory depression, anxiety, constipation, tiredness, hallucinations, and withdrawal. The use of acryloylfentanyl has also been linked to the development of opioid use disorder, overdose, and fatal overdose. Acryloylfentanyl has no commercial or medical uses. On July 14, 2017, the DEA issued a temporary order to temporarily schedule acryloylfentanyl, its isomers, esters, ethers, salts and salts of isomers, esters, and ethers, into Schedule I pursuant to the temporary scheduling provisions of the CSA.

Carfentanil, also known as 4-carbomethoxyfentanyl, is an extremely potent synthetic opioid that is similar in structure to and approximately 100 times more potent than fentanyl as an analgesic. At one time legitimately produced, carfentanil is no longer manufactured, marketed, or used in the United States; it is approved by FDA for use under restricted conditions by veterinarians as a immobilizing agent for certain large animals. Illicitly produced carfentanil is a particularly harmful fentanyl analogue that is also being laced into heroin or sold by itself and trafficked in the United States. It is not approved for human use. Drug seizure data indicate that carfentanil is typically used in small doses to cut heroin and other illicitly abused drugs. The significant risk to public health associated with carfentanil use stems from its respiratory depressive effects with very small amounts. Several fatalities have been reported as the result of carfentanil overdoses. On October 28, 1988, the DEA placed carfentanil in Schedule II of the CSA.

4-fluoroisobutyrfentanyl is a clandestinely produced synthetic opioid that is an analog of fentanyl. It has μ-receptor agonist activity similar to that of fentanyl. This would result in effects associated with opioid agonists such as analgesia, respiratory depression, anxiety, constipation, tiredness, hallucinations, withdrawal, the development of opioid use disorder, overdose, and fatal overdose. The use of 4-fluoroisobutyrfentanyl has been implicated in several cases of overdose and fatal overdoses. 4-fluoroisobutyrfentanyl has not been approved for medical use in the U.S. On May 3, 2017, the DEA issued a temporary order to temporarily schedule 4-fluoroisobutyrfentanyl, its isomers, esters, ethers, salts and salts of isomers, esters and ethers, into Schedule I pursuant to the temporary scheduling provisions of the CSA.

Tetrahydrofuranylfentanyl (THF–F) is a synthetic opioid that is an analog of fentanyl. It has μ-receptor agonist activity similar to that of fentanyl, resulting in effects associated with opioid agonists such as analgesia, respiratory depression, anxiety, constipation, tiredness, hallucinations, withdrawal, the development of opioid use disorder, overdose, and fatal overdose. THF–F is not approved for medical use or controlled in the United States under the CSA.

4-Fluoroamphetamine (4–FA) is a psychoactive substance of the phenethylamine and substituted amphetamine chemical classes and produces stimulant effects. WHO reports that 4–FA is clandestinely produced, and its use is associated with fatal and non-fatal intoxications. 4–FA was reviewed at the 37th ECDD (2015) and, while not placed under international control due to insufficient data, was kept under surveillance. 4–FA is not approved for medical use in the United States and it is not controlled under the CSA.

AB–PINACA is a clandestinely produced synthetic cannabinoid agonist approximately 1.5 times as potent as delta-9-tetrahydrocannabinol. Adverse effects produced by cannabinoid agonists include tachycardia, agitation, hallucination, chest pain, seizure, anxiety, acute psychosis, and death. AB–PINACA has been detected in illicit synthetic cannabinoid substances, and reported in cases of overdose and hospitalizations. It has not been approved for medical use in the United States. On January 27, 2017, the DEA published a Notice of Proposed Rulemaking to permanently control AB–PINACA as a Schedule I substance under the CSA.

AB–CHMINACA is a clandestinely produced synthetic cannabinoid agonist that is approximately 16 times more potent than delta-9-tetrahydrocannabinol. Adverse effects produced by cannabinoid agonists include tachycardia, agitation, hallucination, chest pain, seizure, anxiety, acute psychosis, and death. AB–CHMINACA has been detected in illicit synthetic cannabinoid substances and found in cases of overdose and hospitalizations. AB–CHMINACA has not been pre-reviewed or critically reviewed by the WHO. On January 27, 2017, the DEA published a Notice of Proposed Rulemaking to permanently control AB–CHMINACA as a Schedule I substance under the CSA.

5F–PB–22 is a synthetic cannabinoid agonist with similar effects to delta-9-tetrahydrocannabinol, one of the main psychoactive components of cannabis. Adverse effects produced by cannabinoid agonists include tachycardia, agitation, hallucination, chest pain, seizure, anxiety, acute psychosis, and death. 5F–PB–22 is clandestinely produced. It has been found laced on plant material and marketed as herbal products, and is smoked for its psychoactive effects. According to the WHO, 5F–PB–22 has been associated with fatal intoxications. On September 6, 2016, the DEA issued a final rule to permanently place 5F–PB–22 into Schedule I of the CSA.

UR–144 is a clandestinely produced synthetic cannabinoid agonist. In general, adverse effects produced by cannabinoid agonists include tachycardia, agitation, hallucination, chest pain, seizure, anxiety, and acute psychosis. UR–144 has been detected in herbal smoking blends that are sold as herbal incense. In June 2014, the 36th (2014) ECDD reviewed UR–144 and recommended that it be placed under surveillance. On May 11, 2016, the DEA issued a final rule to permanently schedule UR–144 into Schedule I of the CSA.

5F–ADB is a clandestinely produced synthetic cannabinoid agonist. In general, adverse effects produced by cannabinoid agonists include tachycardia, agitation, hallucination, chest pain, seizure, anxiety, and acute psychosis. 5F–ADB has been identified in overdose and/or cases involving death attributed to their abuse. Adverse health effects reported from incidents involving 5F–ADB and other synthetic cannabinoids have included: Nausea, persistent vomiting, agitation, altered mental status, seizures, convulsions, loss of consciousness, and/or cardio toxicity. On April 10, 2017, the DEA issued a temporary scheduling order to

temporarily schedule 5F–ADB, its isomers, esters, ethers, salts and salts of isomers, esters, and ethers into Schedule I pursuant to the temporary scheduling provisions of the CSA.

Etizolam belongs to a class of substances known as benzodiazepines. Benzodiazepines produce central nervous system depression and are commonly used to treat insomnia, anxiety, and seizure disorders. Etizolam is currently prescribed in some countries to treat generalized anxiety disorder with depressive symptoms, but is not approved for medical use or controlled in the United States under the CSA. WHO reported that non-fatal intoxications that include cases of driving under the influence of drugs have been linked to etizolam. The ECDD at its 37th (2015 meeting reviewed etizolam and recommended that a critical review of etizolam is warranted.

Pregabalin is an anticonvulsant-type drug used to treat pain generated from the nervous system. It is available as an oral capsule and oral solution and approved for medical use in the United States for the management of neuropathic pain associated with diabetic peripheral neuropathy, post-herpetic neuralgia, and adjunctive therapy for partial onset seizures, fibromyalgia, and neuropathic pain associated with spinal cord injury. Although the mechanism of action of pregabalin is unknown, studies in animals suggest that binding to the nervous system tissues may be involved in its pain-relieving and anti-seizure effects. Pregabalin binds with high affinity to the alpha 2-delta receptor site (a subunit of voltage-gated calcium channels) in the central nervous system. The binding of pregabalin at this site is thought to be responsible for its therapeutic effect on neuropathic pain. Reports indicate that patients are self-administering higher than recommended doses to achieve euphoria, especially patients who have a history of substance abuse, particularly opioids, and psychiatric illness. While effects of excessively high doses are generally non-lethal, gabapentinoids such as pregabalin are increasingly being identified in post-mortem toxicology analyses. Pregabalin is a Schedule V controlled substance in the United States under the CSA.

Tramadol is an opioid analgesic that produces its primary opioid-like action through an active metabolite referred to as the M1 metabolite (O-desmethyltramadol). Tramadol was first approved for marketing in the United States in 1995 and is available as immediate-release, extended-release, and combination products for the treatment of moderate to moderately severe pain. On July 2, 2014, the DEA published a final rule in the **Federal Register** controlling tramadol as a Schedule IV substance of the CSA effective from August 18, 2014. Tramadol was pre-reviewed by the ECDD at its 28th (1992) and 32nd (2000) meetings, and critically reviewed at the 33rd (2002) meeting and not recommended for international control but placed on surveillance. Tramadol was pre-reviewed again by the ECDD at its 34th (2006) meeting; however, the ECDD concluded that there was not sufficient evidence to justify a critical review. At the 36th (2014) meeting, the ECDD considered updated information on tramadol, but again concluded that there was insufficient evidence to warrant a critical review.

Cannabidiol (CBD) is one of the active cannabinoids identified in cannabis. CBD has been shown to be beneficial in experimental models of several neurological disorders, including those of seizure and epilepsy. In the United States, CBD-containing products are in human clinical testing in three therapeutic areas, but no such products are approved by FDA for marketing for medical purposes in the United States. CBD is a Schedule I controlled substance under the CSA. At the 37th (2015) meeting of the ECDD, the committee requested that the Secretariat prepare relevant documentation to conduct pre-reviews for several substances, including CBD.

Ketamine is classified as a rapid-acting general anesthetic agent used for short diagnostic and surgical procedures that do not require skeletal muscle relaxation. It is marketed in the United States as a solution for injection. Ketamine is controlled in Schedule III of the CSA in the United States. It is not controlled internationally under the Convention on Psychotropic Substances or the Single Convention on Narcotic Drugs. The ECDD reviewed ketamine at its 34th (2006), 35th (2012), and 36th (2014) meetings. On March 13, 2015, the Commission on Narcotic Drugs (CND) decided by consensus to postpone the consideration of a proposal concerning the recommendation to place ketamine in Schedule IV of the Psychotropic Convention. The CND requested additional information from the WHO. The ECDD reviewed updated information at its 37th (2015) meeting and found no reason to recommend a new pre-review or critical review of ketamine that could potentially change its standing 2014 recommendation that ketamine should not be placed under international control.

IV. Opportunity To Submit Domestic Information

As required by section 201(d)(2)(A) of the CSA, FDA, on behalf of HHS, invites interested persons to submit comments regarding the 17 named drug substances. Any comments received will be considered by HHS when it prepares a scientific and medical evaluation of these drug substances. HHS will forward a scientific and medical evaluation of these drug substances to WHO, through the Secretary of State, for WHO's consideration in deciding whether to recommend international control/decontrol of any of these drug substances. Such control could limit, among other things, the manufacture and distribution (import/export) of these drug substances and could impose certain recordkeeping requirements on them.

Although FDA is, through this notice, requesting comments from interested persons, which will be considered by HHS when it prepares an evaluation of these drug substances, HHS will not now make any recommendations to WHO regarding whether any of these drugs should be subjected to international controls. Instead, HHS will defer such consideration until WHO has made official recommendations to the Commission on Narcotic Drugs, which are expected to be made in early 2018. Any HHS position regarding international control of these drug substances will be preceded by another **Federal Register** notice soliciting public comments, as required by section 201(d)(2)(B) of the CSA.

V. Electronic Access

Persons with access to the Internet may obtain the document at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: August 9, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–17119 Filed 8–11–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Division of Behavioral Health; Office of Clinical and Preventive Services; Behavioral Health Integration Initiative (BH2I)

Announcement Type: New.

Funding Announcement Number: HHS–2017–IHS–BH2I–0001.

Catalog of Federal Domestic Assistance Number: 93.933.

Key Dates

Application Deadline Date: September 16, 2017.

Review Date: September 18, 2017.

Earliest Anticipated Start Date: September 30, 2017.

Signed Tribal Resolutions Due Date: September 16, 2017.

Proof of Non-Profit Status Due Date: September 16, 2017.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) Office of Clinical and Preventative Services, Division of Behavioral Health, is accepting applications for its Behavioral Health Integration Initiative (Short Title: BH2I) to plan, develop, implement, and evaluate behavioral health integration with primary care, community based settings, and/or integrating primary care, nutrition, diabetes care, and chronic disease management with behavioral health. This program is authorized under: The Snyder Act, 25 U.S.C. 13, and 25 U.S.C. 1665j. This program is described in the Catalog of Federal Domestic Assistance (CFDA) under 93.933.

Background

IHS supports changing the paradigm of mental health and substance use disorder services from being episodic, fragmented, specialty, and/or disease focused to incorporating it into the patient-centered home model. Research has shown that more than 70 percent of primary care visits stem from behavioral health issues. Depression is the most common type of mental illness, currently affecting more than a quarter of the U.S. adult population. With major depression currently the second leading cause of disability, it is clear that primary care settings have become an important access point for addressing both physical and behavioral health care needs. In addition, American Indian and Alaska Native (AI/AN) communities experience alarming rates of suicide, alcohol and drug-related deaths, domestic and sexual violence, and homicide. Describing the burden of trauma within any population is difficult, however indicators in terms of socially destructive behaviors are often used to illustrate this public health issue that creates impact through lifespan accumulation and chronic stress. Studies now indicate that resulting trauma from such events can even be passed from one generation to the next, resulting in intergenerational and historical trauma. While mental health needs can often go untreated and even unnoticed, the lasting effects of childhood trauma into adulthood is often evident in physical manifestations leading to negative health consequences. These extreme disparities highlight an urgent need for improving access to mental health services in primary care for children and families through the integration of behavioral health services, including trauma-informed care, within primary care settings. In addition, recognizing that behavioral and physical health problems are interwoven, delivery of behavioral health services in primary care settings reduces stigma and discrimination, and the majority of people with behavioral health disorders treated within an integrated primary care setting have improved outcomes.

Purpose

The purpose of the Behavioral Health Integration Initiative (BH2I) grant opportunity is to improve the physical and mental health status of people with behavioral health issues by developing an integrative, coordinated system of care between behavioral health and primary care providers. This effort supports the IHS mission to raise the physical, mental, social and spiritual health of AI/ANs to the highest level. Increasing capacity among IHS, Tribal, and Urban Indian Organization (I/T/U) health facilities to implement an integrative approach in the delivery of behavioral health services, including trauma-informed care, nutrition, exercise, social, spiritual, cultural, and primary care services will improve morbidity and mortality outcomes among the AI/AN population. In addition, this effort will support activities that address improving the quality of life for individuals suffering from mental illness, substance use disorders, and adverse childhood experiences. Other outcomes related to this effort include improved behavioral health services that will increase access to integrated health and social well-being services and the early identification and intervention of mental health, substance use, and serious physical health issues, including chronic disease. This work will also identify and assess various models addressing unique integrative needs and the challenges, barriers and successes in AI/AN health systems. Finally, an improvement in the overall health of patients participating in integrative programs is expected.

For this grant, the full spectrum of behavioral health services are strongly encouraged and are defined as: Screening for mental and substance use disorders, including serious mental illness; alcohol, substance, and opioid use disorders; suicidality and trauma (*e.g.,* interpersonal violence, physical abuse, adverse childhood experiences) assessment, including risk assessment and diagnosis; patient-centered treatment planning, evidence based outpatient mental and substance use disorder treatment services (including pharmacological and psychosocial services); crisis services; peer support services; and care coordination.

Models of Care

IHS understands unique challenges and circumstances exist across Tribal communities and sites. In fact, integrative models of care vary according to needs and capabilities but all strive to enhance clinical processes and workflow across multi-disciplinary teams. This grant will support sites that have identified gaps in services and established efforts that moved toward linking those critical connections, including those with new and innovative ways of conducting business between differing management of operations between Federal and Tribal health services.

II. Award Information

Type of Award: Grant.

Estimated Funds Available

The total amount of funding identified for the current fiscal year (FY) 2017 is approximately $6,000,000. Individual award amounts are anticipated to be $500,000. The amount of funding available for competing awards issued under this announcement are subject to the availability of appropriations and budgetary priorities of the agency. IHS is under no obligation to make awards that are selected for funding under this announcement.

Anticipated Number of Awards

Approximately 12 awards will be issued under this notice of funding opportunity announcement.

Project Period

The project period will be for three years and will run consecutively from September 30, 2017, to September 29, 2020.

III. Eligibility Information

I.

1. Eligibility

To be eligible for this New Funding Opportunity under this announcement, an applicant must be one of the following as defined by 25 U.S.C. 1603:

- A Federally recognized Indian Tribe as defined by 25 U.S.C. 1603(14);
- A Tribal organization as defined by 25 U.S.C. 1603(26);
- An Urban Indian organization as defined by 25 U.S.C. 1603(29); a nonprofit corporate body situated in an urban center, governed by an Urban Indian controlled board of directors, and providing for the maximum participation of all interested Indian groups and individuals, which body is capable of legally cooperating with other public and private entities for the purpose of performing the activities described in 25 U.S.C. 1653(a). Applicants must provide proof of non-profit status with the application, *e.g.,* 501(c)(3).

Note: Please refer to Section IV.2 (Application and Submission Information/ Subsection 2, Content and Form of Application Submission) for additional proof of applicant status documents required, such as Tribal resolutions, proof of non-profit status, etc.

2. Cost Sharing or Matching

The IHS does not require matching funds or cost sharing for grants or cooperative agreements.

3. Other Requirements

If application budgets exceeds the award amount outlined under the ''Estimated Funds Available'' section within this funding announcement, the application will be considered ineligible and will not be reviewed for further consideration. If deemed ineligible, IHS will not return the application. The applicant will be notified by email by the Division of Grants Management (DGM) of this decision.

Tribal Resolution

An Indian Tribe or Tribal organization that is proposing a project affecting another Indian Tribe must include *Tribal resolutions from all affected Tribes to be served.* Applications by Tribal organizations will not require a specific Tribal resolution if the current Tribal resolution(s) under which they operate would encompass the proposed grant activities.

An official signed Tribal resolution must be received by the DGM prior to a Notice of Award (NoA) being issued to any applicant selected for funding. However, if an official signed Tribal resolution cannot be submitted with the electronic application submission prior to the official application deadline date, a draft Tribal resolution must be submitted by the deadline in order for the application to be considered complete and eligible for review. The draft Tribal resolution is not in lieu of the required signed resolution, but is acceptable until a signed resolution is received. If an official signed Tribal resolution is not received by DGM when funding decisions are made, then a Notice of Award will not be issued to that applicant and they will not receive any IHS funds until such time as they have submitted a signed resolution to the Grants Management Specialist listed in this Funding Announcement.

Proof of Non-Profit Status

Organizations claiming non-profit status must submit proof. A copy of the 501(c)(3) Certificate must be received with the application submission by the Application Deadline Date listed under the Key Dates section on page one of this announcement.

An applicant submitting any of the above additional documentation after the initial application submission due date is required to ensure the information was received by the IHS DGM by obtaining documentation confirming delivery (*i.e.,* FedEx tracking, postal return receipt, etc.).

IV. Application and Submission Information

1. Obtaining Application Materials

The application package and detailed instructions for this announcement can be found at *http://www.Grants.gov* or *http://www.ihs.gov/dgm/funding/.*

Questions regarding the electronic application process may be directed to Mr. Paul Gettys at (301) 443–2114 or (301) 443–5204.

2. Content and Form Application Submission

The applicant must include the project narrative as an attachment to the application package. Mandatory documents for all applicants include:

- Table of contents.
- Abstract (one page) summarizing the project.
- Application forms:
  - SF–424, Application for Federal Assistance.
  - SF–424A, Budget Information—Non-Construction Programs.
  - SF–424B, Assurances—Non-Construction Programs.
- Project Narrative (must be single-spaced and not exceed 12 pages).
  - Statement of need, program planning and implementation approach, staff and organizational capacity, performance assessment and data, and evaluation plan.
- Budget, Budget Justification and Narrative (must be single-spaced and not exceed four pages).
- Tribal Resolution(s).
- Letter(s) of Support:
  - For all applicants: Local organizational partners;
  - For all applicants: Community partners;
  - For Tribal organizations and UIOs: From the board of directors (or relevant equivalent);
- 501(c)(3) Certificate (if applicable).
- Biographical sketches for all Key Personnel (*e.g.,* project coordinator etc.).
- Contractor/Consultant resumes or qualifications and scope of work.
- Disclosure of Lobbying Activities (SF–LLL).
- Certification Regarding Lobbying (GG-Lobbying Form).
- Copy of current Negotiated Indirect Cost rate (IDC) agreement (required in order to receive IDC).
- Organizational Chart (optional).
- Documentation of current Office of Management and Budget (OMB) Financial Audit (if applicable).

Acceptable forms of documentation include:

- Email confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or
- Face sheets from audit reports. These can be found on the FAC Web site: *https://harvester.census.gov/facdissem/Main.aspx.*

Public Policy Requirements

All Federal-wide public policies apply to IHS grants and cooperative agreements with exception of the Discrimination policy.

Requirements for Project and Budget Narratives

A. Project Narrative (12 pages)

The project narrative (Parts A through E listed below) should be in a separate Word document that should not exceed 12 pages and must: Be single-spaced, type written, have consecutively numbered pages, use black type not smaller than 12 points, and be printed on one side only of standard size 8½″ x 11″ paper.

Be sure to succinctly address all items listed under the evaluation criteria section (refer to Section V.1, Evaluation criteria in this announcement) and place all responses and required information in the correct section (noted below), or they will not be considered or scored. These narratives will assist the Objective Review Committee (ORC) in

becoming familiar with the applicant's activities and accomplishments prior to this possible grant award. If the narrative exceeds the page limit, only the first 12 pages will be reviewed. The 12-page limit for the narrative does not include the table of contents, abstract, standard forms, Tribal resolutions, budget, budget justification narrative, and/or other appendix items.

There are five (5) parts to the project narrative:

Part A—Statement of Need;

Part B—Program Planning and Implementation Approach;

Part C—Staff and Organization Capacity;

Part D—Performance Assessment and Data; and

Part E—Evaluation Plan.

Below are additional details about what must be included in the project narrative.

Part A: Statement of Need (2 pages)

The statement of need describes the current situation in the applicant's Tribal community (''community'' means the applicant's Tribe, village, Tribal organization, or consortium of Tribes or Tribal organizations). The statement of need provides the facts and evidence that support the need for the project and establishes that the Tribe, Tribal organization, or UIO understands the problems and can reasonably address them. The statement of need must not exceed two single-spaced pages.

- Describe the community and priority population for your program including the patients or participants that you expect to serve and the reasons integrated behavioral health and primary care services are needed.
- Describe current behavioral health and/or primary care services in place along with challenges and gaps to provide integrated behavioral health/primary care services to individuals.
- Explain how the BH2I can improve or enhance the current systems in place.

Part B: Program Planning and Implementation Approach (5 pages)

- State the purpose, goals and objectives of your proposed project.
- Describe evidence-based programs, services or practices proposed for implementation, or will continue implementation through support of this grant opportunity.
- Describe your current level of behavioral health integration (using the SAMHSA–HRSA Center for Integrated Health Solutions six-level framework (*http://www.integration.samhsa.gov/integrated-care-models/A_Standard_Framework_for_Levels_of_Integrated_Healthcare.pdf*) and forecast how you will progress to higher levels of health integration.
- Describe your plan to formally integrate behavioral health through:
  - Improving workflow in the assessment of behavioral health in primary care such as screenings, referral, and policy development.
  - Health information technology changes or improvements that facilitate behavioral health integration
  - Improving physical environment barriers in the delivery of integrated health care
  - Cross training staff, including psycho-education training for staff within primary care settings and basic medical education for behavioral health staff.
  - Establishing formal and informal channels of communication that facilitates behavioral health integration.
  - Describe how you will identify those individuals during the screening process who may indicate opioid and/or alcohol use disorders and how you will refer them to Medication-Assisted Treatment (MAT)-qualified specialty treatment providers.

Part C: Staff and Organization Capacity (2 pages)

This section should describe applicant agency organization and structure and the capabilities possessed to complete proposed activities. This grant opportunity will focus on applicants and the applicant's ability to implement a formalized integration plan focused on the enhancing the clinical processes for patient care among the IHS service areas.

- Identify qualified professionals who will implement proposed grant activities, administer the grant, including progress and financial reports or provide salary costs for the addition of full-time equivalent (FTE) licensed behavioral health provider(s).
- Describe the organization's current system of providing at least one service of primary care and/or behavioral health, including screening, assessment, and care management. The primary applicant must directly deliver, operate, and/or manage at least one portion of direct primary care or behavioral health treatment services.
- Describe the organization's plan to hire full-time equivalent (FTE) licensed behavioral health provider(s).

Part D: Performance Assessment and Data (2 pages)

This section of the application should describe efforts to collect and report project data that will support and demonstrate BH2I activities. BH2I grantees will be required to collect and report data pertaining to activities, processes and outcomes. Data collection activities should capture and document actions conducted throughout awarded years including those that will contribute relevant project impact.

- Describe specific data collection efforts that will be required as part of the EBP, or proposed evidence-based projects.
- Describe data collection process and workflow that will assist in completing progress and evaluation requirements.
- Explain proposed efforts to utilize health technology including accessibility, collection and monitoring of relevant data for proposed BH2I project.

Part E: Evaluation Plan (1 page)

The evaluation section should describe applicant's plan to evaluate program activities. The evaluation plan should describe expected results and any identified metrics to support program effectiveness. Evaluation plans should incorporate questions related to outcomes and process including documentation of lessons learned.

- Describe proposed evaluation methods including performance measures and other data relevant to evaluation outcomes including intended results (*i.e.,* impact and outcomes), including any partners who will conduct evaluation if separate from the primary applicant.
- Describe efforts to monitor improvements through the evaluation of increased coordination of care, co-located care, and integrated care with reference to the SAMHSA–HRSA Center for Integrated Health Solutions framework at *http://www.integration.samhsa.gov/integrated-care-models/CIHS_Framework_Final_charts.pdf.*

B. Budget Narrative (4 pages)

This narrative must include a line item budget with a narrative justification for all expenditures identifying reasonable allowable, allocable costs necessary to accomplish the goals and objectives as outlined in the project narrative. Budget should match the scope of work described in the project narrative. The budget and budget narrative should not exceed 4 pages.

3. Submission Dates and Times

Applications must be submitted electronically through *Grants.gov* by 11:59 p.m. Eastern Daylight Time (EDT) on the Application Deadline Date listed in the Key Dates section on page one of this announcement. Any application

received after the application deadline will not be accepted for processing, nor will it be given further consideration for funding. *Grants.gov* will notify the applicant via email if the application is rejected.

If technical challenges arise and assistance is required with the electronic application process, contact *Grants.gov* Customer Support via email to *support@grants.gov* or at (800) 518–4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays). If problems persist, contact Mr. Gettys (*Paul.Gettys@ihs.gov*), DGM Grant Systems Coordinator, by telephone at (301) 443–2114 or (301) 443–5204. Please be sure to contact Mr. Gettys at least ten days prior to the application deadline. Please do not contact the DGM until you have received a *Grants.gov* tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

4. Intergovernmental Review

Executive Order 12372 requiring intergovernmental review is not applicable to this program.

5. Funding Restrictions

- Pre-award costs are not allowable.
- The available funds are inclusive of direct and appropriate indirect costs.
- Only one grant/cooperative agreement will be awarded per applicant.
- IHS will not acknowledge receipt of applications.

6. Electronic Submission Requirements

All applications must be submitted electronically. Please use the *http://www.Grants.gov* Web site to submit an application electronically and select the ''Find Grant Opportunities'' link on the homepage. Follow the instructions for submitting an application under the Package tab. Electronic copies of the application may not be submitted as attachments to email messages addressed to IHS employees or offices.

If the applicant needs to submit a paper application instead of submitting electronically through *Grants.gov*, a waiver must be requested. Prior approval must be requested and obtained from Mr. Robert Tarwater, Director, DGM, (see Section IV.6 below for additional information). A written waiver request must be sent to *GrantsPolicy@ihs.gov* with a copy to *Robert.Tarwater@ihs.gov.* The waiver must: (1) Be documented in writing (emails are acceptable), before submitting a paper application, and (2) include clear justification for the need to deviate from the required electronic grants submission process.

Once the waiver request has been approved, the applicant will receive a confirmation of approval email containing submission instructions and the mailing address to submit the application. A copy of the written approval must be submitted along with the hardcopy of the application that is mailed to DGM. Paper applications that are submitted without a copy of the signed waiver from the Director of the DGM will not be reviewed or considered for funding. The applicant will be notified via email of this decision by the Grants Management Officer of the DGM. Paper applications must be received by the DGM no later than 5:00 p.m., EDT, on the Application Deadline Date listed in the Key Dates section on page one of this announcement. Late applications will not be accepted for processing or considered for funding. Applicants that do not adhere to the timelines for System for Award Management (SAM) and/or *http://www.Grants.gov* registration or that fail to request timely assistance with technical issues will not be considered for a waiver to submit a paper application.

Please be aware of the following:

- Please search for the application package in *http://www.Grants.gov* by entering the CFDA number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.
- If you experience technical challenges while submitting your application electronically, please contact *Grants.gov* Support directly at: *support@grants.gov* or (800) 518–4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays).
- Upon contacting *Grants.gov*, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained.
- Applicants are strongly encouraged not to wait until the deadline date to begin the application process through *Grants.gov* as the registration process for SAM and *Grants.gov* could take up to fifteen working days.
- Please use the optional attachment feature in *Grants.gov* to attach additional documentation that may be requested by the DGM.
- All applicants must comply with any page limitation requirements described in this funding announcement.
- After electronically submitting the application, the applicant will receive an automatic acknowledgment from *Grants.gov* that contains a *Grants.gov* tracking number. The DGM will download the application from *Grants.gov* and provide necessary copies to the appropriate agency officials. Neither the DGM nor the DBH will notify the applicant that the application has been received.
- Email applications will not be accepted under this announcement.

Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS)

All IHS applicants and grantee organizations are required to obtain a DUNS number and maintain an active registration in the SAM database. The DUNS number is a unique 9-digit identification number provided by D&B which uniquely identifies each entity. The DUNS number is site specific; therefore, each distinct performance site may be assigned a DUNS number. Obtaining a DUNS number is easy, and there is no charge. To obtain a DUNS number, you may access it through *http://fedgov.dnb.com/webform,* or to expedite the process, call (866) 705–5711.

All HHS recipients are required by the Federal Funding Accountability and Transparency Act of 2006, as amended (''Transparency Act''), to report information on sub-awards. Accordingly, all IHS grantees must notify potential first-tier sub-recipients that no entity may receive a first-tier sub-award unless the entity has provided its DUNS number to the prime grantee organization. This requirement ensures the use of a universal identifier to enhance the quality of information available to the public pursuant to the Transparency Act.

System for Award Management (SAM)

Organizations that were not registered with Central Contractor Registration and have not registered with SAM will need to obtain a DUNS number first and then access the SAM online registration through the SAM home page at *https://www.sam.gov* (U.S. organizations will also need to provide an Employer Identification Number from the Internal Revenue Service that may take an additional 2–5 weeks to become active). Completing and submitting the registration takes approximately one hour to complete and SAM registration will take 3–5 business days to process. Registration with the SAM is free of charge. Applicants may register online at *https://www.sam.gov.*

Additional information on implementing the Transparency Act, including the specific requirements for DUNS and SAM, can be found on the IHS Grants Management, Grants Policy

Web site: *http://www.ihs.gov/dgm/policytopics/.*

V. Application Review Information

The instructions for preparing the application narrative also constitute the evaluation criteria for reviewing and scoring the application. Weights assigned to each section are noted in parentheses. The 12 page project narrative should include only the first budget year of activities; information for multi-year projects should be included as an appendix. See ''Multi-year Project Requirements'' at the end of this section for more information. The narrative section should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well organized, succinct, and contain all information necessary for reviewers to understand the project fully. Points will be assigned to each evaluation criteria adding up to a total of 100 points. A minimum score of 65 points is required for funding. Points are assigned as follows:

1. Evaluation Criteria

Applications will be reviewed and scored according to the quality of responses to the required application components in Sections A–F outlined below. In developing the required sections of this application, use the instructions provided for each section, which have been tailored to this program. The application must use the six sections (Sections A–F) in developing the application. The applicant must place the required information in the correct section *or it will not be considered for review.* The application will be scored according to how well the applicant addresses the requirements for each section listed below. The number of points after each section heading is the maximum number of points the review committee may assign to that section. Although scoring weights are not assigned to individual bullets, each bullet is assessed deriving the overall section score.

A. Statement of Need (25 points)

- The degree to which the applicant's description of the service area/target population demonstrates the need for new/increased integrated primary health care/behavioral health services.
- How well the applicant describes the unique characteristics of the service area and population that impact access to or utilization of behavioral health care.
- How well the applicant describes existing behavioral health care providers in the service area, including identified gaps in behavioral health care services that the applicant can address via BH2I funds.

B. Program Planning and Implementation Approach (25 points)

- The degree to which the applicant's purpose, goals and objectives of proposed project will address the mental and physical health needs through integrated an approach between primary health care/behavioral health services.
- How well the applicant describes the evidence-based practices, practice-based evidence, promising practices and intervention efforts, including culturally appropriate services and interventions, to produce meaning and relevant results including additional detail to support evidence of effectiveness will support proposed project.
- How well the applicant describes their current level of behavioral health integration (using the SAMHSA–HRSA Center for Integrated Health Solutions framework at *http://www.integration.samhsa.gov/integrated-care-models/CIHS_Framework_Final_charts.pdf*) and forecasts how they will progress to higher levels of health integration.
- How well the applicant describe their plan to formally integrate behavioral health through:
  - Improving workflow in the assessment of behavioral health in primary care such as screenings, referral, and policy development.
  - Health information technology changes or improvements that facilitate behavioral health integration.
  - Improving physical environment barriers in the delivery of integrated health care.
  - Cross training staff, including psycho-education training for staff within primary care settings and basic medical education for behavioral health staff.
  - Establishing formal and informal channels of communication that facilitates behavioral health integration.
  - How well the applicant describes how they will identify those individuals during the screening process who may indicate opioid and/or alcohol use disorders and how they will refer them to Medication-Assisted Treatment (MAT)-qualified specialty treatment providers.

C. Staff and Organizational Capacity (20 points)

- The degree to which the applicant describes the organization's current system of providing at least one service of primary care and/or behavioral health, including screening, assessment, and care management. Does the applicant directly deliver, operate, and/or manage at least one portion of direct primary care or behavioral health treatment services?
- How well does the applicant identify qualified professionals who will implement proposed grant activities, administer the grant, including completion and submission of progress and financial reports, and how project continuity will be maintained if/when there is a change in the operational environment (*e.g.,* staff turnover, change in project leadership) to ensure project stability over the life of the grant.
- The degree to which the applicant describes the organization's plan to hire full-time equivalent (FTE) licensed behavioral health provider(s).
- For individuals that are identified and currently on staff, include a biographical sketch for the project director, project coordinator, and other key positions as *attachments* to the project proposal/application. Each biographical sketch should not exceed one page. [Note: Attachments will not count against the 12 page maximum]. Do not include any of the following:
  - Personally Identifiable Information;
  - Resumes; or
  - Curriculum Vitae.

D. Performance Assessment & Data (10 points)

- How well does the applicant describe plans for data collection, management, analysis and reporting for integration activities.
- The degree to which the applicant lists expected data collection efforts that will be required as part of the EBP, or proposed evidence-based projects.
- How well does the applicant explain proposed efforts to utilize health information technology including accessibility, collection and monitoring of relevant data for proposed BH2I project.
- The degree to which the applicant discusses evaluation methods (including expertise and tools) that will be used to assess impacts and outcomes.

E. Evaluation Plan (10 points)

- How well did the applicant propose methods including quantitative and qualitative tools and resources, including techniques that will be utilized to measure outcomes, and partners who will conduct evaluation if separate from the primary applicant.
- The degree to which the applicant describes performance measures and other data relevant to evaluation

outcomes including intended results (*i.e.,* impact and outcomes).

- The degree to which the applicant discusses how expected results will be measured (define indicators or measures that will be used to monitor and measure progress).
- The degree to which the applicant describes a plan to monitor improvements through the evaluation of increased coordinated care, co-located care, and integrated care using the SAMHSA–HRSA Center for Integrated Health Solutions six-level framework (*http://www.integration.samhsa.gov/integrated-care-models/A_Standard_Framework_for_Levels_of_Integrated_Healthcare.pdf.)*

F. Categorical Budget and Budget Justification (10 points)

This narrative must include a line item budget with a narrative justification for all expenditures identifying reasonable allowable, allocable costs necessary to accomplish the goals and objectives as outlined in the project narrative. Budget should match the scope of work described in the project narrative. The budget and budget narrative should not exceed 4 pages.

Multi-Year Project Requirements

Projects requiring a second and third year must include a brief project narrative and budget (one additional page per year) addressing the developmental plans for each additional year of the project.

Additional Documents Can Be Uploaded as Appendix Items in *Grants.gov*

- Work plan, logic model and/or time line for proposed objectives.
- Position descriptions for key staff.
- Resumes of key staff that reflect current duties.
- Consultant or contractor proposed scope of work and letter of commitment (if applicable).
- Current Indirect Cost Agreement.
- Organizational chart.
- Map of area identifying project location(s).
- Additional documents to support narrative (*i.e.* data tables, key news articles, etc.).

2. Review and Selection

Each application will be prescreened by the DGM staff for eligibility and completeness as outlined in the funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the ORC based on evaluation criteria in this funding announcement. The ORC could be composed of both Tribal and Federal reviewers appointed by the IHS Program to review and make recommendations on these applications. The technical review process ensures selection of quality projects in a national competition for limited funding. Incomplete applications and applications that are non-responsive to the eligibility criteria will not be referred to the ORC. The applicant will be notified via email of this decision by the Grants Management Officer of the DGM. Applicants will be notified by DGM, via email, to outline minor missing components (*i.e.,* budget narratives, audit documentation, key contact form) needed for an otherwise complete application. All missing documents must be sent to DGM on or before the due date listed in the email of notification of missing documents required.

To obtain a minimum score for funding by the ORC, applicants must address all program requirements and provide all required documentation.

VI. Award Administration Information

1. Award Notices

The NoA is a legally binding document signed by the Grants Management Officer and serves as the official notification of the grant award. The NoA will be initiated by the DGM in our grant system, GrantSolutions (*https://www.grantsolutions.gov*). Each entity that is approved for funding under this announcement will need to request or have a user account in GrantSolutions in order to retrieve their NoA. The NoA is the authorizing document for which funds are dispersed to the approved entities and reflects the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the award, the effective date of the award, and the budget/project period.

Disapproved Applicants

Applicants who received a score less than the recommended funding level for approval, 65 points, and were deemed to be disapproved by the ORC, will receive an Executive Summary Statement from the IHS program office within 30 days of the conclusion of the ORC outlining the strengths and weaknesses of their application. The summary statement will be sent to the Authorized Organizational Representative that is identified on the face page (SF–424) of the application. The IHS program office will also provide additional contact information as needed to address questions and concerns as well as provide technical assistance if desired.

Approved But Unfunded Applicants

Approved but unfunded applicants that met the minimum scoring range and were deemed by the ORC to be ''Approved,'' but were not funded due to lack of funding, will have their applications held by DGM for a period of one year. If additional funding becomes available during the course of FY 2017 the approved but unfunded application may be re-considered by the awarding program office for possible funding. The applicant will also receive an Executive Summary Statement from the IHS program office within 30 days of the conclusion of the ORC.

Note: Any correspondence other than the official NoA signed by an IHS grants management official announcing to the project director that an award has been made to their organization is not an authorization to implement their program on behalf of IHS.

2. Administrative Requirements

Grants are administered in accordance with the following regulations and policies:

A. The criteria as outlined in this program announcement.

B. Administrative Regulations for Grants:

- Uniform Administrative Requirements for HHS Awards, located at 45 CFR part 75.

C. Grants Policy:

- HHS Grants Policy Statement, Revised 01/07.

D. Cost Principles:

- Uniform Administrative Requirements for HHS Awards, ''Cost Principles,'' located at 45 CFR part 75, subpart E.

E. Audit Requirements:

- Uniform Administrative Requirements for HHS Awards, ''Audit Requirements,'' located at 45 CFR part 75, subpart F.

3. Indirect Costs

This section applies to all grant recipients that request reimbursement of indirect costs (IDC) in their grant application. In accordance with HHS Grants Policy Statement, Part II–27, IHS requires applicants to obtain a current IDC rate agreement prior to award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate covers the applicable grant activities under the current award's budget period. If the current rate is not on file with the DGM at the time of award, the IDC portion of the budget will be restricted. The restrictions

remain in place until the current rate is provided to the DGM.

Generally, IDC rates for IHS grantees are negotiated with the Division of Cost Allocation (DCA) *https://rates.psc.gov/* and the Department of Interior (Interior Business Center) *https://www.doi.gov/ibc/services/finance/indirect-Cost-Services/indian-tribes.* For questions regarding the indirect cost policy, please call the Grants Management Specialist listed under ''Agency Contacts'' or the main DGM office at (301) 443–5204.

4. Reporting Requirements

The grantee must submit required reports consistent with the applicable deadlines. Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in one or both of the following: (1) The imposition of special award provisions; and (2) the non-funding or non-award of other eligible projects or activities. This requirement applies whether the delinquency is attributable to the failure of the grantee organization or the individual responsible for preparation of the reports. Per DGM policy, all reports are required to be submitted electronically by attaching them as a ''Grant Note'' in GrantSolutions. Personnel responsible for submitting reports will be required to obtain a login and password for GrantSolutions. Please see the Agency Contacts list in section VII for the systems contact information.

The reporting requirements for this program are noted below.

A. Progress Reports

Program progress reports are required to be submitted annually, within 30 days after the budget period ends. Progress reports will include a set of standard questions that will be provided to each grantee. Additional information for reporting and associated requirements will be in the ''Programmatic Terms and Conditions'' in the official Notice of Award, if funded.

A final program progress report must be submitted within 90 days of expiration of the budget/project period at the end of the grant funding cycle.

B. Financial Reports

Federal Financial Report (FFR or SF–425), Cash Transaction Reports are due 30 days after the close of every calendar quarter to the Payment Management Services, HHS at *https://pms.psc.gov.* It is recommended that the applicant also send a copy of the FFR (SF–425) report to the Grants Management Specialist. Failure to submit timely reports may cause a disruption in timely payments to the organization.

Grantees are responsible and accountable for accurate information being reported on all required reports: The Progress Reports and Federal Financial Report.

C. Federal Sub-Award Reporting System (FSRS)

This award may be subject to the Transparency Act sub-award and executive compensation reporting requirements of 2 CFR part 170.

The Transparency Act requires the OMB to establish a single searchable database, accessible to the public, with information on financial assistance awards made by Federal agencies. The Transparency Act also includes a requirement for recipients of Federal grants to report information about first-tier sub-awards and executive compensation under Federal assistance awards.

IHS has implemented a Term of Award into all IHS Standard Terms and Conditions, Notice of Funding Opportunities and funding announcements regarding the FSRS reporting requirement. This IHS Term of Award is applicable to all IHS grant and cooperative agreements issued on or after October 1, 2010, with a $25,000 sub-award obligation dollar threshold met for any specific reporting period. Additionally, all new (discretionary) IHS awards (where the project period is made up of more than one budget period) and where: (1) The project period start date was October 1, 2010 or after and (2) the primary awardee will have a $25,000 sub-award obligation dollar threshold during any specific reporting period will be required to address the FSRS reporting.

For the full IHS award term implementing this requirement and additional award applicability information, visit the DGM Grants Policy Web site at: *http://www.ihs.gov/dgm/policytopics/.*

D. Compliance With Executive Order 13166 Implementation of Services

Accessibility Provisions for All Grant Application Packages and Funding Opportunity Announcements

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. HHS provides guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see *http://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/guidance-federal-financial-assistance-recipients-title-VI/.*

The HHS Office for Civil Rights (OCR) also provides guidance on complying with civil rights laws enforced by HHS. Please see *http://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html;* and *http://www.hhs.gov/civil-rights/index.html.* Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see *http://www.hhs.gov/civil-rights/for-individuals/disability/index.html.* Please contact the HHS OCR for more information about obligations and prohibitions under federal civil rights laws at *https://www.hhs.gov/civil-rights/index.html* or call 1–800–368–1019 or TDD 1–800–537–7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at *http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53.*

Pursuant to 45 CFR 80.3(d), an individual shall not be deemed subjected to discrimination by reason of his/her exclusion from benefits limited by federal law to individuals eligible for benefits and services from the IHS.

Recipients will be required to sign the HHS–690 Assurance of Compliance form which can be obtained from the following Web site: *http://www.hhs.gov/sites/default/files/forms/hhs-690.pdf,* and send it directly to the: U.S. Department of Health and Human Services, Office of Civil Rights, 200 Independence Ave. SW., Washington, DC 20201.

E. Federal Awardee Performance and Integrity Information System (FAPIIS)

The IHS is required to review and consider any information about the applicant that is in the Federal Awardee Performance and Integrity Information

System (FAPIIS) before making any award in excess of the simplified acquisition threshold (currently $150,000) over the period of performance. An applicant may review and comment on any information about itself that a federal awarding agency previously entered. IHS will consider any comments by the applicant, in addition to other information in FAPIIS in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when completing the review of risk posed by applicants as described in 45 CFR 75.205.

As required by 45 CFR part 75 Appendix XII of the Uniform Guidance, non-federal entities (NFEs) are required to disclose in FAPIIS any information about criminal, civil, and administrative proceedings, and/or affirm that there is no new information to provide. This applies to NFEs that receive federal awards (currently active grants, cooperative agreements, and procurement contracts) greater than $10,000,000 for any period of time during the period of performance of an award/project.

Mandatory Disclosure Requirements

As required by 2 CFR part 200 of the Uniform Guidance, and the HHS implementing regulations at 45 CFR part 75, effective January 1, 2016, the IHS must require a non-federal entity or an applicant for a federal award to disclose, in a timely manner, in writing to the IHS or pass-through entity all violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award.

Submission is required for all applicants and recipients, in writing, to the IHS and to the HHS Office of Inspector General all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. 45 CFR 75.113.

Disclosures must be sent in writing to:

U.S. Department of Health and Human Services, Indian Health Service, Division of Grants Management, ATTN: Robert Tarwater, Director, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857 (Include ''Mandatory Grant Disclosures'' in subject line), Office: (301) 443–5204, Fax: (301) 594–0899, Email: *Robert.Tarwater@ihs.gov.*

AND

U.S. Department of Health and Human Services, Office of Inspector General, ATTN: Mandatory Grant Disclosures, Intake Coordinator, 330 Independence Avenue SW., Cohen Building, Room 5527, Washington, DC 20201, URL: *http://oig.hhs.gov/fraud/report-fraud/index.asp* (Include ''Mandatory Grant Disclosures'' in subject line), Fax: (202) 205–0604 (Include ''Mandatory Grant Disclosures'' in subject line) or Email: *MandatoryGranteeDisclosures@oig.hhs.gov.*

Failure to make required disclosures can result in any of the remedies described in 45 CFR 75.371 Remedies for noncompliance, including suspension or debarment (See 2 CFR parts 180 & 376 and 31 U.S.C. 3321).

VII. Agency Contacts

1. Questions on the programmatic issues may be directed to: Miranda Carman, Public Health Advisor, Mental Health Lead, Division of Behavioral Health, 5600 Fishers Lane, Mail Stop 08N34A, Rockville, MD 20857, Phone: (301) 443–2038, Fax: (301) 594–6213, Email: *Miranda.Carman@ihs.gov.*

2. Questions on grants management and fiscal matters may be directed to: Willis Grant, Senior Grants Management Specialist, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443–5204, Fax: (301) 594–0899, Email: *Willis.Grant@ihs.gov.*

3. Questions on systems matters may be directed to: Paul Gettys, Grant Systems Coordinator, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443–2114; or the DGM main line (301) 443–5204, Fax: (301) 594–0899, Email: *Paul.Gettys@ihs.gov.*

VIII. Other Information

The Public Health Service strongly encourages all cooperative agreement and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the HHS mission to protect and advance the physical and mental health of the American people.

Dated: August 8, 2017.

Michael D. Weahkee,

Assistant Surgeon General, U.S. Public Health Service, Acting Director, Indian Health Service.

[FR Doc. 2017–17103 Filed 8–11–17; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Preventing Alcohol-Related Deaths (PARD) Through Social Detoxification

Announcement Type: New.

Funding Announcement Number: HHS–2017–IHS–PARD–0001.

Catalog of Federal Domestic Assistance Number: 93.933.

Key Dates

Application Deadline Date: September 16, 2017.

Review Date: September 18, 2017.

Earliest Anticipated Start Date: September 30, 2017.

Signed Tribal Resolutions Due Date: September 16, 2017.

Proof of Non-Profit Status Due Date: September 16, 2017.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) Office of Clinical and Preventive Services' Division of Behavioral Health is accepting applications for cooperative agreements for Preventing Alcohol-Related Deaths (PARD) through Social Detoxification. This program is authorized under: Snyder Act, 25 U.S.C. 13; Consolidated Appropriations Act of 2017, Public Law 115–31, 131 Stat. 135 (2017); and 25 U.S.C. 1665a. This program is described in the Catalog of Federal Domestic Assistance (CFDA) under 93.933.

Background

Alcohol-related deaths are 520 percent greater among the American Indian and Alaska Native (AI/AN) population than the general United States population (IHS Trends in Indian Health, 2014). Providing social detoxification services is often a first step toward recovery for individuals with an alcohol use disorder to minimize physical harm, including death. Detoxification alone is not sufficient treatment for alcohol use disorder but is part of the continuum of care that fosters an individual's entry into treatment and rehabilitation. Alcohol use disorders are brain disorders and not evidence of moral weakness. All individuals with alcohol use disorders should be treated with respect and dignity at all times, in a nonjudgmental and supportive manner. Services should be completed in partnership with the individual and his or her social support network with due consideration for individual background, culture, preferences,

gender identity, vulnerabilities, and strengths.

Purpose

The purpose of this IHS cooperative agreement is to increase access to community-based prevention strategies to provide social detoxification, evaluation, stabilization, fostering patient readiness for and entry into treatment for alcohol use disorders and when appropriate, other substance use disorders. Applicants must have a fully operational and staffed social detoxification program that provides all three critical components of the detoxification process that primarily serves Indians.

IHS will use this funding to focus on the provision of services in the Navajo and Great Plains Areas. Congress has highlighted that the community of Gallup, New Mexico, continues to face urgent needs for substance abuse treatment, residential services, and detoxification services to address an ongoing crisis of alcohol-related deaths of Tribal members. Senate Appropriations Committee Report 114–281 expressed the Committee's expectation that IHS use funds provided in its appropriation to continue its assistance toward addressing this issue in the city of Gallup, New Mexico. Additionally, IHS is aware of the urgent need for alcohol detoxification services in the Great Plains Area after the removal of liquor licenses in White Clay, Nebraska, leading to the potential for increased mortality if services are unavailable for alcohol detoxification and subsequent treatment services.

II. Award Information

Type of Award: Cooperative Agreement.

Estimated Funds Available

The total amount of funding identified for the current fiscal year (FY) 2017 is approximately $2,000,000. Individual award amounts are anticipated to be between $500,000 and $1,500,000. The amount of funding available for competing and continuation awards issued under this announcement are subject to the availability of appropriations and budgetary priorities of the Agency. The IHS is under no obligation to make awards that are selected for funding under this announcement.

Anticipated Number of Awards

Approximately two awards will be issued under this program announcement.

Project Period

The project period is for five years and will run consecutively from September 30, 2017, to September 29, 2022.

Cooperative Agreement

Cooperative agreements awarded by the Department of Health and Human Services (HHS) are administered under the same policies as a grant. However, the funding agency (IHS) is required to have substantial programmatic involvement in the project during the entire award segment. Below is a detailed description of the level of involvement required for both IHS and the grantee. IHS will be responsible for activities listed under section A and the grantee will be responsible for activities listed under section B as stated:

Substantial Involvement Description for Cooperative Agreement

A. IHS Programmatic Involvement

(1) Participate in community-level meetings with key stakeholders that address a strategy to combat the issue of alcohol use disorders and subsequent alcohol-related deaths.

(2) Provide quarterly site visits for technical assistance on increasing the clinical capacity of services offered between the grantee and IHS programs, where available.

(3) Provide subject matter expertise on policies, procedures, guidelines, and other services provided by the grantee.

(4) Provide medical services as appropriate for individuals requiring a higher level of care, or medical clearance.

B. Grantee Cooperative Agreement Award Activities

(1) Provide quarterly reports to the IHS program officer on the number of individuals served, number of individuals referred to treatment services, number of individuals who access services more than once, number of individuals who access safe housing options.

(2) Provide semi-annual reports on successes and challenges, in addition to the data included in quarterly reports.

(3) Host quarterly site visits for IHS officials to discuss progress, partnerships, and clinical capacity, challenges, and opportunities for improvement.

(4) Provide hot meals, showers, hygiene kits, and other activities of daily living that are necessary for individuals in detoxification and treatment services.

(5) Ensure coordination with cultural services and traditional healers to provide services while individuals are participating in services.

(6) Provide transportation to and from medical appointments or for medical clearance and ensure that medication management is offered while individuals are participating in services.

(7) Must use 100 percent of IHS grant funds for services provided to Indians.

III. Eligibility Information

1. Eligibility

To be eligible for this ''New Opportunity'' under this announcement, an applicant must be a public or private institution operated by a state, local, Tribal, or private entity that operates direct, on-site alcohol and/or substance use disorder treatment services, including social alcohol detoxification services, to Indians. For purposes of this announcement, ''institution'' means an entity that provides services on an inpatient services. Eligible applicants must be able to start services on the first day of the award. Eligible applicants must serve Indians that make up at least 85 percent of the institution's average daily census.

Note: Please refer to Section IV.2 (Application and Submission Information/ Subsection 2, Content and Form of Application Submission) for additional proof of applicant status documents required, such as Tribal resolutions, proof of non-profit status, etc.

2. Cost Sharing or Matching

The IHS does not require matching funds or cost sharing for grants or cooperative agreements.

3. Other Requirements

If application budgets exceed the highest dollar amount outlined under the ''Estimated Funds Available'' section within this funding announcement, the application will be considered ineligible and will not be reviewed for further consideration. If deemed ineligible, IHS will not return the application. The applicant will be notified by email by the Division of Grants Management (DGM) of this decision.

Tribal Resolution

An Indian Tribe or Tribal organization that is proposing a project affecting another Indian Tribe must include Tribal resolutions from all affected Tribes to be served. Applications by Tribal organizations will not require a specific Tribal resolution if the current Tribal resolution(s) under which they operate would encompass the proposed grant activities.

An official signed Tribal resolution must be received by the DGM prior to

a Notice of Award (NoA) being issued to any applicant selected for funding. However, if an official signed Tribal resolution cannot be submitted with the electronic application submission prior to the official application deadline date, a draft Tribal resolution must be submitted by the deadline in order for the application to be considered complete and eligible for review. The draft Tribal resolution is not in lieu of the required signed resolution, but is acceptable until a signed resolution is received. If an official signed Tribal resolution is not received by DGM when funding decisions are made, then a NoA will not be issued to that applicant and they will not receive any IHS funds until such time as they have submitted a signed resolution to the Grants Management Specialist listed in this Funding Announcement.

Proof of Non-Profit Status

Organizations claiming non-profit status must submit proof. A copy of the 501(c)(3) Certificate must be received with the application submission by the Application Deadline Date listed under the Key Dates section on page one of this announcement.

An applicant submitting any of the above additional documentation after the initial application submission due date is required to ensure the information was received by the IHS DGM by obtaining documentation confirming delivery (*i.e.* FedEx tracking, postal return receipt, etc.).

IV. Application and Submission Information

1. Obtaining Application Materials

The application package and detailed instructions for this announcement can be found at *http://www.Grants.gov* or *http://www.ihs.gov/dgm/funding/.*

Questions regarding the electronic application process may be directed to Mr. Paul Gettys at (301) 443–2114 or (301) 443–5204.

2. Content and Form Application Submission

The applicant must include the project narrative as an attachment to the application package. Mandatory documents for all applicants include:

- Table of contents.
- Abstract (one page) summarizing the project.
- Application forms:
  - SF–424, Application for Federal Assistance.
  - SF–424A, Budget Information—Non-Construction Programs.
  - SF–424B, Assurances—Non-Construction Programs.
- Budget Justification and Narrative (must be single-spaced and not exceed four pages.
- Project Narrative (must be single-spaced and not exceed 10 pages).
  - Background information on the organization.
  - Proposed scope of work, objectives, and activities that provide a description of what will be accomplished, including a one-page Timeframe Chart.
- Letters of Support from organization's Board of Directors.
- Tribal Resolution(s).
- 501(c)(3) Certificate (if applicable).
- Biographical sketches for all Key Personnel.
- Contractor/Consultant resumes or qualifications and scope of work.
- Disclosure of Lobbying Activities (SF–LLL).
- Certification Regarding Lobbying (GG–Lobbying Form).
- Copy of current Negotiated Indirect Cost rate (IDC) agreement (required in order to receive IDC).
- Organizational Chart (optional).
- Documentation of current Office of Management and Budget (OMB) Financial Audit (if applicable).

Acceptable forms of documentation include:

- Email confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or
- Face sheets from audit reports. These can be found on the FAC Web site: *https://harvester.census.gov/facdissem/Main.aspx.*

Public Policy Requirements

All Federal-wide public policies apply to IHS grants and cooperative agreements with exception of the Discrimination policy.

Requirements for Project and Budget Narratives

A. Project Narrative: This narrative should be a separate Word document that is no longer than 10 pages and must: Be single-spaced, type written, have consecutively numbered pages, use black type not smaller than 12 points, and be printed on one side only of standard size 8½″ x 11″ paper.

Be sure to succinctly answer all questions listed under the evaluation criteria (refer to Section V.1, Evaluation criteria in this announcement) and place all responses and required information in the correct section (noted below), or they will not be considered or scored. These narratives will assist the Objective Review Committee (ORC) in becoming familiar with the applicant's activities and accomplishments prior to this possible cooperative agreement award. If the narrative exceeds the page limit, only the first 10 pages will be reviewed. The 10-page limit for the narrative does not include the work plan, standard forms, Tribal resolutions, table of contents, budget, budget justifications, narratives, and/or other appendix items.

There are three parts to the narrative: Part A—Program Information; Part B—Program Planning and Evaluation; and Part C—Program Report. See below for additional details about what must be included in the narrative.

The page limitations below are for each narrative and budget submitted.

Part A: Program Information (2 Pages)

Section 1: Needs

Describe the current issue of alcohol use disorders, alcohol-related deaths, and rates of alcohol-related liver cirrhosis, as well as other social and health issues impacted by alcohol-related deaths. Describe the program's current social detoxification program, who operates it, number of employees, how long it has been operating, what programs or services are currently being provided. Describe why the program is seeking additional funding and how it will be utilized to enhance current services. Provide a statement of fact on the clientele served, average daily census, and ratio of individuals served who are enrolled members of federally recognized Tribes to those who are not.

Part B: Program Planning and Evaluation (6 Pages)

Section 1: Program Plans

Describe fully and clearly the direction the applicant plans to take to provide social detoxification, including three critical components of evaluation, stabilization, and fostering patient readiness for and entry into treatment. Describe how the applicant will provide safe housing and custodial care in a safe environment by employees who have successfully passed background checks who have been trained in social detoxification and who are familiar with the features of substance use withdrawal, have training in basic life support, and have access to emergency medical systems. Describe how the applicant will provide appropriate monitoring and security to prevent self-harm of served individuals and harm to others. Describe how the applicant has the ability to provide transportation to and from emergency departments, as needed.

Describe fully and clearly the types of community partnerships and referral providers to provide health and behavioral health treatment services,

among others. Include information how the applicant will implement a communication and support strategy that includes with family members of individuals served (with their consent). Describe the applicant's ability to provide daily activities of living, such as exercise, showers, and hot meals, personal hygiene, blankets, appropriate clothing. Include information on how the applicant will provide culturally appropriate interventions and activities. Provide details on nurse support for medical issues and medication management and referral to a higher level of care, when needed; medication management, assessments, and screening of clients; and case management services.

Section 2: Program Evaluation

Describe how the program intends to evaluate its activities to include successes, challenges, outputs, and outcomes.

Part C: Program Report (2 Pages)

Section 1: Describe your organization's capacity to provide the activities that align with the purpose of this funding opportunity. Please identify current staffing and key personnel who will be responsible for the management of the cooperative agreement. Describe significant program activities and accomplishments over the past five years associated with the goals of this announcement.

B. Budget Narrative (4 Pages)

This narrative must include a line item budget with a narrative justification for all expenditures identifying reasonable allowable, allocable costs necessary to accomplish the goals and objectives as outlined in the project narrative. Budget should match the scope of work described in the project narrative.

3. Submission Dates and Times

Applications must be submitted electronically through *Grants.gov* by 11:59 p.m. Eastern Daylight Time (EDT) on the Application Deadline Date listed in the Key Dates section on page one of this announcement. Any application received after the application deadline will not be accepted for processing, nor will it be given further consideration for funding. *Grants.gov* will notify the applicant via email if the application is rejected.

If technical challenges arise and assistance is required with the electronic application process, contact *Grants.gov* Customer Support via email to *support@grants.gov* or at (800) 518–4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays). If problems persist, contact Mr. Gettys (*Paul.Gettys@ihs.gov,*) DGM Grant Systems Coordinator, by telephone at (301) 443–2114 or (301) 443–5204. Please be sure to contact Mr. Gettys at least ten days prior to the application deadline. Please do not contact the DGM until you have received a *Grants.gov* tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

4. Intergovernmental Review

Executive Order 12372 requiring intergovernmental review is not applicable to this program.

5. Funding Restrictions

- Pre-award costs are not allowable.
- The available funds are inclusive of direct and appropriate indirect costs.
- Only one grant/cooperative agreement will be awarded per applicant.
- IHS will not acknowledge receipt of applications.

6. Electronic Submission Requirements

All applications must be submitted electronically. Please use the *http://www.Grants.gov* Web site to submit an application electronically and select the ''Find Grant Opportunities'' link on the homepage. Follow the instructions for submitting an application under the Package tab. Electronic copies of the application may not be submitted as attachments to email messages addressed to IHS employees or offices.

If the applicant needs to submit a paper application instead of submitting electronically through *Grants.gov*, a waiver must be requested. Prior approval must be requested and obtained from Mr. Robert Tarwater, Director, DGM, (see Section IV.6 below for additional information). A written waiver request must be sent to *GrantsPolicy@ihs.gov* with a copy to *Robert.Tarwater@ihs.gov.* The waiver must: (1) Be documented in writing (emails are acceptable), before submitting a paper application, and (2) include clear justification for the need to deviate from the required electronic grants submission process.

Once the waiver request has been approved, the applicant will receive a confirmation of approval email containing submission instructions and the mailing address to submit the application. A copy of the written approval must be submitted along with the hardcopy of the application that is mailed to DGM. Paper applications that are submitted without a copy of the signed waiver from the Director of the DGM will not be reviewed or considered for funding. The applicant will be notified via email of this decision by the Grants Management Officer of the DGM. Paper applications must be received by the DGM no later than 5:00 p.m., EDT, on the Application Deadline Date listed in the Key Dates section on page one of this announcement. Late applications will not be accepted for processing or considered for funding. Applicants that do not adhere to the timelines for System for Award Management (SAM) and/or *http://www.Grants.gov* registration or that fail to request timely assistance with technical issues will not be considered for a waiver to submit a paper application.

Please be aware of the following:

- Please search for the application package in *http://www.Grants.gov* by entering the CFDA number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.
- If you experience technical challenges while submitting your application electronically, please contact *Grants.gov* Support directly at: *support@grants.gov* or (800) 518–4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays).
- Upon contacting *Grants.gov*, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained.
- Applicants are strongly encouraged not to wait until the deadline date to begin the application process through *Grants.gov* as the registration process for SAM and *Grants.gov* could take up to fifteen working days.
- Please use the optional attachment feature in *Grants.gov* to attach additional documentation that may be requested by the DGM.
- All applicants must comply with any page limitation requirements described in this funding announcement.
- After electronically submitting the application, the applicant will receive an automatic acknowledgment from *Grants.gov* that contains a *Grants.gov* tracking number. The DGM will download the application from *Grants.gov* and provide necessary copies to the appropriate agency officials. Neither the DGM nor the Division of Behavioral Health will notify the applicant that the application has been received.
- Email applications will not be accepted under this announcement.

Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS)

All IHS applicants and grantee organizations are required to obtain a DUNS number and maintain an active registration in the SAM database. The DUNS number is a unique 9-digit identification number provided by D&B which uniquely identifies each entity. The DUNS number is site specific; therefore, each distinct performance site may be assigned a DUNS number. Obtaining a DUNS number is easy, and there is no charge. To obtain a DUNS number, you may access it through *http://fedgov.dnb.com/webform,* or to expedite the process, call (866) 705–5711.

All HHS recipients are required by the Federal Funding Accountability and Transparency Act of 2006, as amended (''Transparency Act''), to report information on sub-awards. Accordingly, all IHS grantees must notify potential first-tier sub-recipients that no entity may receive a first-tier sub-award unless the entity has provided its DUNS number to the prime grantee organization. This requirement ensures the use of a universal identifier to enhance the quality of information available to the public pursuant to the Transparency Act.

System for Award Management (SAM)

Organizations that were not registered with Central Contractor Registration and have not registered with SAM will need to obtain a DUNS number first and then access the SAM online registration through the SAM home page at *https://www.sam.gov* (U.S. organizations will also need to provide an Employer Identification Number from the Internal Revenue Service that may take an additional 2–5 weeks to become active). Completing and submitting the registration takes approximately one hour to complete and SAM registration will take 3–5 business days to process. Registration with the SAM is free of charge. Applicants may register online at *https://www.sam.gov.*

Additional information on implementing the Transparency Act, including the specific requirements for DUNS and SAM, can be found on the IHS Grants Management, Grants Policy Web site: *http://www.ihs.gov/dgm/policytopics/.*

V. Application Review Information

The instructions for preparing the application narrative also constitute the evaluation criteria for reviewing and scoring the application. Weights assigned to each section are noted in parentheses. The 10 page narrative should include only the first year of activities; information for multi-year projects should be included as an appendix. See ''Multi-year Project Requirements'' at the end of this section for more information. The narrative section should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well organized, succinct, and contain all information necessary for reviewers to understand the project fully. Points will be assigned to each evaluation criteria adding up to a total of 100 points. A minimum score of 70 points is required for funding. Points are assigned as follows:

1. Criteria

A. Need for Assistance (30 Points)

- The degree to which the applicant describes the issue of alcohol use disorders, alcohol-related deaths, and other social and health issues attributed to alcohol in the community they serve.
- The degree to which the applicant demonstrates the need for funding and how the funding will complement, increase, and/or expand the services currently provided.
- This section must include the applicant's service population, average daily census, and statement of fact that more than 85 percent of the clientele they serve are members of federally recognized Tribes. Without this information, applicants will receive a score of 0 for this section.

B. Work Plan, Approach, and Program Approach (40 Points)

- The degree to which the applicant plans to provide social detoxification, safe housing, and outpatient treatment, including custodial care in a safe environment.
- How well the applicant describes the process of ensuring employees have passed background checks and are training in appropriate substance use disorder intervention and treatment.
- How well the applicant describes its community partnerships and referral network for health and behavioral health treatment services.
- How well the applicant describes appropriate monitoring of individuals accessing services and provides security services to ensure safety and prevention of self-harm and harm to others.
- How well the applicant describes its communication strategy with family members.
- How well the applicant describes its community partnerships and referral network for treatment services, including when medical detoxification is required.
- How well the applicant describes its ability to provide activities of daily living, exercise, showers, hot meals, cultural activities, blankets, and appropriate clothing.
- How well the applicant describes its ability to provide nurse support for medical issues and medication management, assessments, screening, and case management.

C. Program Evaluation (10 Points)

- How well the applicant provides a plan to evaluate its own impact, including successes and challenges, as well as a plan for the type of data that will be collected and submitted on a quarterly basis that demonstrate the program's outputs and annual basis that demonstrate the program's annual outcomes.

D. Organizational Capabilities, Key Personnel and Qualifications (10 Points)

- How well the applicant describes the capacity to provide services on day 1 of the award.
- How well the applicant describes the operations and management of the services currently being provided.
- The degree to which the applicant describes its staffing level, experience and education of staff, and key personnel who will manage the project.

E. Categorical Budget and Budget Justification (10 Points)

- How clear the applicant demonstrates each budget item aligns with its proposed work plan and program approach.
- The degree to which the applicant budgets for evaluation activities.

Multi-Year Project Requirements

Projects requiring a second, third, fourth, and/or fifth year must include a brief project narrative and budget (one additional page per year) addressing the developmental plans for each additional year of the project.

Additional Documents Can Be Uploaded as Appendix Items in Grants.gov

- Work plan, logic model and/or time line for proposed objectives.
- Position descriptions for key staff.
- Resumes of key staff that reflect current duties.
- Consultant or contractor proposed scope of work and letter of commitment (if applicable).
- Current Indirect Cost Agreement.
- Organizational chart.
- Map of area identifying project location(s).
- Additional documents to support narrative (*i.e.* data tables, key news articles, etc.).

2. Review and Selection

Each application will be prescreened by the DGM staff for eligibility and completeness as outlined in the funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the ORC based on evaluation criteria in this funding announcement. The ORC could be composed of both Tribal and Federal reviewers appointed by the IHS Program to review and make recommendations on these applications. The technical review process ensures selection of quality projects in a national competition for limited funding. Incomplete applications and applications that are non-responsive to the eligibility criteria will not be referred to the ORC. The applicant will be notified via email of this decision by the Grants Management Officer of the DGM. Applicants will be notified by DGM, via email, to outline minor missing components (*i.e.,* budget narratives, audit documentation, key contact form) needed for an otherwise complete application. All missing documents must be sent to DGM on or before the due date listed in the email of notification of missing documents required.

To obtain a minimum score for funding by the ORC, applicants must address all program requirements and provide all required documentation.

VI. Award Administration Information

1. Award Notices

The Notice of Award (NoA) is a legally binding document signed by the Grants Management Officer and serves as the official notification of the grant award. The NoA will be initiated by the DGM in our grant system, GrantSolutions (*https://www.grantsolutions.gov*). Each entity that is approved for funding under this announcement will need to request or have a user account in GrantSolutions in order to retrieve their NoA. The NoA is the authorizing document for which funds are dispersed to the approved entities and reflects the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the award, the effective date of the award, and the budget/project period.

Disapproved Applicants

Applicants who received a score less than the recommended funding level for approval, 70 and were deemed to be disapproved by the ORC, will receive an Executive Summary Statement from the IHS program office within 30 days of the conclusion of the ORC outlining the strengths and weaknesses of their application. The summary statement will be sent to the Authorized Organizational Representative that is identified on the face page (SF–424) of the application. The IHS program office will also provide additional contact information as needed to address questions and concerns as well as provide technical assistance if desired.

Approved But Unfunded Applicants

Approved but unfunded applicants that met the minimum scoring range and were deemed by the ORC to be ''Approved,'' but were not funded due to lack of funding, will have their applications held by DGM for a period of one year. If additional funding becomes available during the course of FY 2017 the approved but unfunded application may be re-considered by the awarding program office for possible funding. The applicant will also receive an Executive Summary Statement from the IHS program office within 30 days of the conclusion of the ORC.

Note: Any correspondence other than the official NoA signed by an IHS grants management official announcing to the project director that an award has been made to their organization is not an authorization to implement their program on behalf of IHS.

2. Administrative Requirements

Cooperative agreements are administered in accordance with the following regulations and policies:

A. The criteria as outlined in this program announcement.

B. Administrative Regulations for Grants:

- Uniform Administrative Requirements for HHS Awards, located at 45 CFR part 75.

C. Grants Policy:

- HHS Grants Policy Statement, Revised 01/07.

D. Cost Principles:

- Uniform Administrative Requirements for HHS Awards, ''Cost Principles,'' located at 45 CFR part 75, subpart E.

E. Audit Requirements:

- Uniform Administrative Requirements for HHS Awards, ''Audit Requirements,'' located at 45 CFR part 75, subpart F.

3. Indirect Costs

This section applies to all grant recipients that request reimbursement of indirect costs (IDC) in their grant application. In accordance with HHS Grants Policy Statement, Part II–27, IHS requires applicants to obtain a current IDC rate agreement prior to award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate covers the applicable grant activities under the current award's budget period. If the current rate is not on file with the DGM at the time of award, the IDC portion of the budget will be restricted. The restrictions remain in place until the current rate is provided to the DGM.

Generally, IDC rates for IHS grantees are negotiated with the Division of Cost Allocation (DCA) *https://rates.psc.gov/* and the Department of Interior (Interior Business Center) *https://www.doi.gov/ibc/services/finance/indirect-Cost-Services/indian-tribes.* For questions regarding the indirect cost policy, please call the Grants Management Specialist listed under ''Agency Contacts'' or the main DGM office at (301) 443–5204.

4. Reporting Requirements

The grantee must submit required reports consistent with the applicable deadlines. Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in one or both of the following: (1) The imposition of special award provisions; and (2) the non-funding or non-award of other eligible projects or activities. This requirement applies whether the delinquency is attributable to the failure of the grantee organization or the individual responsible for preparation of the reports. Per DGM policy, all reports are required to be submitted electronically by attaching them as a ''Grant Note'' in GrantSolutions. Personnel responsible for submitting reports will be required to obtain a login and password for GrantSolutions. Please see the Agency Contacts list in section VII for the systems contact information.

The reporting requirements for this program are noted below.

A. Progress Reports

Program progress reports are required semi-annually, within 30 days after the budget period ends. These reports must include a brief comparison of actual accomplishments to the goals established for the period, a summary of progress to date or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required. A final report must be submitted within 90 days of expiration of the budget/project period.

B. Financial Reports

Federal Financial Report (FFR or SF–425), Cash Transaction Reports are due 30 days after the close of every calendar quarter to the Payment Management Services, HHS at *https://pms.psc.gov.* It is recommended that the applicant also send a copy of the FFR (SF–425) report to the Grants Management Specialist. Failure to submit timely reports may cause a disruption in timely payments to the organization.

Grantees are responsible and accountable for accurate information being reported on all required reports: The Progress Reports and Federal Financial Report.

C. Federal Sub-Award Reporting System (FSRS)

This award may be subject to the Transparency Act sub-award and executive compensation reporting requirements of 2 CFR part 170.

The Transparency Act requires the OMB to establish a single searchable database, accessible to the public, with information on financial assistance awards made by Federal agencies. The Transparency Act also includes a requirement for recipients of Federal grants to report information about first-tier sub-awards and executive compensation under Federal assistance awards.

IHS has implemented a Term of Award into all IHS Standard Terms and Conditions, NoAs and funding announcements regarding the FSRS reporting requirement. This IHS Term of Award is applicable to all IHS grant and cooperative agreements issued on or after October 1, 2010, with a $25,000 sub-award obligation dollar threshold met for any specific reporting period. Additionally, all new (discretionary) IHS awards (where the project period is made up of more than one budget period) and where: (1) The project period start date was October 1, 2010 or after and (2) the primary awardee will have a $25,000 sub-award obligation dollar threshold during any specific reporting period will be required to address the FSRS reporting.

For the full IHS award term implementing this requirement and additional award applicability information, visit the DGM Grants Policy Web site at: *http://www.ihs.gov/dgm/policytopics/.*

D. Compliance With Executive Order 13166 Implementation of Services

Accessibility Provisions for All Grant Application Packages and Funding Opportunity Announcements

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. HHS provides guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see *http://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/guidance-federal-financial-assistance-recipients-title-VI/.*

The HHS Office for Civil Rights (OCR) also provides guidance on complying with civil rights laws enforced by HHS. Please see *http://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html;* and *http://www.hhs.gov/civil-rights/index.html.* Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see *http://www.hhs.gov/civil-rights/for-individuals/disability/index.html.* Please contact the HHS OCR for more information about obligations and prohibitions under federal civil rights laws at *https://www.hhs.gov/ocr/about-us/index.html* or call 1–800–368–1019 or TDD 1–800–537–7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at *http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53.*

Pursuant to 45 CFR 80.3(d), an individual shall not be deemed subjected to discrimination by reason of his/her exclusion from benefits limited by federal law to individuals eligible for benefits and services from the IHS.

Recipients will be required to sign the HHS–690 Assurance of Compliance form which can be obtained from the following Web site: *http://www.hhs.gov/sites/default/files/forms/hhs-690.pdf,* and send it directly to the: U.S. Department of Health and Human Services, Office of Civil Rights, 200 Independence Ave. SW., Washington, DC 20201.

F. Federal Awardee Performance and Integrity Information System (FAPIIS)

The IHS is required to review and consider any information about the applicant that is in the Federal Awardee Performance and Integrity Information System (FAPIIS) before making any award in excess of the simplified acquisition threshold (currently $150,000) over the period of performance. An applicant may review and comment on any information about itself that a federal awarding agency previously entered. IHS will consider any comments by the applicant, in addition to other information in FAPIIS in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when completing the review of risk posed by applicants as described in 45 CFR 75.205.

As required by 45 CFR part 75 Appendix XII of the Uniform Guidance, non-federal entities (NFEs) are required to disclose in FAPIIS any information about criminal, civil, and administrative proceedings, and/or affirm that there is no new information to provide. This applies to NFEs that receive federal awards (currently active grants, cooperative agreements, and procurement contracts) greater than $10,000,000 for any period of time during the period of performance of an award/project.

Mandatory Disclosure Requirements

As required by 2 CFR part 200 of the Uniform Guidance, and the HHS implementing regulations at 45 CFR part 75, effective January 1, 2016, the IHS must require a non-federal entity or an applicant for a federal award to disclose, in a timely manner, in writing to the IHS or pass-through entity all violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award.

Submission is required for all applicants and recipients, in writing, to the IHS and to the HHS Office of Inspector General all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. 45 CFR 75.113.

Disclosures must be sent in writing to: U.S. Department of Health and Human Services, Indian Health Service, Division of Grants Management, ATTN: Robert Tarwater, Director, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, (Include ''Mandatory Grant

Disclosures'' in subject line), *Office:* (301) 443–5204, *Fax:* (301) 594–0899, *Email: Robert.Tarwater@ihs.gov.*

AND

U.S. Department of Health and Human Services, Office of Inspector General, ATTN: Mandatory Grant Disclosures, Intake Coordinator, 330 Independence Avenue SW., Cohen Building, Room 5527, Washington, DC 20201, *URL: http://oig.hhs.gov/fraud/report-fraud/index.asp* (Include ''Mandatory Grant Disclosures'' in subject line), *Fax:* (202) 205–0604 (Include ''Mandatory Grant Disclosures'' in subject line) or *Email: MandatoryGranteeDisclosures@oig.hhs.gov.*

Failure to make required disclosures can result in any of the remedies described in 45 CFR 75.371 Remedies for noncompliance, including suspension or debarment (See 2 CFR parts 180 & 376 and 31 U.S.C. 3321).

VII. Agency Contacts

1. Questions on the programmatic issues may be directed to: Dr. Beverly Cotton, Director, Division of Behavioral Health, 5600 Fishers Lane, Mail Stop: 08N34A, Rockville, MD 20857, *Phone:* (301) 443–4754, *Email: beverly.cotton@ihs.gov.*

2. Questions on grants management and fiscal matters may be directed to: Willis Grant, Senior Grants Management Specialist, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, *Phone:* (301) 443–2214, *Fax:* (301) 594–0899, *Email: Willis.Grant@ihs.gov.*

3. Questions on systems matters may be directed to: Paul Gettys, Grant Systems Coordinator, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, *Phone:* (301) 443–2114; or the DGM main line (301) 443–5204, *Fax:* (301) 594–0899, *Email: Paul.Gettys@ihs.gov.*

VIII. Other Information

The Public Health Service strongly encourages all cooperative agreement and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the HHS mission to protect and advance the physical and mental health of the American people.

Dated: August 8, 2017.

Michael D. Weahkee,

Assistant Surgeon General, U.S. Public Health Service, Acting Director, Indian Health Service.

[FR Doc. 2017–17102 Filed 8–11–17; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Initial Review Group Pediatrics Subcommittee.

Date: October 12, 2017.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Rita Anand, Ph.D., Scientific Review Officer Division of Scientific Review National Institute of Child Health and Human Development, NIH, 6710B Rockledge Drive, MSC 7002, Bethesda, MD 20892, (301) 496–1487, *anandr@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: August 8, 2017.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–17041 Filed 8–11–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Multi-Site Investigator-Initiated Clinical Trials AIDS Applications.

Date: September 7, 2017.

Time: 2:30 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7190, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Keary A Cope, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7190, Bethesda, MD 20892–7924, 301–827–7912, *copeka@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: August 8, 2017.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–17038 Filed 8–11–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the

provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Initial Review Group; Biomedical Research Review Subcommittee.

Date: October 17, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, Conference Room 3002, 5635 Fishers Lane, Rockville, MD 20852.

Contact Person: Philippe Marmillot, Ph.D., Scientific Review Officer, Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 5635 Fishers Lane, Room 2017, Bethesda, MD 20892, 301–443–2861, *marmillotp@mail.nih.gov.*

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Initial Review Group; Neuroscience Review Subcommittee.

Date: October 24, 2017.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, Terrace Level Conference Room 508, 5635 Fishers Lane, Rockville, MD 20852.

Contact Person: Beata Buzas, Ph.D., Scientific Review Officer, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 5635 Fishers Lane, Room 2081, Rockville, MD 20852, 301–443–0800, *bbuzas@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards., National Institutes of Health, HHS)

Dated: August 8, 2017.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–17039 Filed 8–11–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Cancer Advisory Board.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting Web site (*http://videocast.nih.gov*).

A portion of the National Cancer Advisory Board meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Advisory Board.

Date: September 12, 2017.

Open: 1:00 p.m. to 2:55 p.m.

Agenda: Acting Director's and program reports and presentations; business of the Board.

Closed: 3:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute—Shady Grove, 9609 Medical Center Drive, Room TE406 & 408, Rockville, MD 20850 (Virtual Meeting).

Contact Person: Paulette S. Gray, Ph.D., Executive Secretary, Division of Extramural Activities, National Cancer Institute—Shady Grove, National Institutes of Health, 9609 Medical Center Drive, Room 7W444, Bethesda, MD 20892, 240–276–6340, *grayp@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NCI-Shady Grove campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: NCAB: *http://deainfo.nci.nih.gov/advisory/ncab/ncab.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: August 8, 2017.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–17037 Filed 8–11–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Scientific Advisory Committee on Alternative Toxicological Methods; Announcement of Meeting; Request for Comments

SUMMARY: This notice announces a meeting of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM). SACATM advises the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), and the Director of the National Institute of Environmental Health Sciences (NIEHS) and NTP regarding statutorily mandated duties of ICCVAM and activities of NICEATM. The meeting is open to the public, and registration is requested for both public attendance and oral comment and required to access the webcast. Information about the meeting and registration is available at *http://ntp.niehs.nih.gov/go/32822.*

DATES:

Meeting: September 18–19, 2017; it begins 9:00 a.m. Eastern Daylight Time (EDT) each day and continues until adjournment.

Written Public Comment Submissions: Deadline is September 11, 2017.

Registration for Oral Comments: Deadline is September 11, 2017.

Registration for the meeting and to View Webcast: Deadline is September 19, 2017.

Registration to view the meeting via the webcast is required.

ADDRESSES:

Meeting Location: Natcher Conference Center, Building 45, Room E1 & E2, National Institutes of Health, Bethesda, MD 20984.

Meeting Web page: The preliminary agenda, registration information, and background materials should be posted at *http://ntp.niehs.nih.gov/go/32822* by August 15, 2017.

Webcast: The meeting will be webcast; the URL will be provided to those who register for viewing.

FOR FURTHER INFORMATION CONTACT: Dr. Mary Wolfe, Designated Federal Official for SACATM, Office of Liaison, Policy, and Review, Division of NTP, NIEHS, P.O. Box 12233, K2–03, Research Triangle Park, NC 27709. Phone: 919–541–7539, fax: 301–451–6890, email: *wolfe@niehs.nih.gov.* Hand Deliver/Courier address: 530 Davis Drive, Room K2130, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Preliminary Agenda and Other Meeting Information: A preliminary agenda, roster of SACATM members, and background materials should be available by August 15, 2017, on the SACATM meeting Web site (*http://ntp.niehs.nih.gov/go/32822*) and available upon request from the Designated Federal Official. Public comments and any additional information will be posted when available. The meeting's agenda will focus on the US strategic roadmap for implementation of new approaches to safety evaluation, which is under development, and ICCVAM agencies' activities related to the development and implementation of alternative methods. Following the meeting, summary minutes will be prepared and available on the SACATM Web site or upon request from the Designated Federal Official.

Meeting and Registration: This meeting is open to the public with time scheduled for oral public comments. The public may attend the meeting at Natcher Conference Center, where attendance is limited only by the space available, or view the webcast. Registration is required to view the webcast; the URL for the webcast will be provided in the email confirming registration. Individuals who plan to attend and/or provide oral comments are encouraged to register at *http://ntp.niehs.nih.gov/go/32822* by September 11, 2017, to facilitate planning for the meeting. Individuals are encouraged to access the Web site to stay abreast of the most current information regarding the meeting. Visitor information for those attending in person is available at *https://www.nih.gov/about-nih/visitor-information.* Campus access and security information is located at *https://www.nih.gov/about-nih/visitor-information/campus-access-security.* Individuals with disabilities who need accommodation to participate in this event should contact Ms. Robbin Guy at phone: 919–541–4363 or email: *guyr2@niehs.nih.gov.* TTY users should contact the Federal TTY Relay Service at 800–877–8339. Requests should be made at least five business days in advance of the event.

Request for Comments: Both written and oral public input on the agenda topics is invited. Written comments submitted in response to this notice should be received by September 11, 2017. Comments will be posted on the SACATM meeting Web site and persons submitting them will be identified by their name and affiliation and/or sponsoring organization, if applicable. Persons submitting written comments should include their name, affiliation (if applicable), and sponsoring organization (if any) with the document. Guidelines for public comments are at *http://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf.*

Time is allotted during the meeting for the public to present oral comments on the agenda topics. Public comments can be presented in-person at the meeting or by teleconference line. There are 50 lines for this call; availability is on a first-come, first-served basis. The lines will be open from 9:00 a.m. until adjournment on September 18 and 19; although SACATM will receive public comments only during the formal public comment periods, as indicated on the preliminary agenda. Each organization is allowed one time slot per agenda topic. Each speaker is allotted at least 7 minutes, which if time permits, may be extended to 10 minutes at the discretion of the SACATM chair.

Persons wishing to present oral comments are encouraged to register using the SACATM meeting registration form (*http://ntp.niehs.nih.gov/go/32822*) by September 11, 2017. Registrants should indicate the topic(s) on which they plan to comment and whether they will present comments in-person or via the teleconference. The access number for the teleconference line for public comments will be provided to registrants by email prior to the meeting. Registrants are requested to, if possible, send a copy of their statement to *wolfe@niehs.nih.gov* by September 11, 2017, to enable review by SACATM, NICEATM, ICCVAM, and NIEHS/NTP staff prior to the meeting. Written statements can supplement and may expand the oral presentation. Registration for on-site oral comments will also be available on the meeting day, although time allowed for comments by these registrants may be limited and will be determined by the number of persons who register at the meeting. If registering on-site and reading from written text, please bring 30 copies of the statement for distribution and to supplement the record.

Background Information on ICCVAM, NICEATM, and SACATM: ICCVAM is an interagency committee composed of representatives from 16 federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods with regulatory applicability and promotes the scientific validation and regulatory acceptance of toxicological and safety-testing methods that more accurately assess the safety and hazards of chemicals and products and that reduce, refine (decrease or eliminate pain and distress), or replace animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*-3) established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM.

NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts independent validation studies to assess the usefulness and limitations of new, revised, and alternative test methods and strategies. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods and strategies applicable to the needs of U.S. Federal agencies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative test methods and strategies for validation studies and technical evaluations. Additional information about ICCVAM and NICEATM can be found at *http://ntp.niehs.nih.gov/go/iccvam* and *http://ntp.niehs.nih.gov/go/niceatm.*

SACATM was established in response to the ICCVAM Authorization Act [Section 285*l*-3(d)] and is composed of scientists from the public and private sectors. SACATM advises ICCVAM, NICEATM, and the Director of the NIEHS and NTP regarding statutorily mandated duties of ICCVAM and activities of NICEATM. SACATM provides advice on priorities and activities related to the development, validation, scientific review, regulatory acceptance, implementation, and national and international

harmonization of new, revised, and alternative toxicological test methods. Additional information about SACATM, including the charter, roster, and records of past meetings, can be found at *http://ntp.niehs.nih.gov/go/167.*

Dated: August 1, 2017.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2017–17036 Filed 8–11–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel NIAID Clinical Trial Planning Grant (R34), Implementation Cooperative Agreement (U01) and SBIR Phase II Implementation Cooperative Agreement (U44).

Date: September 12, 2017.

Time: 10:00 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Maryam Feili-Hariri, Ph.D., Scientific Review Officer Scientific Review Program Division of Extramural Activities, National Institutes of Health/NIAID, 5601 Fishers Lane, Rockville, MD 20852, 240–669–5026, *haririmf@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: August 8, 2017.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–17040 Filed 8–11–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given that the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Prevention (CSAP) National Advisory Council will meet on August 25, 2017, 10:00 a.m.–11:00 a.m., in Rockville, MD.

The meeting will include the review, discussion, and evaluation of grant applications reviewed by the Initial Review Group, and involve an examination of confidential financial and business information as well as personal information concerning the applicants. Therefore, this meeting will be closed to the public as determined by the Acting Deputy Assistant Secretary for Mental Health and Substance Use, in accordance with Title 5 U.S.C. 552b(c)(4) and (c)(6) and 5 U.S.C. App. 2, Section 10(d).

Committee Name: Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Prevention National Advisory Council.

Date/Time/Type: August 25, 2017, 10:00 a.m.–11:00 a.m. (Closed).

Place: SAMHSA Building, 5600 Fishers Lane, Rockville, MD 20852.

Contact: Matthew J. Aumen, Designated Federal Officer, SAMHSA/CSAP National Advisory Council, 5600 Fishers Lane, Rockville, MD 20852, Email: *Matthew.Aumen@samhsa.hhs.gov.*

Carlos R. Castillo,

Committee Management Officer, SAMHSA.

[FR Doc. 2017–17074 Filed 8–11–17; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2017–0194]

Waterway Suitability Assessment for Operation of Liquefied Hazardous Gas Terminal; Port Arthur, TX

AGENCY: Coast Guard, DHS.

ACTION: Notice and request for comments.

SUMMARY: In accordance with Coast Guard regulations, Lynx Terminals LLC (Lynx Terminals) has submitted a Letter of Intent and Preliminary Waterway Suitability Assessment to the Coast Guard Captain of the Port, Port Arthur, TX (COTP) regarding the company's plans to handle and transport Liquefied Hazardous Gas (LHG) at the Port of Port Arthur docks in Port Arthur, TX. The Coast Guard is notifying the public of this proposed increase in LHG marine traffic on the Sabine-Neches Waterway and is soliciting comments relevant to the Coast Guard's preparation of a Letter of Recommendation (LOR) for issue to the federal, state or local agency with jurisdiction over the proposed facility.

DATES: Comments and related material must be received on or before September 13, 2017.

ADDRESSES: You may submit comments identified by docket number USCG–2017–0194 using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email Commander Loan T. O'Brien, U.S. Coast Guard; telephone 409–723–6564, email: *Loan.T.O'Brien@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to submit comments and related material in response to this notice through the Federal eRulemaking Portal at *http://www.regulations.gov.* We will consider all submissions and may adjust our final action based on your comments. If you submit a comment, please include the docket number for this notice, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal

eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published. To view comments, go to *http://www.regulations.gov,* type the docket number (USCG–2017–0194) in the ''SEARCH'' box and click ''SEARCH.'' Click on ''Open Docket Folder'' on the line associated with this notice and request for comment We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Privacy Act

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Public Meeting

We do not now plan to hold a public meeting, but you may submit a request for one, using one of the methods specified under **ADDRESSES**. Please explain why you believe a public meeting would be beneficial. If we determine that a public meeting would aid the Captain of the Port, Port Arthur (COTP) in validating the information in the WSA and preparing the Letter of Recommendation (LOR), we will hold one at a time and place announced by a later notice in the **Federal Register**.

Discussion

Under 33 CFR 127.007(a), an owner or operator planning to build a new facility handling Liquefied Hazardous Gas (LHG), or an owner or operator planning new construction to expand or modify marine terminal operations in an existing facility handling LHG, where the construction, expansion, or modification would result in an increase in the size and/or frequency of LHG marine traffic on the waterway associated with the proposed facility or modification to an existing facility, must submit a Letter of Intent (LOI) to the COTP of the zone in which the facility is or will be located. Under 33 CFR 127.007(e), an owner or operator planning such new construction or expansion of an existing facility must also file or update a Waterway Suitability Assessment (WSA) that addresses the proposed increase in LHG marine traffic in the associated waterway. Lynx Terminals, located in Port Arthur, TX submitted an LOI and WSA on August 09, 2016 regarding the company's proposed plans to handle and transport LHG at the Port of Port Arthur, TX facility.

Under 33 CFR 127.009, after receiving an LOI, the COTP issues a LOR as to the suitability of the waterway for LNG or LHG marine traffic to the appropriate jurisdictional authorities. The LOR is based on a series of factors listed in 33 CFR 127.009 that relate to the physical nature of the affected waterway and issues of safety and security associated with LHG marine traffic on the affected waterway.

The purpose of this notice is to solicit public comments on the proposed increase in LHG marine traffic on the Sabine-Neches Waterway. The Coast Guard believes that input from the public may be useful to the COTP with respect to validating the information provided in Lynx Terminals' WSA and development of the LOR. Additionally, the Coast Guard intends to task the Area Maritime Security Committee, Port Arthur, TX and the Southeast Texas Waterways Advisory Council with forming a subcommittee comprised of affected port users and stakeholders. The goal of this subcommittee will be to gather information to help the COTP assess the suitability of the associated waterway for increased LHG marine traffic as it relates to navigational safety and maritime security. In addition to the other documents referenced in this notice, a brief summation of LYNX Terminals' proposal is available for viewing in the public docket for this notice.

On January 24, 2011, the Coast Guard published Navigation and Vessel Inspection Circular (NVIC) 01–2011, ''Guidance Related to Waterfront Liquefied Natural Gas (LNG) Facilities''. NVIC 01–2011 provides guidance for owners and operators seeking approval to build and operate LNG facilities. While NVIC 01–2011 is specific to LNG, it provides useful process information and guidance for owners and operators seeking approval to build and operate LHG facilities as well. The Coast Guard will refer to NVIC 01–2011 for process information and guidance in evaluating Lynx Terminals' WSA. A copy of NVIC 01–2011 is available for viewing in the public docket for this notice and also on the Coast Guard's Web site at *http://www.uscg.mil/hq/cg5/nvic/2010s.asp.*

Dated: August 8, 2017.

Jaqueline Twomey,

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

[FR Doc. 2017–17106 Filed 8–11–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Automated Commercial Environment (ACE) Export Manifest for Air Cargo Test: Expansion of Test To Include Additional Participants, Modification of Required Data Elements, and Extension of Test

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

ACTION: General notice.

SUMMARY: This notice announces that CBP is modifying the U.S. Customs and Border Protection's (CBP's) Automated Commercial Environment (ACE) Export Manifest for Air Cargo Test, a National Customs Automation Program (NCAP) test concerning ACE export manifest capability, by making certain of the export manifest data elements optional. CBP is also extending the test and will be accepting additional applications for participation in this modified test from all parties meeting the eligibility requirements.

DATES: The modifications of the ACE Export Manifest for Air Cargo Test set forth in this document are effective August 14, 2017. The modified test will run until August 10, 2018. Applications from additional participants may be submitted at any time. Current test participants do not need to reapply. Comments concerning this notice and all aspects of the test may be submitted at any time during the test period to the email address below.

ADDRESSES: Applications to participate in the ACE Export Manifest for Air Cargo Test must be submitted via email to CBP Export Manifest at *cbpexportmanifest@cbp.dhs.gov.* In the subject line of the email, please use ''ACE Export Manifest for Air Cargo Test Application''. Written comments

concerning program, policy, and technical issues may also be submitted via email to CBP Export Manifest at *cbpexportmanifest@cbp.dhs.gov.* In the subject line of the email, please use ''Comment on ACE Export Manifest for Air Cargo Test''.

FOR FURTHER INFORMATION CONTACT: Robert C. Rawls, Outbound Enforcement and Policy Branch, Office of Field Operations, U.S. Customs and Border Protection, via email at *cbpexportmanifest@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

The ACE Export Manifest for Air Cargo Test is a voluntary test in which participants agree to submit export manifest data to CBP electronically, at least 4 hours prior to loading of the cargo onto the aircraft in preparation for departure from the United States. The ACE Export Manifest for Air Cargo Test is authorized under § 101.9(b) of title 19 of the Code of Federal Regulations (19 CFR 101.9(b)), which provides for the testing of NCAP programs or procedures.

CBP announced the procedures and criteria related to participation in the ACE Export Manifest for Air Cargo Test in a notice published in the **Federal Register** on July 10, 2015 (80 FR 39790). This test was originally set to run for approximately two years. For further details on the background and procedures regarding the test, please refer to the July 10, 2015 notice.

Expansion of Test to Additional Participants

In the July 10, 2015 notice announcing the initial phase of the ACE Export Manifest for Air Cargo Test, CBP stated that participation in the test was limited to nine stakeholders composed of air carriers and freight forwarders who met the eligibility requirements. This notice announces that the ACE Export Manifest for Air Cargo Test is now open to all eligible applicants. CBP will endeavor to accept all new eligible applicants on a first come first serve basis; however, if the number of eligible applicants exceeds CBP's administrative capabilities, CBP reserves the right to select eligible participants in order to achieve a diverse participant pool.

Eligibility Requirements

Except for the expansion to additional participants, the eligibility requirements for the ACE Export Manifest for Air Cargo Test set forth in the July 10, 2015 notice are not changing. For clarity and convenience to the public, CBP sets forth below the eligibility requirements for participation in the test.

Participation in the ACE Export Manifest for Air Cargo Test is limited to those parties able to electronically transmit manifest data in the identified acceptable format. Prospective ACE Export Manifest for Air Cargo Test participants must have the technical capability to electronically submit data to CBP and receive response message sets via Cargo-IMP, AIR CAMIR, IATA XML, or Unified XML,[1] and must successfully complete certification testing with their client representative. Once parties have applied to participate, they must complete a test phase to determine if the data transmission is in the required readable format. Applicants will be notified once they have successfully completed testing and are permitted to participate fully in the test. In selecting participants, CBP will take into consideration the order in which the applications are received.

There are no restrictions with regard to the participant's organization size, location or commodity type for participation in the test.

Modification of the Filing Condition of Certain Data Elements

One of the main purposes of the ACE Export Manifest for Air Cargo Test is to test the feasibility of requiring the manifest information to be filed electronically in ACE within a specified time before the cargo is loaded on the aircraft. Another purpose is to test the functionality regarding the filing of export manifest data for air cargo electronically to ACE within a specified time before the cargo is loaded on the aircraft. Under the current regulatory requirements, advance electronic filing of export data is generally not required. In most cases, the aircraft commander or agent must file a general declaration on CBP Form 7507 pertaining to the outbound flight. Also, the aircraft commander or agent must file the air cargo manifest, CBP Form 7509, with CBP at each port where export cargo is loaded on the aircraft. Additionally, the airline must file the complete air cargo manifest generally within 4 days after departure of the aircraft. *See* 19 CFR 122.72, 19 CFR 122.73, 19 CFR 122.74, 19 CFR 122.75, and 19 CFR 192.14. The U.S. Principal Party in Interest (USPPI) must file any required Electronic Export Information (EEI) for the cargo on the aircraft. *See* 15 CFR part 30. (For additional details about filing requirements for the aircraft commander and USPPI, please see the July 10, 2015 notice.) The data and the results of the ACE Export Manifest for Air Cargo Test will aid CBP in determining which parties are the best source of the export manifest data and when the data is available to be submitted to CBP.

CBP has been consulting with the Commercial Customs Operations Advisory Committee (COAC) to address ongoing issues concerning the quality, accessibility, and timeliness of export manifest data received during the test. Through this process, the COAC advised CBP that certain data elements currently required under the test may not be available to the party submitting the export manifest data to CBP 4 hours prior to loading the cargo on the aircraft in preparation for departure from the United States and urged CBP to make those data elements optional. For some, such as the in-bond number, COAC has suggested that the information may not be necessary because it is available to CBP through other electronic systems.

After evaluating the initial phase of the ACE Export Manifest for Air Cargo Test and considering the COAC's comments, CBP has determined that, in order to better test the functionality and feasibility of submitting the specified export data 4 hours in advance, five of the mandatory or conditional data elements should be changed to optional. This will enable participants to submit the optional information when and if it is available. These data elements are listed below. (Data elements which are ''mandatory'' must be provided to CBP for every shipment. Data elements which are ''conditional'' must be provided to CBP only if the particular information pertains to the cargo. Data elements which are ''optional'' may be provided to CBP but are not required).

- Number of pieces/unit of measure (Data Element #11)
- Number of house air waybills (Data Element #13)
- Split air waybill indicator (Data Element #18)
- In-bond number (Data Element #21)
- Mode of transportation (Data Element #22)

The remaining data elements under the ACE Export Manifest for Air Cargo Test continue to be mandatory, conditional or optional as provided in the July 10, 2015 notice. The full list of data elements is set forth below. Unless otherwise noted, the data elements are mandatory.

(1) Exporting Carrier (As reflected in the July 10, 2015 notice, CBP finds this term to be clearer than the term ''Owner/Operator'' used on CBP Form 7509.)

(2) Marks of nationality and registration

[1] Unified XML was not yet functional at the time of the original Automated Commercial Environment (ACE) Export Manifest for Air Cargo Test. It is now fully functional and available for use.

(3) Flight number
(4) Port of lading
(5) Port of unlading
(6) Scheduled date of departure (As reflected in the July 10, 2015 notice, CBP finds this term to be clearer than the term ''Date'' used on CBP Form 7509.)
(7) Consolidator (conditional)
(8) De-consolidator (conditional)
(9) Air waybill type (Master, House, Simple or Sub)
(10) Air waybill number
(11) Number of pieces and unit of measure (optional)
(12) Weight (kg./lb.)
(13) Number of house air waybills (optional)
(14) Shipper name and address
(15) Consignee name and address
(16) Cargo description (As reflected in the July 10, 2015 notice, CBP finds this term to be clearer than the term ''Nature of goods'' used on CBP Form 7509.)
(17) AES Internal Transaction Number (ITN) or AES Exemption Statement/ Exception Classification (per shipment)
(18) Split air waybill indicator (optional)
(19) Hazmat indicator (Yes/No)
(20) UN Number (conditional) (If the hazmat indicator is yes, the four-digit UN (United Nations) Number assigned to the hazardous material must be provided.)
(21) In-bond number (optional)
(22) Mode of transportation (Air, containerized or Air, non-containerized) (optional)

If, after the conclusion of the ACE Export Manifest for Air Cargo Test, CBP decides to conduct rulemaking to amend the regulations concerning the filing of the air export cargo manifest, CBP will reevaluate the filing conditions for each data element to determine the feasibility of requiring that data element to be filed electronically in ACE within a specified time before the cargo is loaded on the aircraft.

Extension of the Test

To continue further evaluation of the ACE Export Manifest for Air Cargo Test, CBP is extending the test for an additional year. The expanded and modified test will run until August 10, 2018.

Applicability of Initial Test Notice

Unless explicitly changed by this or subsequent notices published in the **Federal Register**, all other aspects of the initial test announced in the July 10, 2015 notice, including test procedures and conditions, the application process, and the waiver of certain regulatory requirements, remain in effect.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. 3507), an agency may not conduct, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by the Office of Management and Budget (OMB). The collections of information in this NCAP test have been approved by OMB in accordance with the requirements of the Paperwork Reduction Act and assigned OMB control number 1651–0001.

Dated: August 8, 2017.

Todd C. Owen,

Executive Assistant Commissioner, Office of Field Operations.

[FR Doc. 2017–17080 Filed 8–11–17; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Automated Commercial Environment (ACE) Export Manifest for Vessel Cargo Test: Expansion of Test To Include Additional Participants, Modification of Required Data Elements, and Extension of Test

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

ACTION: General notice.

SUMMARY: This notice announces that CBP is modifying the U.S. Customs and Border Protection's (CBP's) Automated Commercial Environment (ACE) Export Manifest for Vessel Cargo Test, a National Customs Automation Program (NCAP) test concerning ACE export manifest capability, by making certain of the export manifest data elements optional. CBP is also extending the test and will be accepting additional applications for participation in this modified test from all parties meeting the eligibility requirements.

DATES: The modifications of the ACE Export Manifest for Vessel Cargo Test set forth in this document are effective August 14, 2017. The modified test will run until September 21, 2018. Applications from additional participants may be submitted at any time. Current test participants do not need to reapply. Comments concerning this notice and all aspects of the test may be submitted at any time during the test period to the email address below.

ADDRESSES: Applications to participate in the ACE Export Manifest for Vessel Cargo Test must be submitted via email to CBP Export Manifest at *cbpvesselexportmanifest@cbp.dhs.gov.* In the subject line of the email, please use ''ACE Export Manifest for Vessel Cargo Test Application''. Written comments concerning program, policy, and technical issues may also be submitted via email to CBP Export Manifest at *cbpvesselexportmanifest@cbp.dhs.gov.* In the subject line of the email, please use ''Comment on ACE Export Manifest for Vessel Cargo Test''.

FOR FURTHER INFORMATION CONTACT: Robert C. Rawls, Outbound Enforcement and Policy Branch, Office of Field Operations, U.S. Customs and Border Protection, via email at *cbpvesselexportmanifest@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

The ACE Export Manifest for Vessel Cargo Test is a voluntary test in which participants agree to submit export manifest data to CBP electronically, at least 24 hours prior to loading of the cargo onto the vessel in preparation for departure from the United States. The ACE Export Manifest for Vessel Cargo Test is authorized under § 101.9(b) of title 19 of the Code of Federal Regulations (19 CFR 101.9(b)), which provides for the testing of NCAP programs or procedures. *See* Treasury Decision (T.D.) 95–21.

CBP announced the procedures and criteria related to participation in the ACE Export Manifest for Vessel Cargo Test in a notice published in the **Federal Register** on August 20, 2015 (80 FR 50644). On October 20, 2015, CBP issued a notice published in the **Federal Register** (80 FR 63575) correcting an error in the initial notice that misstated the technical capability requirements for submitting data to CBP. This test was originally set to run for approximately two years. For further details on the background and procedures regarding the test, please refer to the August 20, 2015 notice.

Expansion of Test to Additional Participants

In the August 20, 2015 notice announcing the initial phase of the ACE Export Manifest for Vessel Cargo Test, CBP stated that participation in the test was limited to nine stakeholders composed of a mix of a certain number of vessel carriers and freight forwarders or non-vessel operating common carriers (NVOCCs) who met the eligibility requirements. This notice announces that the ACE Export Manifest for Vessel Cargo Test is now open to all eligible applicants. CBP will endeavor

to accept all new eligible applicants on a first come first serve basis; however, if the number of eligible applicants exceeds CBP's administrative capabilities, CBP reserves the right to select eligible participants in order to achieve a diverse participant pool.

Eligibility Requirements

Except for the expansion to additional participants, the eligibility requirements for the ACE Export Manifest for Vessel Cargo Test have not changed since the October 20, 2015 correction notice. For clarity and convenience to the public, CBP sets forth below the eligibility requirements for participation in the test.

Participation in the ACE Export Manifest for Vessel Cargo Test is limited to those parties able to electronically transmit manifest data in the identified acceptable format. Prospective ACE Export Manifest for Vessel Cargo Test participants must have the technical capability to electronically submit data to CBP and receive response message sets via Ocean CAMIR, ANSI X12, or Unified XML,[1] and must successfully complete certification testing with their client representative. Once parties have applied to participate, they must complete a test phase to determine if the data transmission is in the required readable format. Applicants will be notified once they have successfully completed testing and are permitted to participate fully in the test. In selecting participants, CBP will take into consideration the order in which the applications are received.

There are no restrictions with regard to the participant's organization size, location, or commodity type for participation in the test.

Modification of the Filing Condition of Certain Data Elements

One of the main purposes of the ACE Export Manifest for Vessel Cargo Test is to test the feasibility of requiring certain manifest information to be filed electronically in ACE at least 24 hours before the cargo is loaded on the vessel. Another purpose is to test the functionality regarding the filing of such export manifest data within the above specified time. Under the current regulatory requirements, the complete manifest is generally not required to be submitted until after the departure of the vessel. *See* 19 CFR 4.75, 4.76 and 4.84. The data and the results of the ACE Export Manifest for Vessel Cargo Test will aid CBP in determining which parties are the best source of the export manifest data and when the data is available to be submitted to CBP.

CBP has been consulting with the Commercial Customs Operations Advisory Committee (COAC) to address ongoing issues concerning the quality, accessibility, and timeliness of export manifest data received during the test. Through this process, the COAC advised CBP that certain data elements currently required under the test may not be available to the party submitting the export manifest data to CBP 24 hours prior to loading of the cargo onto the vessel in preparation for departure from the United States and urged CBP to make those data elements optional.

After evaluating the initial phase of the ACE Export Manifest for Vessel Cargo Test and considering COAC's comments, CBP has determined that, in order to better test the functionality and feasibility of submitting the specified export data at least 24 hours prior to loading of the cargo on the vessel, four of the previously mandatory or conditional data elements should be changed to optional. This will enable participants to submit the optional information when and if it is available. (Data elements which are ''mandatory'' must be provided to CBP for every shipment. Data elements which are ''conditional'' must be provided to CBP only if the particular information pertains to the cargo. Data elements which are ''optional'' may be provided to CBP but are not required.)

CBP is modifying the ACE Export Manifest for Vessel Cargo Test to change the following four mandatory or conditional data elements to optional:

- Name of the Master (Data Element #4)
- Number of House Bills of Lading (Data Element #9)
- Split Shipment Indicator (Data Element #22)
- Portion of Split Shipments (Data Element #23)

The remaining data elements under the ACE Export Manifest for Vessel Cargo Test continue to be mandatory, conditional, or optional as provided in the August 20, 2015 notice. The full list of data elements is set forth below. Unless otherwise noted, the data elements are mandatory.

(1) Mode of transportation (Vessel, containerized or Vessel, non-containerized)
(2) Name of ship or vessel
(3) Nationality of ship
(4) Name of Master (optional)
(5) Port of loading
(6) Port of discharge
(7) Bill of Lading number (Master and House)
(8) Bill of Lading type (Master, House, Simple or Sub)
(9) Number of House Bills of Lading (optional)
(10) Marks and Numbers (conditional)
(11) Container Numbers (conditional)
(12) Seal Numbers (conditional)
(13) Number and kind of packages
(14) Description of goods
(15) Gross Weight (lb. or kg.) or Measurements (per HTSUS)
(16) Shipper name and address
(17) Consignee name and address
(18) Notify Party name and address (conditional)
(19) Country of Ultimate Destination
(20) In-bond number (conditional)
(21) Internal Transaction Number (ITN) or AES Exemption Statement (per shipment)
(22) Split Shipment Indicator (Yes/No) (optional)
(23) Portion of split shipment (*e.g.,* 1 of 10, 4 of 10, 5 of 10—Final, etc.) (optional)
(24) Hazmat Indicator (Yes/No)
(25) UN Number (conditional) (If the hazmat indicator is yes, then UN (for United Nations Number) or NA (North American Number) and the corresponding 4-digit identification number assigned to the hazardous material must be provided.)
(26) Chemical Abstract Service (CAS) Registry Number (conditional)
(27) Vehicle Identification Number (VIN) or Product Identification Number (conditional) (For shipments of used vehicles, the VIN must be reported, or for used vehicles that do not have a VIN, the Product Identification Number must be reported.)

If, after the conclusion of the ACE Export Manifest for Vessel Cargo Test, CBP decides to conduct rulemaking to amend the regulations concerning the filing of the vessel export cargo manifest, CBP will reevaluate the filing conditions for each data element to determine the feasibility of requiring that data element to be filed electronically in ACE within the specified time before the cargo is loaded on the vessel.

Extension of the Test

To continue further evaluation of the ACE Export Manifest for Vessel Cargo Test, CBP is extending the test for an additional year. The expanded and modified test will run until September 21, 2018.

Applicability of Initial Test Notice

Unless explicitly changed by this or subsequent notices published in the **Federal Register**, all other aspects of the initial test announced in the August 20,

[1] Unified XML was not yet functional at the time of the original Automated Commercial Environment (ACE) Export Manifest for Vessel Cargo Test. It is now fully functional and available for use.

2015 notice (and corrected in the October 20, 2015 notice), including test procedures and conditions, the application process, and the waiver of certain regulatory requirements, remain in effect.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. 3507), an agency may not conduct, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by the Office of Management and Budget (OMB). The collections of information in this NCAP test have been approved by OMB in accordance with the requirements of the Paperwork Reduction Act and assigned OMB control number 1651–0001.

Dated: August 8, 2017.

Todd C. Owen,

Executive Assistant Commissioner, Office of Field Operations.

[FR Doc. 2017–17079 Filed 8–11–17; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[CBP Dec. No. 17–09]

Expansion of Global Entry Eligibility to Citizens of the Republic of Colombia, Citizens of the Republic of Singapore, and Citizens of Switzerland

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

ACTION: General notice.

SUMMARY: U.S. Customs and Border Protection (CBP) operates the Global Entry international trusted traveler program at most major U.S. airports. Global Entry allows pre-approved participants dedicated CBP processing into the United States using Global Entry kiosks located at designated airports. This document announces that CBP is expanding eligibility for Global Entry to include citizens of the Republic of Colombia, citizens of the Republic of Singapore, and citizens of Switzerland. All of these individuals also must satisfy the requirements to participate in the Global Entry program. Additionally, this document announces that U.S. citizens who participate in Global Entry will have the option to apply for membership in Singapore's enhanced-Immigration Automated Clearance System (e-IACS).

DATES: Applications will be accepted from qualified citizens of the Republic of Colombia, qualified citizens of the Republic of Singapore, and qualified citizens of Switzerland beginning on August 14, 2017.

FOR FURTHER INFORMATION CONTACT: Garret Conover, Office of Field Operations, (202) 325–4062, *Garret.A.Conover@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

Global Entry Program

Global Entry is a voluntary program that provides pre-approved travelers arriving in the United States dedicated CBP processing at Global Entry kiosks located at designated airports. In a final rule published in the **Federal Register** (77 FR 5681) on February 6, 2012, CBP promulgated the regulation (8 CFR 235.12) to establish Global Entry as an ongoing voluntary regulatory program. Section 235.12 contains a description of the program, the eligibility criteria, the application and enrollment process, and the redress procedures. Travelers who wish to participate in Global Entry must apply via the Global On-Line Enrollment System (GOES) Web site, *https://goes-app.cbp.dhs.gov,* and pay the applicable fee. Applications for Global Entry must be completed and submitted electronically. The list of airports with Global Entry kiosks is available at *http://www.globalentry.gov.*

Eligibility for participation in Global Entry is limited to U.S. citizens, U.S. nationals, U.S. lawful permanent residents, and certain nonimmigrant aliens from countries that have entered into arrangements with CBP regarding international trusted traveler programs. Specifically, certain nonimmigrant aliens from countries that have entered into arrangements with CBP concerning international trusted traveler programs may be eligible to apply for participation in Global Entry. CBP announces the arrangement by publication of a notice in the **Federal Register.** The notice includes the country, the scope of eligibility of nonimmigrant aliens from that country (*e.g.,* whether only citizens of the foreign country or citizens and noncitizens are eligible) and other conditions that may apply based on the terms of the arrangement. *See* 8 CFR 235.12(b)(1)(ii). Since establishing the Global Entry program, CBP has announced several expansions of the program.[1]

CBP may deny applicants enrollment in the Global Entry program for various reasons. An individual who is inadmissible to the United States under U.S. immigration law or has, at any time, been granted a waiver of inadmissibility or parole is ineligible to participate in Global Entry. CBP will automatically reject applications from such individuals. CBP also may reject an application for Global Entry if an applicant has ever been arrested for, or convicted of, a criminal offense, or if the individual has ever been found in violation of customs or immigration laws, or of any criminal law. Additionally, CBP will not accept an applicant for participation in Global Entry if CBP determines that the applicant presents a potential risk of terrorism, or criminality (including smuggling), or if CBP cannot sufficiently determine that the applicant meets all the program eligibility criteria. The eligibility criteria are set forth in more detail in the Global Entry final rule and 8 CFR 235.12. *See also http://www.globalentry.gov.*

The Republic of Colombia

On April 27, 2015, the U.S. Department of Homeland Security, CBP and the Ministry of Foreign Affairs of the Republic of Colombia signed a Joint Statement regarding the development of an initiative involving their respective international trusted traveler programs. In the Joint Statement, the parties agreed to cooperate in the expansion of Global Entry to certain eligible citizens of Colombia and to mutually develop procedures for the implementation and operation of the expansion. Based on this Joint Statement, CBP is announcing that citizens of the Republic of Colombia are eligible to apply for participation in Global Entry.

In order to apply for Global Entry, citizens of the Republic of Colombia must first complete the on-line application located on the GOES Web site, pay the nonrefundable Global Entry fee, and satisfy all the requirements of Global Entry. These applicants will then undergo a thorough risk assessment by both CBP and the Republic of Colombia's Ministry of Foreign Affairs and an interview with CBP. The vetting criteria were mutually developed and

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[1] For further information see 75 FR 82202, December 29, 2010 (utilization of Global Entry kiosks by NEXUS and SENTRI participants); 78 FR 48706, August 9, 2013 (expansion to certain citizens of the Republic of Korea and expansion through limited pilots to a number of citizens from the United Kingdom, the State of Qatar and Germany); 80 FR 1509, January 12, 2015 (expansion to certain citizens of Panama); 81 FR 7822, February 16, 2016 (expansion to all German citizens); and, 81 FR 45170, July 12, 2016 (expansion to all citizens of the United Kingdom).

are consistent with each agency's applicable domestic laws and policies.

Once the risk assessment has been completed, CBP will notify the applicant of the results and next steps necessary to complete the enrollment. More information on how to apply is available at *www.globalentry.gov.*

U.S. Citizens' Participation in Colombia's Trusted Traveler Program

Consistent with the Joint Statement, U.S. citizens who participate in Global Entry will have the option to apply for participation in Colombia's trusted traveler program, once such program is established. Once the program is established, CBP plans to announce it on CBP's Web site at *http://www.globalentry.gov.*

The Republic of Singapore

On December 1, 2014, the U.S. Department of Homeland Security, CBP and the Ministry of Home Affairs for the Republic of Singapore, Immigration & Checkpoints Authority signed a Joint Statement regarding the development of an initiative involving their respective international trusted traveler programs. In the Joint Statement, the parties agreed to cooperate in the expansion of their respective trusted traveler programs to eligible citizens of Signapore and the United States and to mutually develop procedures for the implementation and operation of the expansions. Based on this Joint Statement, CBP is announcing that citizens of the Republic of Singapore are eligible to apply for participation in Global Entry.

In order to apply for Global Entry, citizens of the Republic of Singapore must first complete the on-line application located on the GOES Web site, pay the nonrefundable Global Entry fee, and satisfy all the requirements of Global Entry. These applicants will then undergo a thorough risk assessment by both CBP and the Republic of Singapore's Immigration & Checkpoints Authority and an interview with CBP. The vetting criteria were mutually developed and are consistent with each agency's applicable domestic laws and policies.

Once the risk assessment has been completed, CBP will notify the applicant of the results and next steps necessary to complete the enrollment. More information on how to apply is available at *www.globalentry.gov.*

U.S. Citizens' Participation in Singapore's Enhanced-Immigration Automated Clearance System (e-IACS)

Pursuant to the Joint Statement, U.S. citizens who are Global Entry participants will have the option to apply for Singapore's enhanced-Immigration Automated Clearance System (e-IACS). e-IACS is a trusted traveler program in Singapore that uses automated kiosks to offer expedited processing for travelers through clearance formalities when entering the Republic of Singapore. All U.S. applicants must apply for e-IACS directly with the Government of Singapore, be thoroughly vetted by the Republic of Singapore, meet specific passport and travel qualifications, and appear in person at an e-IACS enrollment center to complete the enrollment process. There is no fee for participation in e-IACS. The Republic of Singapore will notify the U.S. applicant directly about whether he or she was approved for e-IACS. More information about how to apply for e-IACS is available at *https://ltpass.ica.gov.sg/ttp/.*

Switzerland

On December 16, 2015, the U.S. Department of Homeland Security, CBP and the Federal Department of Justice and Police of the Swiss Confederation signed a Joint Statement regarding the development of an initiative involving their respective international trusted traveler programs. In the Joint Statement, the parties agreed to cooperate in the expansion of Global Entry to certain eligible citizens of Switzerland and to mutually develop procedures for the implementation and operation of the expansion. Based on this Joint Statement, CBP is announcing that citizens of Switzerland are eligible to apply for participation in Global Entry.

In order to apply for Global Entry, citizens of Switzerland must first obtain clearance from the Swiss Federal Office of Police. CBP will not process applications from citizens of Switzerland unless such clearance has been obtained. To apply for clearance, an applicant must submit an application and pay a nonrefundable fee to the Swiss Federal Office of Police. The Swiss Federal Office of Police will notify the applicants whether clearance has been granted.

After the applicant has obtained the necessary clearance, the applicant must complete the Global Entry on-line application located on the GOES Web site, pay the nonrefundable Global Entry fee, and satisfy all the requirements of Global Entry. These applicants will then undergo a thorough risk assessment by both CBP and the Federal Department of Justice and Police of the Swiss Confederation and an interview with CBP. The vetting criteria were mutually developed and are consistent with each agency's applicable domestic laws and policies.

After the risk assessment has been completed, CBP will notify the applicant of the results and next steps necessary to complete the enrollment. More information on how to apply is available at *www.globalentry.gov.*

U.S. Citizens' Participation in Switzerland's Trusted Traveler Program

Consistent with the Joint Statement, U.S. citizens who participate in Global Entry will have the option to apply for participation in Switzerland's trusted traveler program, once such program is established. Once the program is established, CBP plans to announce it on CBP's Web site at *http://www.globalentry.gov.*

Dated: August 8, 2017.

Todd C. Owen,

Executive Assistant Commissioner, Office of Field Operations.

[FR Doc. 2017–17077 Filed 8–11–17; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Automated Commercial Environment (ACE) Export Manifest for Rail Cargo Test: Expansion of Test To Include Additional Participants, Modification of Required Data Elements, and Extension of Test

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

ACTION: General notice.

SUMMARY: This notice announces that CBP is modifying the U.S. Customs and Border Protection's (CBP's) Automated Commercial Environment (ACE) Export Manifest for Rail Cargo Test, a National Customs Automation Program (NCAP) test concerning ACE export manifest capability by changing the reporting requirements for certain data elements. CBP is also extending the test and will be accepting additional applications for participation in this modified test from all parties meeting the eligibility requirements.

DATES: The modifications of the ACE Export Manifest for Rail Cargo Test set forth in this document are effective August 14, 2017. The modified test will run until October 9, 2018. Applications from additional participants may be submitted at any time. Current test participants do not need to reapply. Comments concerning this notice and all aspects of the test may be submitted

at any time during the test period to the email address below.

ADDRESSES: Applications to participate in the ACE Export Manifest for Rail Cargo Test must be submitted via email to CBP Export Manifest at *cbprailexportmanifest@cbp.dhs.gov.* In the subject line of the email, please use ''ACE Export Manifest for Rail Cargo Test Application''. Written comments concerning program, policy, and technical issues may also be submitted via email to CBP Export Manifest at *cbprailexportmanifest@cbp.dhs.gov.* In the subject line of the email, please use ''Comment on ACE Export Manifest for Rail Cargo Test''.

FOR FURTHER INFORMATION CONTACT: Robert C. Rawls, Outbound Enforcement and Policy Branch, Office of Field Operations, U.S. Customs and Border Protection, via email at *cbprailexportmanifest@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

The ACE Export Manifest for Rail Cargo Test is a voluntary test in which participants agree to submit export manifest data to CBP electronically, at least 2 hours prior to loading of the cargo onto the train in preparation for departure from the United States or, for empty rail cars, upon assembly of the train. The ACE Export Manifest for Rail Cargo Test is authorized under § 101.9(b) of title 19 of the Code of Federal Regulations (19 CFR 101.9(b)), which provides for the testing of NCAP programs or procedures. *See* Treasury Decision (T.D.) 95–21.

CBP announced the procedures and criteria related to participation in the ACE Export Manifest for Rail Cargo Test in a notice published in the **Federal Register** on September 9, 2015 (80 FR 54305). This test was originally set to run for approximately two years. For further details on the background and procedures regarding the test, please refer to the September 9, 2015 notice.

Expansion of Test to Additional Participants

In the September 9, 2015 notice announcing the initial phase of the ACE Export Manifest for Rail Cargo Test, CBP stated that participation in the test was limited to nine stakeholders composed of rail carriers who met the eligibility requirements. This notice announces that the ACE Export Manifest for Rail Cargo Test is now open to all eligible applicants. CBP will endeavor to accept all new eligible applicants on a first come first serve basis. If the number of eligible applicants exceeds CBP's administrative capabilities, CBP reserves the right to select eligible participants in order to achieve a diverse participant pool.

Eligibility Requirements

Except for the expansion to additional participants, the eligibility requirements for the ACE Export Manifest for Rail Cargo Test have not changed since the September 9, 2015 notice. For clarity and convenience to the public, CBP sets forth below the eligibility requirements for participation in the test.

Participation in the ACE Export Manifest for Rail Cargo Test is limited to those parties able to electronically transmit manifest data in the identified acceptable format. Prospective ACE Export Manifest for Rail Cargo Test participants must have the technical capability to electronically submit data to CBP and receive response message sets via Cargo-ANSI X12 (also known as ''Rail X12'') or Unified XML, [1] and must successfully complete certification testing with their client representative. Once parties have applied to participate, they must complete a test phase to determine if the data transmission is in the required readable format. Applicants will be notified once they have successfully completed testing and are permitted to participate fully in the test. In selecting participants, CBP will take into consideration the order in which the applications are received.

There are no restrictions with regard to the participant's organization size, location, or commodity type for participation in the test.

Modification of the Filing Condition of Certain Data Elements

One of the main purposes of the ACE Export Manifest for Rail Cargo Test is to test the feasibility of requiring rail carriers to file export manifest data to CBP. Another purpose is to test the functionality regarding the filing of export manifest data for rail cargo electronically to ACE within a specified time before the cargo is loaded on the train. Under the current regulatory requirements, the rail carrier is not required to submit a paper or electronic manifest for cargo exported from the United States by rail. The U.S. Principal Party in Interest (USPPI) is required to transmit and verify system acceptance of certain advance information to CBP for export cargo leaving the United States by rail *See* 19 CFR 192.14. For further details about current requirements, please refer to the September 9, 2015 notice. The data and the results of the ACE Export Manifest for Rail Cargo Test will aid CBP in determining which parties are the best source of the export manifest data and when the data is available to be submitted to CBP.

CBP has been consulting with the Commercial Customs Operations Advisory Committee (COAC) to address ongoing issues concerning the quality, accessibility, and timeliness of export manifest data received during the test. One issue of concern to COAC is the availability of certain data elements currently required under the test 2 hours prior to loading of the cargo on the train in preparation for departure from the United States. COAC urged CBP to change the filing condition of those data elements.

After evaluating the initial phase of the ACE Export Manifest for Rail Cargo Test and considering COAC's comments, CBP has determined that, in order to better test the functionality and feasibility of submitting the specified export data 2 hours prior to loading of the cargo on the train, the filing condition for nine of the data elements should be changed. The modified filing conditions will enable CBP to better determine the appropriate reporting requirements for each data element. (Data elements which are ''mandatory'' must be provided to CBP for every shipment. Data elements which are ''conditional'' must be provided to CBP only if the particular information pertains to the cargo. Data elements which are ''optional'' may be provided to CBP but are not required.)

CBP is modifying the ACE Export Manifest for Rail Cargo Test to change the following eight mandatory or conditional data elements to optional:

- Mode of Transportation (Rail, containerized or Rail, non-containerized) (Data Element #1)
- Place where the carrier took possession (Data Element #14)
- Country of Ultimate Destination (Data Element #16)
- Equipment Type Code (Data Element #17)
- Number of House Bills of Lading (Data Element #22)
- Split Shipment Indicator (Data Element #29)
- Portion of Split Shipment (Data Element #30)
- Mexican Pedimento Number (Data Element #32)

CBP is modifying the ACE Export Manifest for Rail Cargo Test to change the following data element from mandatory to conditional:

- Marks and Numbers (Data Element #10)

[1] Unified XML was not yet functional at the time of the original Automated Commercial Environment (ACE) Export Manifest for Rail Cargo Test. It is now fully functional and available for use.

The remaining data elements under the ACE Export Manifest for Rail Cargo Test continue to be mandatory, conditional, or optional as provided in the September 9, 2015 notice. The full list of data elements for all shipments, including empty rail cars, is set forth below. Unless otherwise noted, the data elements are mandatory.

(1) Mode of Transportation (Rail, containerized or Rail, non-containerized) (optional)
(2) Port of Departure from the United States
(3) Date of Departure
(4) Manifest Number
(5) Train Number
(6) Rail Car Order
(7) Car Locator Message
(8) Hazmat Indicator (Yes/No)
(9) 6-character Hazmat Code (conditional) (If the hazmat indicator is yes, then UN (for United Nations Number) or NA (North American Number) and the corresponding 4-digit identification number assigned to the hazardous material must be provided.)
(10) Marks and Numbers (conditional)
(11) SCAC (Standard Carrier Alpha Code) for exporting carrier
(12) Shipper name and address (For empty rail cars, the shipper may be the railroad from whom the rail carrier received the empty rail car to transport.)
(13) Consignee name and address (For empty rail cars, the consignee may be the railroad to whom the rail carrier is transporting the empty rail car.)
(14) Place where the rail carrier takes possession of the cargo shipment or empty rail car (optional)
(15) Port of Unlading
(16) Country of Ultimate Destination (optional)
(17) Equipment Type Code (optional)
(18) Container Number(s) (for containerized shipments) or Rail Car Number(s) (for all other shipments)
(19) Empty Indicator (Yes/No)

If the empty indicator is no, then the following data elements must also be provided, unless otherwise noted:

(20) Bill of Lading Numbers (Master and House)
(21) Bill of Lading type (Master, House, Simple or Sub)
(22) Number of house bills of lading (optional)
(23) Notify Party name and address (conditional)
(24) AES Internal Transaction Number or AES Exemption Statement (per shipment)
(25) Cargo Description
(26) Weight of Cargo (may be expressed in either pounds or kilograms)
(27) Quantity of Cargo and Unit of Measure
(28) Seal Number (only required if the container was sealed)
(29) Split Shipment Indicator (Yes/No) (optional)
(30) Portion of split shipment (*e.g.* 1 of 10, 4 of 10, 5 of 10—Final. etc.) (optional)
(31) In-bond number (conditional)
(32) Mexican Pedimento Number (only for shipments for export to Mexico) (optional)

If, after the conclusion of the ACE Export Manifest for Rail Cargo Test, CBP decides to conduct rulemaking to amend the regulations concerning the filing of the manifest for rail cargo, CBP will reevaluate the filing conditions for each data element to determine the feasibility of requiring that data element to be filed electronically in ACE within a specified time before the cargo is loaded on the train.

Extension of the Test

To continue further evaluation of the ACE Export Manifest for Rail Cargo Test, CBP is extending the test for an additional year. The expanded and modified test will run until October 9, 2018.

Applicability of Initial Test Notice

Unless explicitly changed by this or subsequent notices published in the **Federal Register**, all other aspects of the initial test announced in the September 9, 2015 notice, including test procedures and conditions, the application process, and the waiver of certain regulatory requirements, remain in effect.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. 3507), an agency may not conduct, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by the Office of Management and Budget (OMB). The collections of information in this NCAP test have been approved by OMB in accordance with the requirements of the Paperwork Reduction Act and assigned OMB control number 1651–0001.

Dated: August 8, 2017.

Todd C. Owen,

Executive Assistant Commissioner, Office of Field Operations.

[FR Doc. 2017–17076 Filed 8–11–17; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–R–2017–N118; FXGO1664091HCC0–FF09D00000–178]

Wildlife and Hunting Heritage Conservation Council; Public Teleconference

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of teleconference.

SUMMARY: We, the U.S. Fish and Wildlife Service, announce a public teleconference of the Wildlife and Hunting Heritage Conservation Council (Council). The Council provides advice about wildlife and habitat conservation endeavors that benefit wildlife resources; encourage partnership among the public, sporting conservation organizations, states, Native American tribes, and the Federal Government; and benefit recreational hunting.

DATES: *Meeting:* Wednesday August 30, 2017, from 9 a.m. to 5 p.m. (Eastern Daylight Time). For deadlines and directions on registering to participate, submitting written material, and giving an oral presentation, please see Public Input under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Joshua Winchell, Council Designated Federal Officer, by U.S. mail at the U.S. Fish and Wildlife Service, National Wildlife Refuge System, 5275 Leesburg Pike, Falls Church, VA 22041–3803; by telephone at (703) 358–2639; or by email at *joshua_winchell@fws.gov.*

SUPPLEMENTARY INFORMATION: In accordance with the requirements of the Federal Advisory Committee Act, 5 U.S.C. Appendix 2, we announce that the Wildlife and Hunting Heritage Conservation Council (Council) will hold a teleconference.

Background

Formed in February 2010, the Council provides advice about wildlife and habitat conservation endeavors that:

1. Benefit wildlife resources;
2. Encourage partnership among the public, sporting conservation organizations, states, Native American tribes, and the Federal Government; and
3. Benefit recreational hunting.

The Council advises the Secretary of the Interior and the Secretary of Agriculture, reporting through the Director, U.S. Fish and Wildlife Service (Service), in consultation with the Director, Bureau of Land Management (BLM); Director, National Park Service (NPS); Chief, Forest Service (USFS);

Chief, Natural Resources Conservation Service (NRCS); and Administrator, Farm Services Agency (FSA). The Council's duties are strictly advisory and consist of, but are not limited to, providing recommendations for:

1. Implementing the Recreational Hunting and Wildlife Resource Conservation Plan;
2. Increasing public awareness of and support for the Wildlife Restoration Program;
3. Fostering wildlife and habitat conservation and ethics in hunting and shooting sports recreation;
4. Stimulating sportsmen and women's participation in conservation and management of wildlife and habitat resources through outreach and education;
5. Fostering communication and coordination among state, tribal, and Federal governments; industry; hunting and shooting sportsmen and women; wildlife and habitat conservation and management organizations; and the public;
6. Providing appropriate access to Federal lands for recreational shooting and hunting;
7. Providing recommendations to improve implementation of Federal conservation programs that benefit wildlife, hunting, and outdoor recreation on private lands; and
8. When requested by the Designated Federal Officer in consultation with the Council Chairperson, performing a variety of assessments or reviews of policies, programs, and efforts through the Council's designated subcommittees or workgroups.

Background information on the Council is available at *http://www.fws.gov/whhcc.*

Meeting Agenda

The Council will convene to consider issues including:

1. Implementing Department of the Interior Secretarial Order 3347—Conservation Stewardship and Outdoor Recreation;
2. Status of the Recreation Hunting and Wildlife Conservation Plan, as directed by Executive Order 13443; and
3. Other Council business.

The final agenda will be posted on the internet at *http://www.fws.gov/whhcc.*

Public Input

If you wish to:	You must contact the Council Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**) no later than:
Listen to the Teleconference	August 17, 2017.
Submit written information or questions before the teleconference for the Council to consider during the meeting.	August 17, 2017.
Give an oral presentation during the teleconference	August 17, 2017.

Submitting Written Information or Questions

Interested members of the public may submit relevant information or questions for the Council to consider during the public teleconference. Written statements must be received by the date in Public Input so that the information may be made available to the Council for consideration prior to this meeting. Written statements must be supplied to the Council Designated Federal Officer in both of the following formats: One hard copy with original signature, and one electronic copy via email (acceptable file formats are Adobe Acrobat PDF, MS Word, MS PowerPoint, or rich text file).

Giving an Oral Presentation

Individuals or groups who want to make an oral presentation during the teleconference will be limited to 2 minutes per speaker, with no more than a total of 30 minutes for all speakers. Interested parties should contact the Council Designated Federal Officer, in writing (preferably via email; see **FOR FURTHER INFORMATION CONTACT**), to be placed on the public speaker list for this teleconference. Nonregistered public speakers cannot be accommodated during the teleconference. Registered speakers who wish to expand upon their oral statements, or those who had wished to speak but could not be accommodated on the agenda, may submit written statements to the Council Designated Federal Officer up to 30 days subsequent to the teleconference.

Meeting Minutes

Summary minutes of the teleconference will be maintained by the Council Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). They will be available for public inspection within 90 days of the teleconference, and will be posted on the Council's Web site at *http://www.fws.gov/whhcc.*

Public Disclosure of Comments: Before including your address, phone number, email address, or other personal identifying information in your comment, please be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 5 U.S.C. Appendix 2.

Joshua Winchell,

Designated Federal Officer, U.S. Fish and Wildlife Service.

[FR Doc. 2017–16841 Filed 8–11–17; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R1–ES–2017–N097; FXES11140100000–178–FF01E00000]

Proposed Low-Effect Habitat Conservation Plan for the Olympia Subspecies of the Mazama Pocket Gopher, Thurston County, Washington

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), received an application from Mr. Steven McLain (applicant) for an Incidental Take Permit (ITP) pursuant to the Endangered Species Act of 1973, as amended (ESA). The applicant requests an ITP that would authorize ''take'' of the threatened Olympia subspecies of the Mazama pocket gopher incidental to otherwise lawful construction of a single-family home in Thurston County, Washington. The application includes a draft Habitat Conservation Plan (HCP) with measures to minimize and mitigate the impacts of the taking on the covered species. We have also prepared a draft Environmental Action Statement (EAS) for our preliminary determination that the HCP and permit decision may be eligible for categorical exclusion under the National Environmental Policy Act

(NEPA). We invite comments from all interested parties regarding the permit application, draft HCP, and the draft EAS.

DATES: To ensure consideration, please submit written comments by September 13, 2017.

ADDRESSES: You may view or download copies of the draft HCP and obtain additional information on the Internet at *http://www.fws.gov/wafwo/.* To request further information or submit written comments, please use one of the following methods, and note that your information request or comments are in reference to ''The McLain HCP'':

- *Electronic: wfwocomments@fws.gov.*
- *U.S. Mail:* Public Comments Processing, Attn: FWS–R1–ES–2017–N097; U.S. Fish and Wildlife Service; Washington Fish and Wildlife Office, 510 Desmond Drive SE., Suite 102; Lacey, Washington 98503.
- *In-Person Drop-off, Viewing, or Pickup:* Call 360–753–5823 to make an appointment (necessary for viewing or picking up documents only) during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Tim Romanski, Conservation Planning and Hydropower Branch Manager, Washington Fish and Wildlife Office, U.S. Fish and Wildlife Service (see **ADDRESSES**), telephone: 360–753–5823. If you use a telecommunications device for the deaf, please call the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Background

Section 9 of the ESA prohibits ''take'' of fish and wildlife species listed as endangered or threatened. Under the ESA, the term ''take'' means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct (16 U.S.C. 1532(19)). The term ''harm,'' as defined in our regulations, includes significant habitat modification or degradation that results in death or injury to listed species by significantly impairing essential behavioral patterns, including breeding, feeding, or sheltering (50 CFR 17.3). The term ''harass'' is defined in our regulations as to carry out actions that create the likelihood of injury to listed species to such an extent as to significantly disrupt normal behavioral patterns, which include, but are not limited to, breeding, feeding, or sheltering (50 CFR 17.3).

Section 10(a)(1)(B) of the ESA contains provisions that authorize the Service to issue permits to non-federal entities for the take of endangered and threatened species caused by otherwise lawful activities, provided the following criteria are met: (1) The taking will be incidental; (2) the applicant will, to the maximum extent practicable, minimize and mitigate the impact of such taking; (3) the applicant will ensure that adequate funding for the plan will be provided; (4) the taking will not appreciably reduce the likelihood of the survival and recovery of the species in the wild; and (5) the applicant will carry out any other measures that the Service may require as being necessary or appropriate for the purposes of the plan. Regulations governing permits for endangered and threatened species are found in 50 CFR 17.22 and 17.32, respectively.

We received an application from the applicant for an ITP pursuant to Section 10(a)(1)(B) of the ESA. The applicant requests an ITP having a 2-year term that would authorize ''take'' of the threatened Olympia subspecies of the Mazama pocket gopher (*Thomomys mazama pugetensis*), hereafter referred to as Olympia pocket gopher, incidental to otherwise lawful construction of one single-family home on land he owns in Thurston County, Washington. The application includes a draft HCP that describes actions the applicant will take to minimize and mitigate the impacts of the taking on covered species.

Proposed Action

The Service proposes to issue the requested 2-year ITP based on the applicant's commitment to implement the draft HCP, if permit issuance criteria are met. Covered activities include construction of the single-family home. The area covered under the draft HCP consists of an approximately one-half acre project development site and an approximately one acre conservation site on land owned by the applicant. Take of the Olympia pocket gopher would occur within the half-acre development site and will be offset by permanently managing an acre of occupied habitat for the covered species on the applicant's land until and unless the take impacts are offset by purchasing equivalent credits from a Service-approved conservation bank for the Olympia pocket gopher.

National Environmental Policy Act Compliance

The proposed issuance of an ITP is a Federal action that triggers the need for compliance with NEPA (42 U.S.C. 4321 *et seq.*). Pursuant to NEPA, we prepared an Environmental Action Statement (EAS) to analyze the environmental impacts of the proposed Federal action of issuing the requested ITP and implementation of the conservation program under the proposed HCP.

Based on the EAS, we have preliminarily determined that the applicant's proposal, including the proposed mitigation measures, would have minor or negligible effects on the species covered in the HCP. Therefore, we determined that the proposed HCP is eligible for ''low-effect'' status and qualifies for categorical exclusion under NEPA, as provided by the Department of the Interior NEPA regulations (43 CFR part 46). A low-effect HCP is one involving (1) minor or negligible effects on federally listed or candidate species and their habitat, and (2) minor or negligible effects on other environmental values or resources.

Public Comments

You may submit your comments and materials by one of the methods listed in the **ADDRESSES** section. We specifically request information, views, and suggestions from interested parties regarding our proposed Federal action, including adequacy of the draft HCP pursuant to the requirements for permits at 50 CFR parts 13 and 17 and adequacy of the EAS pursuant to NEPA.

Public Availability of Comments

All comments and materials we receive become part of the public record associated with this action. Before including your address, phone number, email address, or other personally identifiable information in your comments, you should be aware that your entire comment—including your personally identifiable information—may be made publicly available at any time. While you can ask us in your comment to withhold your personally identifiable information from public review, we cannot guarantee that we will be able to do so. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety. Comments and materials we receive will be available for public inspection by appointment, during normal business hours, at our Washington Fish and Wildlife Office (see **ADDRESSES**).

Next Steps

We will evaluate the permit application, the HCP, and any comments received to determine whether the permit application meets the requirements of section 10(a)(1)(B) of the ESA. We will also evaluate whether issuance of the requested permit would comply with section 7 of

the ESA by conducting an intra-Service section 7 consultation on anticipated ITP actions. We will use the results of this consultation, in combination with the above findings, in our final analysis to determine whether to issue the ITP. If we determine that all requirements are met, we will issue an ITP under section 10(a)(1)(B) of the ESA to the applicant for the take of the covered species, incidental to otherwise lawful covered activities. We will make the final permit decision no sooner than 30 days after the date of this notice.

Authority

We provide this notice in accordance with the requirements of section 10 of the ESA and NEPA and their implementing regulations (50 CFR 17.32 and 40 CFR 1506.6, respectively).

Dated: June 20, 2017.

Theresa E. Rabot,

Deputy Regional Director, Pacific Region, U.S. Fish and Wildlife Service, Portland, Oregon.

[FR Doc. 2017–17082 Filed 8–11–17; 8:45 am]

BILLING CODE 4333–15–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1066]

Certain Recombinant Factor IX Products; Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on July 7, 2017, under section 337 of the Tariff Act of 1930, as amended, on behalf of Bioverativ Inc. of Waltham, Massachusetts; Bioverativ Therapeutics Inc. of Waltham, Massachusetts; and Bioverativ U.S. LLC of Waltham, Massachusetts. A supplement to the complaint was filed on July 14, 2017. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain recombinant Factor IX products by reason of infringement of certain claims of U.S. Patent No. 9,670,475 (''the '475 patent''); U.S. Patent No. 9,623,091 (''the '091 patent''); and U.S. Patent No. 9,629,903 (''the '903 patent''). The complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute.

The complainants request that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Room 112, Washington, DC 20436, telephone (202) 205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: Pathenia M. Proctor, The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2017).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on August 8, 2017, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain recombinant Factor IX products by reason of infringement of one or more of claims 1, 2, 4–19, 24, 25, 29, and 34 of the '475 patent; claims 1–7, 11–16, 18, 19, 21, and 23–27 of the '091 patent; and claims 1–10, 13–15, and 17–28 of the '903 patent; and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to Commission Rule 210.50(b)(1), 19 CFR 210.50(b)(1), the presiding Administrative Law Judge shall take evidence or other information and hear arguments from the parties or other interested persons with respect to the public interest in this investigation, as appropriate, and provide the Commission with findings of fact and a recommended determination on this issue, which shall be limited to the statutory public interest factors set forth in 19 U.S.C. 1337(d)(1), (f)(1), (g)(1);

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are: Bioverativ Inc., 225 Second Avenue, Waltham, MA 02451. Bioverativ Therapeutics Inc., 225 Second Avenue, Waltham, MA 02451. Bioverativ U.S. LLC, 225 Second Avenue, Waltham, MA 02451.

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served: CSL Behring LLC, 1020 First Avenue, King of Prussia, PA 19406. CSL Behring GmbH, Emil-von-Behring-Strasse 76, Marburg, Hessen 35041 Germany. CSL Behring Recombinant Facility AG, Wankdorfstrasse 10, Bern, Bern 3014 Switzerland.

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW., Suite 401, Washington, DC 20436; and

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease

and desist order or both directed against the respondent.

By order of the Commission.

Issued: August 8, 2017.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2017–17058 Filed 8–11–17; 8:45 am]

BILLING CODE P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1065]

Certain Mobile Electronic Devices and Radio Frequency and Processing Components Thereof; Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on July 7, 2017, under section 337 of the Tariff Act of 1930, as amended, on behalf of Qualcomm Incorporated of San Diego, California. A supplement was filed on July 7, 2017. The complaint, as supplemented, alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain mobile electronic devices and radio frequency and processing components thereof by reason of infringement of U.S. Patent No. 8,633,936 (''the '936 patent''); U.S. Patent No. 8,698,558 (''the '558 patent''); U.S. Patent No. 8,487,658 (''the '658 patent''); U.S. Patent No. 8,838,949 (''the '949 patent''); U.S. Patent No. 9,535,490 (''the '490 patent''); and U.S. Patent No. 9,608,675 (''the '675 patent''). The complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute.

The complainant requests that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and a cease and desist order.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Room 112, Washington, DC 20436, telephone (202) 205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: Pathenia M. Proctor, The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2017).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on August 8, 2017, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain mobile electronic devices and radio frequency and processing components thereof by reason of infringement of one or more of claims 1–27, 29, 38, 49, 55–60, 67, and 68 of the '936 patent; claims 1 and 6–20 of the '558 patent; claims 9, 10, 12, 14, and 20–22 of the '658 patent; claims 1–8, 10–14, 16, 20, and 22 of the '949 patent; claims 1–6, 8, 10, 16, 17, and 31 of the '490 patent; and claims 1–3 and 7–14 of the '675 patent; and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to Commission Rule 210.50(b)(1), 19 CFR 210.50(b)(1), the presiding Administrative Law Judge shall take evidence or other information and hear arguments from the parties or other interested persons with respect to the public interest in this investigation, as appropriate, and provide the Commission with findings of fact and a recommended determination on this issue, which shall be limited to the statutory public interest factors set forth in 19 U.S.C. 1337(d)(1), (f)(1), (g)(1);

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is: Qualcomm Incorporated, 5775 Morehouse Drive, San Diego, CA 92121.

(b) The respondent is the following entity alleged to be in violation of section 337, and is the party upon which the complaint is to be served: Apple Inc., 1 Infinite Loop, Cupertino, CA 95014.

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW., Suite 401, Washington, DC 20436; and

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondent in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of the respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: August 8, 2017.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2017–17057 Filed 8–11–17; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. TA–201–75]

Crystalline Silicon Photovoltaic Cells (Whether or Not Partially or Fully Assembled Into Other Products) Determination Not To Close Any Portion of the Commission's Hearing on Injury Issues

AGENCY: United States International Trade Commission.

ACTION: Commission determination not to close any part of the hearing on injury issues in the above-captioned investigation to the public.

SUMMARY: The Commission has determined to deny a request to conduct a portion of its hearing on injury issues scheduled for August 15, 2017 *in camera.*

FOR FURTHER INFORMATION CONTACT: Mary Jane Alves, Office of the General Counsel, U.S. International Trade Commission, telephone 202–708–2969. Hearing-impaired individuals are advised that information on this matter may be obtained by contacting the Commission's TDD terminal on 202–205–1810.

SUPPLEMENTARY INFORMATION: On August 4, 2017, the Solar Energy Industries Association and its member company SunPower Inc. (collectively SEIA) requested in the above-captioned investigation that the Commission conduct *in camera* a portion of its hearing on injury issues scheduled for August 15, 2017. The Commission believes it should conduct its business in public in all but the most unusual circumstances. The Commission has determined that, in light of the nature of this investigation and the ample opportunity given parties to present written arguments, including those relying on confidential information, it will be able to assess adequately all arguments raised by SEIA without resorting to the extraordinary measure of an *in camera* hearing. Accordingly, the Commission has determined that the public interest would be best served by a hearing that is entirely open to the public. *See* 19 CFR 201.36(c)(1).

Authority: This notice is provided pursuant to 19 CFR 201.35(b).

By order of the Commission.

Issued: August 9, 2017.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2017–17081 Filed 8–11–17; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Bureau of Justice Statistics

[OMB Number 1121–0064]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of a Currently Approved Collection: Annual Parole Survey, Annual Probation Survey, and Annual Probation Survey (Short Form)

AGENCY: Bureau of Justice Statistics, Department of Justice.

ACTION: 30-day notice.

SUMMARY: The Department of Justice (DOJ), Office of Justice Programs, Bureau of Justice Statistics, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection was previously published in the **Federal Register** on April 25, 2017, allowing a 60-day comment period. Following publication of the 60-day notice, the Bureau of Justice Statistics received one request for survey instruments and comments from two organizations. These comments will be addressed in the supporting statement.

DATES: Comments are encouraged and will be accepted for an additional 30 days until September 13, 2017.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Danielle Kaeble, Statistician, Bureau of Justice Statistics, 810 Seventh Street NW., Washington, DC 20531 (email: *Danielle.kaeble@usdoj.gov;* telephone: 202–305–2017).

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;
—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of this information collection:

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *The Title of the Form/Collection:* Annual Parole Survey, Annual Probation Survey

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form numbers for the questionnaire are CJ–7 Annual Parole Survey; CJ–8 Annual Probation Survey; CJ–8a Annual Probation Survey (Short Form). The applicable component within the Department of Justice is the Bureau of Justice Statistics, in the Office of Justice Programs.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: state departments of corrections or state probation and parole authorities. Others: The Federal Bureau of Prisons, city and county courts and probation offices for which a central reporting authority does not exist. For the CJ–7 form, the affected public consists of 53 respondents including 51 central reporters (two state respondents in Pennsylvania, and one each from the remaining states), the District of Columbia, and the Federal Bureau of Prisons responsible for keeping records on parolees. For the CJ–8 form, the affected public includes 305 reporters including 35 state respondents, the District of Columbia, the Federal Bureau of Prisons, and 268 from local authorities responsible for keeping records on probationers. For the CJ–8A form, the affected public includes 151 reporters who are all local authorities responsible for keeping records on probationers. The Annual Parole Survey and Annual Probation surveys have been used since 1977 to collect annual yearend counts and yearly movements of community corrections populations; characteristics of the community supervision population, such as gender, racial composition, ethnicity, conviction status, offense, and supervision status.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 506 respondents each taking an average of 1.20 hours to respond.

6. *An estimate of the total public burden (in hours) associated with the collection:* There is an estimated 716 total burden hours associated with this collection.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., 3E.405A, Washington, DC 20530.

Dated: August 9, 2017.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2017–17097 Filed 8–11–17; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF JUSTICE

[OMB Number 1122–NEW]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Approval of a New Collection

AGENCY: Office on Violence Against Women, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice, Office on Violence Against Women (OVW) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until October 13, 2017.

FOR FURTHER INFORMATION CONTACT: Written comments and/or suggestion regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to Cathy Poston, Office on Violence Against Women, at 202–514–5430 or *Catherine.poston@usdoj.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Approval of a new collection.

(2) *Title of the Form/Collection:* Semi-annual progress report for the Grants to Tribal Governments to Exercise Special Domestic Violence Criminal Jurisdiction Program (Tribal Jurisdiction Program).

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: 1122–XXXX. U.S. Department of Justice, Office on Violence Against Women.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* The affected public includes the estimated 20 grantees under the Tribal Jurisdiction Program, a new grant program authorized in the Violence Against Women reauthorization Act of 2013. The Tribal Jurisdiction Program is designed to assist Indian tribes in exercising special domestic violence criminal jurisdiction (SDVCJ). Through this grant program, Indian tribes will receive support and technical assistance for planning, developing and implementing changes in their criminal justice systems necessary to exercise SDVCJ. The program encourages collaborations among tribal leadership, tribal courts, tribal prosecutors, tribal attorneys, tribal defenders, law enforcement, probation, service providers, and other partners to ensure that non-Indians who commit crimes of domestic violence, dating violence, and violations of protection orders are held accountable. The Tribal Jurisdiction Program encourages the coordinated involvement of the entire tribal criminal justice system and victim service providers to incorporate systemic change that ensures victim safety and offender accountability.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that it will take the 20 respondents (Tribal Jurisdiction Program grantees) approximately one hour to complete a semi-annual progress report. The semi-annual progress report is divided into sections that pertain to the different types of activities that grantees may engage in (*i.e.* victim services, training, prosecutions, law enforcement activities) and grantees will be expected to provide information only in connection with those activities supported by OVW funding.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total annual hour burden to complete the annual progress report is 40 hours.

If additional information is required contact: Melody Braswell, Deputy Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., 3E, 405B, Washington, DC 20530.

Dated: August 9, 2017.

Melody Braswell,

Department Clearance Officer, PRA, U.S. Department of Justice.

[FR Doc. 2017–17078 Filed 8–11–17; 8:45 am]

BILLING CODE 4410–FX–P

OFFICE OF MANAGEMENT AND BUDGET

Uniform Administrative Requirements, Cost Principles, and Audit Requirements

AGENCY: Executive Office of the President, Office of Management and Budget.

ACTION: Notice.

SUMMARY: This Notice announces the availability of the 2017 OMB Audit Requirements, Appendix XI—Compliance Supplement (2017 Supplement). This Notice also offers interested parties an opportunity to comment on the 2017 Supplement.

DATES: The 2017 Supplement supersedes the 2016 Supplement and will apply to audits of fiscal years beginning after June 30, 2016. All comments on the 2017 Supplement must be in writing and received by October 31, 2017. Late comments will be considered to the extent practicable. OMB received no comments on the 2016 Supplement.

Due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, we encourage respondents to submit comments electronically to ensure timely receipt. We cannot guarantee that comments mailed will be received before the comment closing date.

ADDRESSES: Electronic mail comments may be submitted to: *Hai_M._Tran@omb.eop.gov.* Please include ''2 CFR Part 200 Subpart F—Audit Requirements, Appendix XI—Compliance Supplement—2017'' in the subject line and the full body of your comments in the text of the electronic message and as an attachment. Please include your name, title, organization, postal address, telephone number, and email address in the text of the message. Comments may also be submitted via facsimile at 202–395–3952.

Comments may be mailed to Gilbert Tran, Office of Federal Financial Management, Office of Management and Budget, 725 17th Street NW., Room 6025, New Executive Office Building, Washington, DC 20503.

Comments may also be sent through *http://www.regulations.gov*—a Federal E-Government Web site that allows the public to find, review, and submit comments on documents that agencies have published in the **Federal Register** and that are open for comment. Simply type ''2 CFR part 200 Subpart F—Audit Requirements, Appendix XI-Compliance Supplement—2017'' (in quotes) in the Comment or Submission search box, click Go, and follow the instructions for submitting comments. Comments received through the Web site by the date specified above will be included as part of the official record.

The 2017 Supplement is available online on the OMB home page at *https://www.whitehouse.gov/omb/offices/offm.*

FOR FURTHER INFORMATION CONTACT: Recipients and auditors should contact their cognizant or oversight agency for audit, or Federal awarding agency, as appropriate under the circumstances. The Federal agency contacts are listed in Appendix III of the Supplement. Subrecipients should contact their pass-through entity. Federal agencies should contact Gilbert Tran, Office of Management and Budget, Office of Federal Financial Management, at (202) 395–3052.

SUPPLEMENTARY INFORMATION: The 2017 Supplement adds four new programs, including one added to an existing cluster; adds two new clusters; and, deletes three programs (see listing below). The 2017 Supplement is also updated to reflect program changes and technical corrections. Part 3 of the 2017 Supplement—Compliance Requirements continues to be divided into two subparts. Subpart 3.1 is applicable to awards issued prior to December 26, 2014 and Subpart 3.2 is applicable to awards issued on or after December 26, 2014.

The added programs/clusters are:

- CFDA 20.224—Federal Lands Access Program, add to the existing Highway Planning and Construction cluster
- CFDA 87.051—Gulf Coast Ecosystem Restoration Council Comprehensive Plan Component Program
- CFDA 87.052—Gulf Coast Ecosystem Restoration Council Spill Impact Program
- CFDA 93.870—Maternal, Infant, and Early Childhood Home Visiting Grant Program to form a new cluster with CFDA 93.505, Affordable Care Act—Maternal, Infant, And Early Childhood Home Visiting Program
- The 477 cluster, a cross-agency cluster, that applies to the following Department of Interior, Department of Labor, and Department of Health and Human Services (HHS) programs as indicated therein:
  - CFDA 15.025—Services to Indian Children, Elderly and Families
  - CFDA 15.026—Indian Adult Education
  - CFDA 15.113—Indian Social Services—Welfare Assistance
  - CFDA 15.114—Indian Education-Higher Education Grant
  - CFDA 15.130—Indian Education-Assistance to Schools
  - CFDA 17.265—Native American Employment and Training
  - CFDA 93.558—Temporary Assistance for Needy Families
  - CFDA 93.569—Community Services Block Grant
  - CFDA 93.575—Child Care and Development Block Grant
  - CFDA 93.594—Tribal Work Grants—Native Employment Works
  - CFDA 93.596—Child Care Mandatory and Matching Funds of the Child Care and Development Fund.

The deleted programs are:

- CFDA 11.558—State Broadband Data and Development Grant Program.
- CFDA 93.889—Bioterrorism Hospital Preparedness Program.
- CFDA 10.781—Water and Waste Disposal Systems for Rural Communities—(American Recovery and Reinvestment Act), resulting in the elimination of a cluster.

Highlights of the changes in the Appendices of the Supplement include the following:

- Appendix III provides the updated list of the National Single Audit Coordinators and Single Audit Key Management Liaisons, along with their distinct roles for answering public inquiries regarding Single Audit.
- Appendix V lists the changes to the 2017 Supplement.
- Appendix VII adds information related to treatment of an existing cluster if a new program is added to the cluster.

Due to its length, the 2017 Supplement is not included in this Notice.

Mark Reger,

Deputy Controller.

[FR Doc. 2017–17054 Filed 8–11–17; 8:45 am]

BILLING CODE P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0203]

Information Collection: NRC Form 64, ''Travel Voucher'' (Part 1); NRC Form 64A, ''Travel Voucher'' (Part 2); and NRC Form 64B, ''Optional Travel Voucher'' (Part 2)

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of submission to the Office of Management and Budget; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has recently submitted a request for renewal of an existing collection of information to the Office of Management and Budget (OMB) for review. The information collection is entitled, ''NRC Form 64, ''Travel Voucher'' (Part 1); NRC Form 64A, ''Travel Voucher'' (Part 2); and NRC Form 64B, ''Optional Travel Voucher'' (Part 2).''

DATES: Submit comments by September 13, 2017.

ADDRESSES: Submit comments directly to the OMB reviewer at: Aaron Szabo, Desk Officer, Office of Information and Regulatory Affairs (3150–0192), NEOB–10202, Office of Management and Budget, Washington, DC 20503; telephone: 202–395–3621, email: *oira_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: David Cullison, NRC Clearance Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *INFOCOLLECTS.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2016–0203 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0203.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* A copy of the collection of information and related instructions may be obtained without charge by accessing ADAMS Accession ML17179A612.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *INFOCOLLECTS.Resource@NRC.GOV.*

B. Submitting Comments

Please include Docket ID NRC–2016–0203 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at *http://www.regulations.gov* and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the OMB, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Background

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC recently submitted a request for renewal of an existing collection of information to OMB for review entitled, NRC Form 64, ''Travel Voucher'' (Part 1); NRC Form 64A, ''Travel Voucher'' (Part 2); and NRC Form 64B, ''Optional Travel Voucher'' (Part 2). The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The NRC published a **Federal Register** notice with a 60-day comment period on this information collection on March 31, 2017; 82 FR16074.

1. *The title of the information collection:* NRC Form 64, ''Travel Voucher'' (Part 1); NRC Form 64A, ''Travel Voucher'' (Part 2); and NRC Form 64B, ''Optional Travel Voucher'' (Part 2).
2. *OMB approval number: 3150–0192.*
3. *Type of submission:* Extension.
4. *The form number if applicable:* NRC Forms 64, 64A and 64B.
5. *How often the collection is required or requested:* On occasion.
6. *Who will be required or asked to respond:* Contractors, consultants and invited

NRC travelers who travel in the course of conducting business for the NRC.

7. *The estimated number of annual responses:* 100.
8. *The estimated number of annual respondents:* 100.
9. *An estimate of the total number of hours needed annually to comply with the information collection requirement or request:* 100 (1 hour per form).
10. *Abstract:* Consultants, contractors, and those invited by the NRC to travel (*e.g.,* prospective employees) must file travel vouchers and trip reports in order to be reimbursed for their travel expenses. The information collected includes the name, address, social security number, and the amount to be reimbursed. Travel expenses that are reimbursed are confined to those expenses essential to the transaction of official business for an approved trip.

Dated at Rockville, Maryland, this 9th day of August, 2017.

For the Nuclear Regulatory Commission.

Dave Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2017–17124 Filed 8–11–17; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 70–1151; License No. SNM–1107; EA–16–173; NRC–2017–0176]

Westinghouse Electric Company, LLC

AGENCY: Nuclear Regulatory Commission.

ACTION: Confirmatory order; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) issued a confirmatory order (Order) to Westinghouse Electric Company, LLC, (the licensee), confirming the agreement reached in an Alternative Dispute Resolution mediation session held on May 19, 2017, and follow-up discussions held between May 19, 2017, and August 3, 2017. This Order will ensure the licensee restores compliance with NRC's regulations.

DATES: The Order was issued on August 9, 2017.

ADDRESSES: Please refer to Docket ID NRC–2017–0176 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2017–0176. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Documents'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in

ADAMS) is provided the first time that it is mentioned in this document.

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Scott Sparks, Region II, U.S. Nuclear Regulatory Commission, Atlanta, Georgia 30303–1257; telephone: 404–997–4422; email: *Scott.Sparks@nrc.gov.*

SUPPLEMENTARY INFORMATION: The text of the Order is attached.

Dated at Atlanta, Georgia, this 9th day of August, 2017.

For the Nuclear Regulatory Commission.

Catherine Haney,

Regional Administrator.

NUCLEAR REGULATORY COMMISSION

[Docket No. 70–1151; License No. SNM–1107; EA–16–173; NRC–2017–0176]

In the Matter of Westinghouse Electric Company, LLC

CONFIRMATORY ORDER (EFFECTIVE UPON ISSUANCE)

I

Westinghouse Electric Company (Westinghouse, or the licensee) is the holder of NRC License No. SNM–1107, issued by the U.S. Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR part 70 on September 30, 2007. The license authorizes the operation of the Columbia Fuel Fabrication Facility (CFFF) in accordance with the conditions specified therein. The facility is located on the licensee's site in Hopkins, South Carolina.

This Confirmatory Order (CO) is the result of an agreement reached during an alternative dispute resolution (ADR) mediation session conducted on May 19, 2017, and follow-up discussions held between May 19, 2017, and August 3, 2017.

II

On May 28, 2016, as part of the licensee's routine maintenance activities, the licensee started the S–1030 scrubber inspection and cleanout activities. The licensee completed the S–1030 scrubber cleanout activities on June 1, 2016, removing a total of 197 kilograms (kg) of material. The scrubber was subsequently restarted following the maintenance outage on June 2, 2016. On July 13, 2016, the preliminary results of samples taken of the material removed from the S–1030 scrubber indicated a 40–50% concentration of uranium (U) enriched to less than 5%. This equates to approximately 100 kg of U in the scrubber, exceeding the mass limit in the Criticality Safety Evaluation (CSE) of 29 kg U.

The scrubber was shut down on July 14, 2016, when the determination was made by the licensee that the mass limit in the CSE had been exceeded. The licensee reported this event to the NRC as a 24-hour event due to a high consequence event being ''unlikely'' (EN 52090). On July 31, 2016, the event report was updated to a one hour report per 10 CFR 70 Appendix A (a)(4) because no items relied upon for safety (IROFS) remained available and reliable to perform their function.

On August 11, 2016, the NRC issued a Confirmatory Action Letter (CAL) to Westinghouse (ML16224B082). The purpose of the CAL was to confirm the commitments made by Westinghouse regarding additional actions Westinghouse will take in response to the U buildup reported to the NRC in July 2016. These actions were intended to ensure that the causes of the U buildup have been adequately identified and evaluated and that appropriate corrective actions have been implemented to improve the performance of the Nuclear Criticality Safety (NCS) program.

On September 27, 2016, the NRC completed an Augmented Inspection at the Westinghouse facility, the details of which are documented in NRC Inspection Report 70–1151/2016–007 (ML16301A001).

A follow-up NRC inspection (70–1151/2017–007) was also conducted, the results of which were issued on February 27, 2017 (ML17058A448). This inspection report identified the following four Apparent Violations (AVs), all of which were considered for escalated enforcement in accordance with the NRC's Enforcement Policy:

1. An AV was identified for failure to ensure criticality accident sequences remain highly unlikely, as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 10 CFR 70.61(b).

2. An AV was identified for failure to assure that under normal and credible abnormal conditions, all nuclear processes were subcritical including use of an approved margin of subcriticality, as required by 10 CFR 70.61(d).

3. An AV was identified for failure to establish adequate management measures to ensure that items relied on for safety (IROFS) perform their function when needed, as required by 10 CFR 70.62(d).

4. An AV was identified for failure to make a one hour report, as required by Appendix A (a)(4) of 10 CFR part 70.

In response to the NRC's inspection report of February 27, 2017, Westinghouse advised the NRC of its desire to participate in the Agency's ADR program to resolve the enforcement aspects of this matter.

III

On May 19, 2017, the NRC and Westinghouse met in an ADR session mediated by a professional mediator, arranged through Cornell University's Institute on Conflict Resolution. Additional discussions were held between the NRC and Westinghouse between May 19, 2017, and August 3, 2017, to resolve the enforcement aspects of this matter. ADR is a process in which a neutral mediator with no decision-making authority assists the parties in reaching an agreement or resolving any differences regarding their dispute. This CO is issued pursuant to the agreement reached during the ADR process. The elements of the agreement consist of the following:

1. Westinghouse acknowledges that four violations occurred, as stated in NRC Inspection Report 70–1151/2017–007.

2. Based on ADR, the parties agreed that the safety significance of violations described in Section II above is characterized as escalated enforcement as described in the NRC Enforcement Policy.

3. Approximately two years (+/− 6 months) after issuance of the CO, Westinghouse shall conduct an additional Nuclear Safety Culture (NSC) survey by the Westinghouse corporate nuclear safety culture organization or an experienced independent third party, consistent with the depth and scope of the NSC survey completed under the CAL dated August 11, 2016. Identified deficiencies shall be entered into the corrective action program (CAP) for tracking corrective actions to completion.

4. Westinghouse shall implement improvements to reduce uranium carryover from the Calciner scrubbers, and implement additional design changes to reduce U carryover from the Blue M oven filtration system. Specifically:

(1) For the calciner scrubbers, within eighteen (18) months of issuance of the CO, an engineering evaluation of the calciner and calciner off-gas scrubber design and operation shall be completed to determine methods to reduce uranium carry-over into the S–1030 scrubber.

(2) For the Blue M oven, within eighteen (18) months of issuance of the CO, an engineering evaluation of the Conversion Scrap Cage Blue M oven shall be completed to determine methods to improve the functionality of

the Blue M oven in a wet environment and improve accessibility for inspection and maintenance activities.

(3) Within three (3) years of issuance of the CO, improvements based on the engineering evaluations described above shall be implemented.

5. In response to the May 2016 event, Westinghouse implemented several modifications to the S–1030 scrubber system, as part of its overall corrective actions to preclude recurrence and enhance performance. These modifications were considered by the NRC, under the CAL, in support of a safety basis to authorize restart of conversion process equipment and the S–1030 scrubber system, as documented in the NRC's letter to Westinghouse dated October 20, 2016 (ML16294A296). The modifications included but were not limited to:

(1) The plenums for the scrap cage Blue M oven hoods were equipped with a filter to capture at least 95% of the mass entrained in the air stream based on particle size distribution and the manufacturer's published efficiency data.

(2) Packing baskets were implemented to permit complete removal and inspection of the packed media and to maintain clearance between the packed media and the scrubber floor.

(3) A feed and bleed system for the scrubber recirculating liquid was maintained at a minimum output flow of 0.5 gallons per minute. If feed and bleed is not available, a controlled shutdown of the scrubber would be initiated in accordance with plant procedures.

(4) The scrubber was opened to remove the packed media baskets, to clean and inspect the inlet transition and scrubber body on a quarterly basis.

(5) Weekly visual inspections of the scrubber inlet transition were to be conducted.

6. Within two (2) years of issuance of the CO, Westinghouse shall develop and implement additional methods to monitor system parameters that are early indicators of an abnormal accumulation in the S–1030 scrubber from a process upset that could challenge the accumulation rate and/or criticality safety mass limits. The methods will provide timely indications to enable the operators to take appropriate actions in accordance with approved procedures.

7. A member of senior Westinghouse leadership shall present training on lessons learned from the scrubber event at an industry forum, including NSC and criticality safety standards aspects.

This item was completed on June 14, 2017, when the site vice president of CFFF presented training on lessons learned from the scrubber event at Fuel Cycle Information Exchange (an industry-wide forum), including NSC and criticality safety standards aspects.

8. Within eighteen (18) months of issuance of the CO, Westinghouse shall develop and implement a criticality safety basis/IROFS database to help maintain the proper flow down of the safety basis into implementing documents.

9. Within six (6) months of issuance of the CO, Westinghouse shall develop a method to reinforce positive NSC leadership behavior and monitor for effectiveness in the NSC monitoring panel. Westinghouse shall implement such method for three years, after which it may evaluate the need to continue this item.

10. Within three (3) months of issuance of the CO, Westinghouse shall develop and implement a new metric or periodic report that creates an aggregate picture of the health of the criticality safety program. This shall include items such as IROFS challenges, trends, audit and inspection finding status, violations, and health of management measures and be made available for inspection. Identified deficiencies shall be evaluated in accordance with the CAP.

11. Within nine (9) months, Westinghouse shall implement risk-informed standards for the preparation of procedures and data sheets informed by appropriate guidance in INPO 11–003, ''Guideline for Excellence in Procedure and Work Instruction Use and Adherence.'' This will consist of issuance of a procedure writers' guide, procedure format template, and a procedure use and adherence standard.

12. The NRC agrees that issuance of this CO serves to close the CAL issued to Westinghouse on August 11, 2016. NRC acknowledges that Westinghouse has taken extensive actions to address items in the CAL including completing a root cause analysis (RCA), completing a review of criticality safety evaluations, performing inspections to validate system design and operating parameters, installing physical modifications to support the safety basis to improve safety performance, conducting an independent third party nuclear safety culture assessment, and completing several corrective actions designed to preclude recurrence.

NRC also acknowledges that Westinghouse has taken some actions to close post-restart CAL items 1, 3, and 5, but are not yet complete. Therefore, post-restart CAL items 1, 3, and 5, as modified below, are transferred to this CO. Upon completion of these items, Westinghouse will notify the NRC Region II Administrator.

a. CAL Item 1—Westinghouse shall implement the remaining corrective actions to prevent recurrence identified in their RCA.

b. CAL Item 3—Westinghouse shall conduct effectiveness reviews of corrective actions to prevent recurrence specified in their RCA.

c. CAL Item 5—Westinghouse shall evaluate the results of the independent third party nuclear safety culture assessment, and any identified deficiencies will be entered into the CAP to track to completion.

The NRC concludes that CAL post-restart items 2 and 4 are closed because these items will be sampled as part of the NRC's inspection program.

The NRC concludes that CAL post-restart item 6 is closed because of the extensive corrective actions completed by Westinghouse to date.

13. Within three (3) months of completion of the terms of the CO, Westinghouse will provide the NRC with a letter discussing its basis for concluding that the CO has been satisfied.

14. In consideration of the commitments delineated herein, the NRC agrees to refrain from proposing a civil penalty or issuing a Notice of Violation for all four AVs identified in NRC Inspection Report 70–1151/2017–007 (EA–16–173).

15. The NRC and Westinghouse agree that the above elements will be incorporated into a CO.

16. This agreement is binding upon successors and assigns of Westinghouse.

On August 8, 2017, Westinghouse consented to issuance of this CO with the commitments, as described in Section V below. Westinghouse further agreed that this CO is to be effective upon issuance and that it has waived its right to a hearing.

IV

Because Westinghouse has taken corrective actions to address NRC concerns, as set forth in Section III above, and has agreed to take additional corrective actions as set forth in Section V below, the NRC has concluded that its concerns can be resolved through issuance of this CO.

I find that Westinghouse's commitments as set forth in Section V are acceptable and necessary and conclude that with these commitments, the public health and safety are reasonably assured. In view of the foregoing, I have determined that public health and safety require that Westinghouse's commitments be confirmed by this CO. Based on the

above and Westinghouse's consent, this CO is effective upon issuance.

V

Accordingly, pursuant to Sections 104b., 161b., 161i., 161o., 182, and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR part 70, *it is hereby ordered, that License No. SNM–1107 is modified as follows:*

1. In recognition of the corrective actions taken in response to the four violations, as discussed at the ADR, and in response to the Confirmatory Action Letter dated August 11, 2016 (ML16224B082), Westinghouse agrees to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a copy to the Document Control Desk, Washington, DC 20555–0001, within 30 days of the date of the CO. This reply should include for each of the four violations: (1) The reason for the violation; (2) the corrective steps that have been taken to restore compliance; and (3) additional corrective actions and enhancements taken to preclude repetition.

2. Approximately two years (+/− 6 months) after issuance of the CO, Westinghouse shall conduct an additional NSC survey by the Westinghouse corporate nuclear safety culture organization or an experienced independent third party, consistent with the depth and scope of the NSC survey completed under the CAL dated August 11, 2016. Identified deficiencies shall be entered into the CAP for tracking corrective actions to completion.

3. Westinghouse shall implement improvements to reduce uranium carryover from the Calciner scrubbers, and implement additional design changes to reduce U carryover from the Blue M oven filtration system. Specifically:

(1) For the calciner scrubbers, within eighteen (18) months of issuance of the CO, an engineering evaluation of the calciner and calciner off-gas scrubber design and operation shall be completed to determine methods to reduce uranium carry-over into the S–1030 scrubber.

(2) For the Blue M oven, within eighteen (18) months of issuance of the CO, an engineering evaluation of the Conversion Scrap Cage Blue M oven shall be completed to determine methods to improve the functionality of the Blue M oven in a wet environment and improve accessibility for inspection and maintenance activities.

(3) Within three (3) years of issuance of the CO, improvements based on the engineering evaluations described above shall be implemented.

4. Westinghouse shall notify the NRC within fifteen (15) working days prior to implementing changes to the modifications to the S–1030 scrubber system, as discussed below. This requirement ends once the Regional Administrator determines that the CO has been satisfied. These modifications were incorporated as corrective actions prior to the October 20, 2016, system restart authorization (ML16294A296) and support, in part, the safety basis for the S–1030 scrubber. Specifically, these modifications are:

(1) The plenums for the scrap cage Blue M oven hoods shall be equipped with a filter to capture at least 95% of the mass entrained in the air stream based on particle size distribution and the manufacturer's published efficiency data.

(2) Packing baskets were implemented to permit complete removal and inspection of the packed media and to maintain clearance between the packed media and the scrubber floor.

(3) A feed and bleed system for the scrubber recirculating liquid shall be maintained at a minimum output flow of 0.5 gallons per minute. If feed and bleed is not available, a controlled shutdown of the scrubber shall be initiated in accordance with plant procedures.

(4) The scrubber shall be opened to remove the packed media baskets, to clean and inspect the inlet transition and scrubber body on a quarterly basis.

(5) Weekly visual inspections of the scrubber inlet transition shall be conducted.

5. Within two (2) years of issuance of the CO, Westinghouse shall develop and implement additional methods to monitor system parameters that are early indicators of an abnormal accumulation in the S–1030 scrubber from a process upset that could challenge the accumulation rate and/or criticality safety mass limits. The methods will provide timely indications to enable the operators to take appropriate actions in accordance with approved procedures.

6. Within eighteen (18) months of issuance of the CO, Westinghouse shall develop and implement a criticality safety basis/IROFS database to maintain the proper flow down of the safety basis into implementing documents.

7. Within six (6) months of issuance of the CO, Westinghouse shall develop a method to reinforce positive NSC leadership behavior and monitor for effectiveness in the NSC monitoring panel. Westinghouse shall implement such method for three (3) years, after which it may evaluate the need to continue this item.

8. Within three (3) months of issuance of the CO, Westinghouse shall develop and implement a new metric or periodic report that creates an aggregate picture of the health of the criticality safety program. This shall include items such as IROFS challenges, trends, audit and inspection finding status, violations, and health of management measures and be made available for inspection. Identified deficiencies shall be evaluated in accordance with the CAP.

9. Within nine (9) months of issuance of the CO, Westinghouse shall implement risk-informed standards for the preparation of procedures and data sheets informed by appropriate guidance in INPO 11–003, ''Guideline for Excellence in Procedure and Work Instruction Use and Adherence.'' This shall consist of issuance of a procedure writers' guide, procedure format template, and a procedure use and adherence standard.

10. The NRC agrees that issuance of this CO serves to close the CAL issued to Westinghouse on August 11, 2016. NRC acknowledges that Westinghouse has taken extensive actions to address items in the CAL including completing an RCA, completing a review of criticality safety evaluations, performing inspections to validate system design and operating parameters, installing physical modifications to support the safety basis to improve safety performance, conducting an independent third party nuclear safety culture assessment, and completing several corrective actions designed to preclude recurrence.

The NRC also acknowledges that Westinghouse has taken some actions to close post-restart CAL items 1, 3, and 5, but are not yet complete. Therefore, post-restart CAL items 1, 3, and 5, as modified below, are transferred to this CO. Upon completion of these items, Westinghouse will notify the NRC Region II Administrator.

a. CAL Item 1—Westinghouse shall implement the remaining corrective actions to prevent recurrence identified in their RCA.

b. CAL Item 3—Westinghouse shall conduct effectiveness reviews of corrective actions to prevent recurrence specified in their RCA.

c. CAL Item 5—Westinghouse shall evaluate the results of the independent third party nuclear safety culture assessment, and any identified deficiencies will be entered into the CAP to track to completion.

This CO supersedes the CAL issued to Westinghouse on August 11, 2016. Post -restart CAL items 2 and 4 will be

sampled as part of the NRC's inspection program.

Post-restart CAL item 6 is closed because of the extensive corrective actions completed by Westinghouse to date.

11. Within three (3) months of completing implementation of the terms of the CO, Westinghouse will provide the NRC with a letter discussing its basis for concluding that the CO has been satisfied.

This agreement is binding upon successors and assigns of Westinghouse.

Unless otherwise specified, all dates are from the date of issuance of the CO.

The Regional Administrator, NRC Region II, may relax or rescind, in writing, any of the above conditions upon a showing by Westinghouse of good cause.

VI

In accordance with 10 CFR 2.202 and 10 CFR 2.309, any person adversely affected by this CO, other than Westinghouse, may request a hearing within 30 calendar days of the date of issuance of this CO. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and include a statement of good cause for the extension.

All documents filed in the NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139, August 28, 2007, as amended at 77 FR 46562, August 3, 2012). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Detailed guidance on making electronic submissions may be found in the Guidance for Electronic Submissions to the NRC and on the NRC's Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/getting-started.html.* Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit adjudicatory documents. Submissions must be in Portable Document Format (PDF). Additional guidance on PDF submissions is available on the NRC's public Web site at *http://www.nrc.gov/site-help/electronic-sub-ref-mat.html.* A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed so that they can obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the ''Contact Us'' link located on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene through the EIE System. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC public Web site at *https://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the ''Contact Us'' link located on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission,

Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing adjudicatory documents in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *https://adams.nrc.gov/ehd,* unless excluded pursuant to an order of the Commission or the presiding officer. If you do not have an NRC-issued digital ID certificate as described above, click cancel when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or personal phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. For example, in some instances, individuals provide home addresses in order to demonstrate proximity to a facility or site. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

If a person (other than Westinghouse) requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this CO and shall address the criteria set forth in 10 CFR 2.309(d) and (f).

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue an order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this CO should be sustained.

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section V above shall be final 30 days from the date of this CO without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section V shall be final when the extension expires if a hearing request has not been received.

Dated at Atlanta, Georgia, this 9th day of August, 2017.

For the Nuclear Regulatory Commission.

Catherine Haney,

Regional Administrator.

[FR Doc. 2017–17101 Filed 8–11–17; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–458; NRC–2017–0141]

Entergy Operations, Inc.; River Bend Station, Unit 1

AGENCY: Nuclear Regulatory Commission.

ACTION: License renewal application; opportunity to request a hearing and to petition for leave to intervene.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is considering an application for the renewal of operating license NPF–47, which authorizes Entergy Operations, Inc., (the applicant), to operate River Bend Station, Unit 1 (RBS). The renewed license would authorize the applicant to operate RBS for an additional 20 years beyond the period specified in the current license. The current operating license for RBS expires at midnight on August 29, 2025.

DATES: A request for a hearing or petition for leave to intervene must be filed by October 13, 2017.

ADDRESSES: Please refer to Docket ID NRC–2017–0141 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2017–0141. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The License Renewal Application is available in ADAMS under Accession No. ML17153A282.
- NRC's PDR: You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Emmanuel Sayoc, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–4084; email: *Emmanuel.Sayoc@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC received a license renewal application (LRA) from Entergy Operations, Inc., dated May 25, 2017, requesting renewal of operating license No. NPF–47, which authorizes Entergy Operations, Inc., to operate RBS at 3091 megawatts thermal. The RBS is a boiling-water reactor designed by General Electric and is located in St. Francisville, Louisiana. Entergy Operations, Inc., submitted the application, pursuant to part 54 of title 10 of the *Code of Federal Regulations* (10 CFR). A notice of receipt of the LRA was published in the **Federal Register** on June 28, 2017 (82 FR 29344).

The NRC's staff has determined that Entergy Operations, Inc. has submitted sufficient information in accordance with 10 CFR 54.19, 54.21, 54.22, 54.23, 51.45, and 51.53(c), to enable the staff to undertake a review of the application, and that the application is, therefore, acceptable for docketing. The current docket No., 50–458, for operating license No. NPF–47, will be retained. The determination to accept the LRA for docketing does not constitute a determination that a renewed license should be issued, and does not preclude the NRC staff from requesting additional information as the review proceeds.

Before issuance of the requested renewed license, the NRC will have made the findings required by the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. In accordance with 10 CFR 54.29, the NRC may issue a

renewed license on the basis of its review if it finds that actions have been identified and have been or will be taken with respect to: (1) Managing the effects of aging during the period of extended operation on the functionality of structures and components that have been identified as requiring aging management review; and (2) time-limited aging analyses that have been identified as requiring review, such that there is reasonable assurance that the activities authorized by the renewed license will continue to be conducted in accordance with the current licensing basis (CLB) and that any changes made to the plant's CLB will comply with the Act and the Commission's regulations.

Additionally, in accordance with 10 CFR 51.95(c), the NRC will prepare an environmental impact statement as a supplement to the Commission's NUREG–1437, ''Generic Environmental Impact Statement for License Renewal of Nuclear Power Plants,'' dated June 2013. In considering the LRA, the Commission must find that the applicable requirements of Subpart A of 10 CFR part 51 have been satisfied, and that matters raised under 10 CFR 2.335 have been addressed. Pursuant to 10 CFR 51.26, and as part of the environmental scoping process, the staff intends to hold public scoping meetings. Detailed information regarding the environmental scoping meetings will be the subject of a separate **Federal Register** notice.

II. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any persons (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the action. Petitions shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309. The NRC's regulations are accessible electronically from the NRC Library on the NRC's Web site at *http://www.nrc.gov/reading-rm/doc-collections/cfr/.* Alternatively, a copy of the regulations is available at the NRC's Public Document Room, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of hearing will be issued.

As required by 10 CFR 2.309, a petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements for standing: (1) The name, address, and telephone number of the petitioner; (2) the nature of the petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the petitioner's interest.

In accordance with 10 CFR 2.309(f), the petition must also set forth the specific contentions which the petitioner seeks to have litigated in the proceeding. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner must provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to the specific sources and documents on which the petitioner intends to rely to support its position on the issue. The petition must include sufficient information to show that a genuine dispute exists with the applicant or licensee on a material issue of law or fact. Contentions must be limited to matters within the scope of the proceeding. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to satisfy the requirements at 10 CFR 2.309(f) with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene. Parties have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that party's admitted contentions, including the opportunity to present evidence, consistent with the NRC's regulations, policies, and procedures.

Petitions must be filed no later than 60 days from the date of publication of this notice. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii). The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document.

A State, local governmental body, Federally-recognized Indian Tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission by October 13, 2017. The petition must be filed in accordance with the filing instructions in the ''Electronic Submission (E-Filing)'' section of this document, and should meet the requirements for petitions set forth in this section, except that under 10 CFR 2.309(h)(2) a State, local governmental body, or federally recognized Indian Tribe, or agency thereof does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. Alternatively, a State, local governmental body, Federally-recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

If a hearing is granted, any person who is not a party to the proceeding and is not affiliated with or represented by a party may, in the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of his or her position on the issues but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Details regarding the opportunity to make a limited appearance will be provided by the presiding officer if such sessions are scheduled.

III. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing and petition for leave to intervene (petition), any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities that request to participate under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562, August 3, 2012). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Detailed guidance on making electronic submissions may be found in the Guidance for Electronic Submissions to the NRC and on the NRC's Web site at *http://www.nrc.gov/*

site-help/e-submittals.html. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to request (1) a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/getting-started.html.* Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit adjudicatory documents. Submissions must be in Portable Document Format (PDF). Additional guidance on PDF submissions is available on the NRC's public Web site at *http://www.nrc.gov/site-help/electronic-sub-ref-mat.html.* A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed so that they can obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the ''Contact Us'' link located on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing adjudicatory documents in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *https://adams.nrc.gov/ehd,* unless excluded pursuant to an order of the Commission or the presiding officer. If you do not have an NRC-issued digital ID certificate as described above, click cancel when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or personal phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. For example, in some instances, individuals provide home addresses in order to demonstrate proximity to a facility or site. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

Detailed information about the license renewal process can be found under the Nuclear Reactors icon at *http://www.nrc.gov/reactors/operating/licensing/renewal.html* on the NRC's Web site. Copies of the application to renew the operating license for RBS are available for public inspection at the NRC's PDR, and at *http://www.nrc.gov/reactors/operating/licensing/renewal/applications.html,* the NRC's Web site while the application is under review.

The NRC staff has verified that a copy of the license renewal application is also available to local residents near the site at the St. Charles Parish Library—East Regional Library, 160 W. Campus Drive, Destrehan, Louisiana 70047.

Dated at Rockville, Maryland, this 9th day of August, 2017.

For the Nuclear Regulatory Commission.

Sheldon Stuchell,

Chief, Projects Management and Guidance Branch, Division of License Renewal, Office of Nuclear Reactor Regulation.

[FR Doc. 2017–17125 Filed 8–11–17; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81348; File No. SR–BX–2017–038]

Self-Regulatory Organizations; NASDAQ BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Chapter V, Section 6, Nullification and Adjustment of Options Transactions Including Obvious Errors

August 8, 2017.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 3, 2017, NASDAQ BX, Inc. (''BX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Chapter V, Section 6 of the Exchange's Options Rules (the ''Rules''), entitled ''Nullification and Adjustment of Options Transactions including Obvious Errors.''

While these amendments are effective upon filing, the Exchange has designated the proposed amendments to be operative on a date that is within ninety (90) days after the Commission approved a similar proposal filed by Bats BZX on July 6, 2017.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqbx.cchwallstreet.com/*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange and other options exchanges recently adopted a new, harmonized rule related to the adjustment and nullification of erroneous options transactions, including a specific provision related to coordination in connection with large-scale events involving erroneous options transactions.[3] The Exchange believes that the changes the options exchanges implemented with the new, harmonized rule have led to increased transparency and finality with respect to the adjustment and nullification of erroneous options transactions. However, as part of the initial initiative, the Exchange and other options exchanges deferred a few specific matters for further discussion. Specifically, as described in the Initial Filing, the Exchange and all other options exchanges have been working to further improve the review of potentially erroneous transactions as well as their subsequent adjustment by creating an objective and universal way to determine Theoretical Price in the event a reliable NBBO is not available. Because this initiative required additional exchange and industry discussion as well as additional time for development and implementation, the Exchange and the other options exchanges determined to proceed with the Initial Filing and to undergo a secondary initiative to complete any additional improvements to the applicable rule. In this filing, the Exchange proposes to adopt procedures that will lead to a more objective and uniform way to determine Theoretical Price in the event a reliable NBBO is not available. In addition to this change, the Exchange has proposed two additional minor changes to its rules. The Exchange's proposal mirrors that of Bats BZX, which the Exchange [sic] approved on July 6, 2017,[4] and those that the other options exchanges intend to file.

Calculation of Theoretical Price Using a Third Party Provider

Under the harmonized rule, when reviewing a transaction as potentially erroneous, the Exchange needs to first determine the ''Theoretical Price'' of the option, *i.e.,* the Exchange's estimate of the correct market price for the option. Pursuant to Chapter V, Section 6 of the Rules, if the applicable option series is traded on at least one other options exchange, then the Theoretical Price of an option series is the last national best bid (''NBB'') just prior to the trade in question with respect to an erroneous sell transaction or the last national best offer (''NBO'') just prior to the trade in question with respect to an erroneous buy transaction unless one of the exceptions described below exists. Thus, whenever the Exchange has a reliable NBB or NBO, as applicable, just prior to the transaction, then the Exchange uses this NBB or NBO as the Theoretical Price.

The Rule also contains various provisions governing specific situations where the NBB or NBO is not available or may not be reliable. Specifically, the Rule specifies situations in which there are no quotes or no valid quotes for comparison purposes, when the national best bid or offer (''NBBO'') is determined to be too wide to be reliable, and at the open of trading on each trading day. In each of these circumstances, in turn, because the NBB or NBO is not available or is deemed to be unreliable, the Exchange determines Theoretical Price. Under the current Rule, when determining Theoretical Price, Exchange personnel generally consult and refer to data such as the prices of related series, especially the closest strikes in the option in question. Exchange personnel may also take into account the price of the underlying security and the volatility characteristics of the option as well as historical pricing of the option and/or similar options. Although the Rule is administered by experienced personnel and the Exchange believes the process is currently appropriate, the Exchange recognizes that it is also subjective and could lead to disparate results for a transaction that spans multiple options exchanges.

The Exchange proposes to adopt Commentary .04 to specify how the Exchange will determine Theoretical Price when required by sub-paragraphs (b)(1)–(3) of the Rule (*i.e.,* at the open, when there are no valid quotes or when there is a wide quote). In particular, the Exchange has been working with other options exchanges to identify and select a reliable third party vendor (''TP Provider'') that would provide Theoretical Price to the Exchange whenever one or more transactions is under review pursuant to Chapter V, Section 6 of the Rules and the NBBO is unavailable or deemed unreliable pursuant to Chapter V, Section 6(b) of the Rules. The Exchange and other options exchanges have selected CBOE Livevol, LLC (''Livevol'') as the TP Provider, as described below. As further described below, proposed Commentary .04 would codify the use of the TP Provider as well as limited exceptions where the Exchange would be able to deviate from the Theoretical Price given by the TP Provider.

Pursuant to proposed Commentary .04, when the Exchange must determine Theoretical Price pursuant to the sub-paragraphs (b)(1)–(3) of the Rule, the Exchange will request Theoretical Price from the third party vendor to which the Exchange and all other options exchanges have subscribed. Thus, as set forth in this proposed language, Theoretical Price would be provided to the Exchange by the TP Provider on

[3] *See* Securities Exchange Act Release No. 34–74916 (May 8, 2015); 80 FR 27733 (May 14, 2015) (SR–BX–2015–028) (the ''Initial Filing'').

[4] *See* Securities Exchange Act Release No. 34–81084 (July 6, 2017) (granting approval of Bats BZX proposal), 82 FR 32216 (July 12, 2017); 82 FR 23684 (May 23, 2017) (SR–BatsBZX–2017–035) (notice of filing of Bats BZX proposal).

request and not through a streaming data feed.[5] This language also makes clear that the Exchange and all other options exchanges will use the same TP Provider.

As noted above, the proposed TP Provider selected by the Exchange and other options exchanges is Livevol. The Exchange proposes to codify this selection in proposed paragraph (d) to Commentary .04. As such, the Exchange would file a rule proposal and would provide notice to the options industry of any proposed change to the TP Provider.

The Exchange and other options exchanges have selected Livevol as the proposed TP Provider after diligence into various alternatives. Livevol has, since 2009, been the options industry leader in providing equity and index options market data and analytics services.[6] The Exchange believes that Livevol has established itself within the options industry as a trusted provider of such services and notes that it and all other options exchanges already subscribe to various Livevol services. In connection with this proposal, Livevol will develop a new tool based on its existing technology and services that will supply Theoretical Price to the Exchange and other options exchanges upon request. The Theoretical Price tool will leverage current market data and surrounding strikes to assist in a relative value pricing approach to generating a Theoretical Price. When relative value methods are incapable of generating a valid Theoretical Price, the Theoretical Price tool will utilize historical trade and quote data to calculate Theoretical Price.

Because the purpose of the proposal is to move away from a subjective determination by Exchange personnel when the NBBO is unavailable or unreliable, the Exchange intends to use the Theoretical Price provided by the TP Provider in all such circumstances. However, the Exchange believes it is necessary to retain the ability to contact the TP Provider if it believes that the Theoretical Price provided is fundamentally incorrect and to determine the Theoretical Price in the limited circumstance of a systems issue experienced by the TP Provider, as described below.

As proposed, to the extent an Official[7] of the Exchange believes that the Theoretical Price provided by the TP Provider is fundamentally incorrect and cannot be used consistent with the maintenance of a fair and orderly market, the Official shall contact the TP Provider to notify the TP Provider of the reason the Official believes such Theoretical Price is inaccurate and to request a review and correction of the calculated Theoretical Price. For example, if an Official received from the TP Provider a Theoretical Price of $80 in a series that the Official might expect to be instead in the range of $8 to $10 because of a recent corporate action in the underlying, the Official would request that the TP Provider review and confirm its calculation and determine whether it had appropriately accounted for the corporate action. In order to ensure that other options exchanges that may potentially be relying on the same Theoretical Price that, in turn, the Official believes to be fundamentally incorrect, the Exchange also proposes to promptly provide notice to other options exchanges that the TP Provider has been contacted to review and correct the calculated Theoretical Price at issue and to include a brief explanation of the reason for the request.[8] Although not directly addressed by the proposed Rule, the Exchange expects that all other options exchanges once in receipt of this notification would await the determination of the TP Provider and would use the corrected price as soon as it is available. The Exchange further notes that it expects the TP Provider to cooperate with, but to be independent of, the Exchange and other options exchanges.[9]

The Exchange believes that the proposed provision to allow an Official to contact the TP Provider if he or she believes the provided Theoretical Price is fundamentally incorrect is necessary, particularly because the Exchange and other options exchanges will be using the new process for the first time. Although the exchanges have conducted thorough diligence with respect to Livevol as the selected TP Provider and would do so with any potential replacement TP Provider, the Exchange is concerned that certain scenarios could arise where the Theoretical Price generated by the TP Provider does not take into account relevant factors and would result in an unfair result for market participants involved in a transaction. The Exchange notes that if such situations do indeed arise, to the extent practicable the Exchange will also work with the TP Provider and other options exchanges to improve the TP Provider's calculation of Theoretical Price in future situations. For instance, if the Exchange determines that a particular type of corporate action is not being appropriately captured by the TP Provider when such provider is generating Theoretical Price, while the Exchange believes that it needs the ability to request a review and correction of the Theoretical Price in connection with a specific review in order to provide a timely decision to market participants, the Exchange would share information regarding the specific situation with the TP Provider and other options exchanges in an effort to improve the Theoretical Price service for future use. The Exchange notes that it does not anticipate needing to rely on this provision frequently, if at all, but believes the provision is necessary nonetheless to best prepare for all potential circumstances. Further, the Theoretical Price used by the Exchange in connection with its rulings will always be that received from the TP Provider and the Exchange has not proposed the ability to deviate from such price.[10]

Pursuant to proposed paragraph (c) to Commentary .04, an Official of the Exchange may determine the Theoretical Price if the TP Provider has experienced a systems issue that has rendered its services unavailable to accurately calculate Theoretical Price and such issue cannot be corrected in a timely manner. The Exchange notes that it does not anticipate needing to rely on this provision frequently, if at all, but believes the provision is necessary nonetheless to best prepare for all potential circumstances. Further, consistent with existing text in Chapter V, Section 6(e)(4) of the Rules, the Exchange has not proposed a specific time by which the service must be available in order to be considered

[5] Though the Exchange and other options exchanges considered a streaming feed, it was determined that it would be more feasible to develop and implement an on demand service and that such a service would satisfy the goals of the initiative.

[6] The Exchange notes that in 2015, Livevol was acquired by CBOE Holdings, Inc., the ultimate parent company of the Chicago Board Options Exchange (''CBOE'') and C2 Options Exchange (''C2'').

[7] For purposes of the Rule, an Official is an Exchange staff member or contract employee designated as such by the Chief Regulatory Officer. *See* BX Rules, Chapter V, Sec. 6(a)(3).

[8] *See* proposed paragraph (b) to Commentary .04.

[9] The Exchange expects any TP Provider selected by the Exchange and other options exchanges to act independently in its determination and calculation of Theoretical Price. With respect to Livevol specifically, the Exchange again notes that Livevol is a subsidiary of CBOE Holdings, Inc., which is also the ultimate parent company of multiple options exchanges. The Exchange expects Livevol to calculate Theoretical Price independent of its affiliated exchanges in the same way it will calculate Theoretical Price independent of non-affiliated exchanges.

[10] To the extent the TP Provider has been contacted by an Official of the Exchange, reviews the Theoretical Price provided but disagrees that there has been any error, then the Exchange would be bound to use the Theoretical Price provided by the TP Provider.

timely.[11] The Exchange expects that it would await the TP Provider's services becoming available again so long as the Exchange was able to obtain information regarding the issue and the TP Provider had a reasonable expectation of being able to resume normal operations within the next several hours based on communications with the TP Provider. More specifically with respect to Livevol, Livevol has business continuity and disaster recovery procedures that will help to ensure that the Theoretical Price tool remains available or, in the event of an outage, that service is restored in a timely manner.

The Exchange also notes that if a wide-scale event occurred, even if such event did not qualify as a ''Significant Market Event'' pursuant to Chapter V, Section 6(e) of the Rules, and the TP Provider was unavailable or otherwise experiencing difficulty, the Exchange believes that it and other options exchanges would seek to coordinate to the extent possible. In particular, the Exchange and other options exchanges now have a process, administered by the Options Clearing Corporation, to invoke a discussion amongst all options exchanges in the event of any widespread or significant market events. The Exchange believes that this process could be used in the event necessary if there were an issue with the TP Provider.

The Exchange also proposes to adopt language in paragraph (d) of Commentary .04 to Chapter V, Section 6 of the Rules to disclaim the liability of the Exchange and the TP Provider in connection with the proposed Rule, the TP Provider's calculation of Theoretical Price, and the Exchange's use of such Theoretical Price. Specifically, the proposed rule would state that neither the Exchange, the TP Provider, nor any affiliate of the TP Provider (the TP Provider and its affiliates are referred to collectively as the ''TP Provider''), makes any warranty, express or implied, as to the results to be obtained by any person or entity from the use of the TP Provider pursuant to Commentary .04. The proposed rule would further state that the TP Provider does not guarantee the accuracy or completeness of the calculated Theoretical Price and that the TP Provider disclaims all warranties of merchantability or fitness for a particular purpose or use with respect to such Theoretical Price. Finally, the proposed Rule would state that neither the Exchange nor the TP Provider shall have any liability for any damages, claims, losses (including any indirect or consequential losses), expenses, or delays, whether direct or indirect, foreseen or unforeseen, suffered by any person arising out of any circumstance or occurrence relating to the use of such Theoretical Price or arising out of any errors or delays in calculating such Theoretical Price. This proposed language is modeled after existing language in Exchange Rules regarding ''reporting authorities'' that calculate indices.[12]

In connection with the proposed change described above, the Exchange proposes to modify Chapter V, Section 6 of the Rules to state that the Exchange will rely on paragraph (b) and Commentary .04 when determining Theoretical Price.

No Valid Quotes—Market Participant Quoting on Multiple Exchanges

As described above, one of the times where the NBB or NBO is deemed to be unreliable for purposes of Theoretical Price is when there are no quotes or no valid quotes for the affected series. In addition to when there are no quotes, the Exchange does not consider the following to be valid quotes: (i) All quotes in the applicable option series published at a time where the last NBB is higher than the last NBO in such series (a ''crossed market''); (ii) quotes published by the Exchange that were submitted by either party to the transaction in question; and (iii) quotes published by another options exchange against which the Exchange has declared self-help. In recognition of today's market structure where certain participants actively provide liquidity on multiple exchanges simultaneously, the Exchange proposes to add an additional category of invalid quotes. Specifically, in order to avoid a situation where a market participant has established the market at an erroneous price on multiple exchanges, the Exchange proposes to consider as invalid the quotes in a series published by another options exchange if either party to the transaction in question submitted the quotes in the series representing such options exchange's best bid or offer. Thus, similar to being able to ignore for purposes of the Rule the quotes published by the Exchange if submitted by either party to the transaction in question, the Exchange would be able to ignore for purposes of the rule quotations on other options exchanges by that same market participant.

In order to continue to apply the Rule in a timely and organized fashion, however, the Exchange proposes to initially limit the scope of this proposed provision in two ways. First, because the process will take considerable coordination with other options exchanges to confirm that the quotations in question on an away options exchange were indeed submitted by a party to a transaction on the Exchange, the Exchange proposes to limit this provision to apply to up to twenty-five (25) total options series (*i.e.,* whether such series all relate to the same underlying security or multiple underlying securities). Second, the Exchange proposes to require the party that believes it established the best bid or offer on one or more other options exchanges to identify to the Exchange the quotes which were submitted by such party and published by other options exchanges. In other words, as proposed, the burden will be on the party seeking that the Exchange disregard their quotations on other options exchanges to identify such quotations. In turn, the Exchange will verify with such other options exchanges that such quotations were indeed submitted by such party.

Below are examples of both the current rule and the rule as proposed to be amended.

Example 1—Current Rule, Member Erroneously Quotes on One Exchange

Assumptions

For purposes of this example, assume the following:

- A Member acting as a Market Maker on the Exchange (''Market Maker A'') is quoting in twenty series of options underlying security ABCD on the Exchange (and only the Exchange).
- Market Maker A makes an error in calculating the market for options on ABCD, and publishes quotes in all twenty series to buy options at $1.00 and to sell options at $1.05.
- In fact, options on ABCD in these series are nearly worthless and no other market participant is quoting in such series.
- Therefore, the NBBO in the twenty series at issue is $1.00 × $1.05 (with the Exchange representing the NBBO based on Market Maker A's quotes).
- Assume Member A immediately enters sell orders and executes against Market Maker A's quotes at $1.00.
- Assume Market Maker A submits to the Exchange a timely request for review of the trades with Member A as potentially erroneous transactions to buy.

[11] In the context of a Significant Market Event, the Exchange may determine, ''in consultation with other options exchanges . . . that timely adjustment is not feasible due to the extraordinary nature of the situation.'' *See* BX Rules, Chapter V, Sec. 6(e)(4).

[12] *See, e.g.,* BX Rules, Chapter XIV, Sec. 13, which relates to index options potentially listed and traded on the Exchange and disclaims liability for a reporting authority and their affiliates.

Result

• Based on the Exchange's current rules, the Exchange would identify Market Maker A as a participant to the trades at issue and would consider Market Maker A's quotations invalid pursuant to Chapter V, Section 6(b)(2) of the Rules.

• As there were no other valid quotes to use as a reference price, the Exchange would then determine Theoretical Price.

• Assume the Exchange determines a Theoretical Price of $0.05.

• The execution price of $1.00 exceeds the $0.25 minimum amount set forth in the Exchange's table to determine whether an obvious error has occurred (*i.e.,* $0.05 + $0.25 = $0.30) so any execution at or above this price is an obvious error.

• Accordingly, the executions in all series would be adjusted by the Exchange to executions at $0.20 per contract (Theoretical Price of $0.05 plus $0.15) to the extent the incoming orders submitted by Member A were non-Customer orders.

• The executions in all series would be nullified to the extent the incoming orders submitted by Member A were Customer orders.

Example 2—Current Rule, Member Erroneously Quotes on Multiple Exchanges

Assumptions

For purposes of this example, assume the following:

• A Member acting as a Market Maker on the Exchange (''Market Maker A'') is quoting in twenty series of options underlying security ABCD on the Exchange and on a second exchange (''Away Exchange'').

• Market Maker A makes an error in calculating the market for options on ABCD, and publishes quotes on both the Exchange and the Away Exchange in all twenty series to buy options at $1.00 and to sell options at $1.05.

• In fact, options on ABCD in these series are nearly worthless and no other market participant is quoting in such series.

• Therefore, the NBBO in the twenty series at issue is $1.00 × $1.05 (with the Exchange and the Away Exchange representing the NBBO based on Market Maker A's quotes).

• Assume Member A immediately enters sell orders and executes against Market Maker A's quotes at $1.00.

• Assume Market Maker A submits to the Exchange and to the Away Exchange timely requests for review of the trades with Member A as potentially erroneous transactions to buy.

Result

• Based on the Exchange's current rules, the Exchange would identify Market Maker A as a participant to the trades at issue and would consider Market Maker A's quotations on the Exchange invalid pursuant to Chapter V, Section 6(b)(2) of the Rules. The Exchange, however, would view the Away Exchange's quotations as valid, and would thus determine Theoretical Price to be $1.05 (*i.e.,* the NBO in the case of a potentially erroneous buy transaction).

• The execution price of $1.00 does not exceed the $0.25 minimum amount set forth in the Exchange's table to determine whether an obvious error has occurred (*i.e.,* $1.05 + $0.25 = $1.30) so any execution at or above this price is an obvious error.

• The transactions on the Exchange would not be nullified or adjusted.

• As the Exchange and all other options exchanges have identical rules with respect to the process described above, the transactions on the Away Exchange would not be nullified or adjusted.

Example 3—Proposed Rule, Member Erroneously Quotes on Multiple Exchanges [13]

Assumptions

For purposes of this example, assume the following:

• A Member acting as a Market Maker on the Exchange (''Market Maker A'') is quoting in twenty series of options underlying security ABCD on the Exchange and on a second exchange (''Away Exchange'').[14]

• Market Maker A makes an error in calculating the market for options on ABCD, and publishes quotes on both the Exchange and the Away Exchange in all twenty series to buy options at $1.00 and to sell options at $1.05.

• In fact, options on ABCD in these series are nearly worthless and no other market participant is quoting in such series.

• Therefore, the NBBO in the twenty series at issue is $1.00 × $1.05 (with the Exchange and the Away Exchange representing the NBBO based on Market Maker A's quotes).

• Assume Member A immediately enters sell orders and executes against Market Maker A's quotes at $1.00.

• Assume Market Maker A submits to the Exchange and to the Away Exchange timely requests for review of the trades with Member A as potentially erroneous transactions to buy. At the time of submitting the requests for review to the Exchange and the Away Exchange, Market Maker A identifies to the Exchange the quotes on the Away Exchange as quotes also represented by Market Maker A (and to the Away Exchange, the quotes on the Exchange as quotes also represented by Market Maker A).

Result

• Based on the proposed rules, the Exchange would identify Market Maker A as a participant to the trades at issue and would consider Market Maker A's quotations on the Exchange invalid pursuant to Chapter V, Section 6(b)(2) of the Rules.

• The Exchange and the Away Exchange would also coordinate to confirm that the quotations identified by Market Maker A on the other exchange were indeed Market Maker A's quotations. Once confirmed, each of the Exchange and the Away Exchange would also consider invalid the quotations published on the other exchange.

• As there were no other valid quotes to use as a reference price, the Exchange would then determine Theoretical Price.

• Assume the Exchange determines a Theoretical Price of $0.05.

• The execution price of $1.00 exceeds the $0.25 minimum amount set forth in the Exchange's table to determine whether an obvious error has occurred (*i.e.,* $0.05 + $0.25 = $0.30) so any execution at or above this price is an obvious error.

• Accordingly, the executions in all series would be adjusted by the Exchange to executions at $0.20 per contract (Theoretical Price of $0.05 plus $0.15) to the extent the incoming orders submitted by Member A were non-Customer orders.

• The executions in all series would be nullified to the extent the incoming orders submitted by Member A were Customer orders.

• As the Exchange and all other options exchanges would have identical rules with respect to the process described above, as other options exchanges intend to adopt the same rule if the proposed rule is approved, the transactions on the Away Exchange would also be nullified or adjusted as set forth above.

[13] The Exchange notes that its proposed rule will not impact the proposed handling of a request for review where a market participant is quoting only on the Exchange, thus, the Exchange has not included a separate example for such a fact pattern.

[14] The Exchange notes that the proposed rule would operate the same if Market Maker A was quoting on more than two exchanges. The Exchange has limited the example to two exchanges for simplicity.

• If this example was instead modified such that Market Maker A was quoting in 200 series rather than 20, the Exchange notes that Market Maker A could only request that the Exchange consider as invalid their quotations in 25 of those series on other exchanges. As noted above, the Exchange has proposed to limit the proposed rule to 25 series in order to continue to process requests for review in a timely and organized fashion in order to provide certainty to market participants. This is due to the amount of coordination that will be necessary in such a scenario to confirm that the quotations in question on an away options exchange were indeed submitted by a party to a transaction on the Exchange.

Trading Halts—Clarifying Change to Chapter V, Section 6

Commentary .03 to Chapter V, Section 6 of the Rules describes the Exchange's authority to declare trading halts in one or more options traded on the Exchange. The Exchange proposes to modify this provision to provide that, with respect to equity options, the Exchange shall nullify any transaction that occurs during a regulatory halt as declared by the primary listing market for the underlying security. The Exchange believes this change is necessary to distinguish a declared regulatory halt, where the underlying security should not be actively trading on any venue, from an operational issue on the primary listing exchange where the security continues to safely trade on other trading venues.

Implementation Date

The Exchange proposes to delay the operative date of this proposal to a date within ninety (90) days after the Commission approved the Bats BZX proposal on July 6, 2017. The Exchange will announce the operative date in a Regulatory Alert made available to its Members.

2. Statutory Basis

The Exchange believes that its proposal is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.[15]

Specifically, the proposal is consistent with Section 6(b)(5) of the Act[16] because it would promote just and equitable principles of trade, remove impediments to, and perfect the mechanism of, a free and open market and a national market system, and, in general, protect investors and the public interest.

As described above, the Exchange and other options exchanges are seeking to further modify their harmonized rules related to the adjustment and nullification of erroneous options transactions. The Exchange believes that the proposal to utilize a TP Provider in the event the NBBO is unavailable or unreliable will provide greater transparency and clarity with respect to the adjustment and nullification of erroneous options transactions. Particularly, the proposed changes seek to achieve consistent results for participants across U.S. options exchanges while maintaining a fair and orderly market, protecting investors and protecting the public interest. Thus, the Exchange believes that the proposal is consistent with Section 6(b)(5) of the Act[17] in that the proposed Rule will foster cooperation and coordination with persons engaged in regulating and facilitating transactions.

The Exchange again reiterates that it has retained the standard of the current rule for most reviews of options transactions pursuant to Chapter V, Section 6 of the Rules, which is to rely on the NBBO to determine Theoretical Price if such NBBO can reasonably be relied upon. The proposal to use a TP Provider when the NBBO is unavailable or unreliable is consistent with Section 6(b)(5) of the Act[18] in that the proposed Rule will foster cooperation and coordination with persons engaged in regulating and facilitating transactions by further reducing the possibility of disparate results between options exchanges and increasing the objectivity of the application of Chapter V, Section 6 of the Rules. Further, the Exchange believes that the proposed Rule is transparent with respect to the limited circumstances under which the Exchange will request a review and correction of Theoretical Price from the TP Provider, and has sought to limit such circumstances as much as possible. The Exchange notes that under the current Rule, Exchange personnel are required to determine Theoretical Price in certain circumstances and yet rarely do so because such circumstances have already been significantly limited under the harmonized rule (for example, because the wide quote provision of the harmonized rule only applies if the quote was narrower and then gapped but does not apply if the quote had been persistently wide). Thus, the Exchange believes it will need to request Theoretical Price from the TP Provider only in very rare circumstances and in turn, the Exchange anticipates that the need to contact the TP Provider for additional review of the Theoretical Price provided by the TP Provider will be even rarer. Similarly, the Exchange believes it is unlikely that an Exchange Official will ever be required to determine Theoretical Price, as such circumstance would only be in the event of a systems issue that has rendered the TP Provider's services unavailable and such issue cannot be corrected in a timely manner.

The Exchange also believes its proposal to adopt language in paragraph (d) of Commentary .04 to Chapter V, Section 6 of the Rules to disclaim the liability of the Exchange and the TP Provider in connection with the proposed Rule, the TP Provider's calculation of Theoretical Price, and the Exchange's use of such Theoretical Price is consistent with the Act. As noted above, this proposed language is modeled after existing language in Exchange Rules regarding ''reporting authorities'' that calculate indices,[19] and is consistent with Section 6(b)(5) of the Act[20] in that the proposed Rule will foster cooperation and coordination with persons engaged in regulating and facilitating transactions.

As described above, the Exchange proposes a modification to the valid quotes provision to also exclude quotes in a series published by another options exchange if either party to the transaction in question submitted the orders or quotes in the series representing such options exchange's best bid or offer. The Exchange believes this proposal is consistent with Section 6(b)(5) of the Act[21] because the application of the rule will foster cooperation and coordination with persons engaged in regulating and facilitating transactions by allowing the Exchange to coordinate with other options exchanges to determine whether a market participant that is party to a potentially erroneous transaction on the Exchange established the market in an option on other options exchanges; to the extent this can be established, the Exchange believes such participant's quotes should be excluded in the same way such quotes are excluded on the Exchange. The Exchange also believes it is reasonable to limit the scope of this provision to twenty-five (25) series and to require the party that believes it established the best bid or offer on one

[15] 15 U.S.C. 78f(b).

[16] 15 U.S.C. 78f(b)(5).

[17] *Id.*

[18] *Id.*

[19] *See supra,* note 12.

[20] 15 U.S.C. 78f(b)(5).

[21] 15 U.S.C. 78f(b)(5).

or more other options exchanges to identify to the Exchange the quotes which were submitted by that party and published by other options exchanges. The Exchange believes these limitations are consistent with Section 6(b)(5) of the Act [22] because they will ensure that the Exchange is able to continue to apply the Rule in a timely and organized fashion, thus fostering cooperation and coordination with persons engaged in regulating and facilitating transactions and also removing impediments to and perfecting the mechanism of a free and open market and a national market system.

Finally, with respect to the proposed modification to Commentary .03 to Chapter V, Section 6, the Exchange believes that this proposal is consistent with Section 6(b)(5) of the Act [23] because it specifically provides for nullification where a trading halt exists with respect to an underlying security across the industry (*i.e.,* a regulatory halt) as distinguished from a situation where the primary exchange has experienced a technical issue but the underlying security continues to trade on other equities platforms. The Exchange notes that a similar provision already exists in the rules of certain other options exchanges, and thus, has been found to be consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes the entire proposal is consistent with Section 6(b)(8) of the Act [24] in that it does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act as explained below.

Importantly, the Exchange does not believe that the proposal will impose a burden on intermarket competition but rather that it will alleviate any burden on competition because it is the result of a collaborative effort by all options exchanges to further harmonize and improve the process related to the adjustment and nullification o [sic] erroneous options transactions. The Exchange does not believe that the rules applicable to such process is an area where options exchanges should compete, but rather, that all options exchanges should have consistent rules to the extent possible. Particularly where a market participant trades on several different exchanges and an erroneous trade may occur on multiple markets nearly simultaneously, the Exchange believes that a participant should have a consistent experience with respect to the nullification or adjustment of transactions. To that end, the selection and implementation of a TP Provider utilized by all options exchanges will further reduce the possibility that participants with potentially erroneous transactions that span multiple options exchanges are handled differently on such exchanges. Similarly, the proposed ability to consider quotations invalid on another options exchange if ultimately originating from a party to a potentially erroneous transaction on the Exchange represents a proposal intended to further foster cooperation by the options exchanges with respect to market events. The Exchange understands that all other options exchanges either have or they intend to file proposals that are substantially similar to this proposal.

The Exchange does not believe that the proposed rule change imposes a burden on intramarket competition because the proposed provisions apply to all market participants equally.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act [25] and Rule 19b–4(f)(6) [26] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BX–2017–038 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BX–2017–038. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BX–2017–038, and should be submitted on or before September 5, 2017.

[22] *Id.*

[23] *Id.*

[24] 15 U.S.C. 78f(b)(8).

[25] 15 U.S.C. 78s(b)(3)(A).

[26] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[27] 17 CFR 200.30–3(a)(12).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[27]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–17053 Filed 8–11–17; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81347; File No. SR–ICC–2017–011]

Self-Regulatory Organizations; ICE Clear Credit LLC; Order Granting Accelerated Approval of Proposed Rule Change Relating to the ICC Liquidity Risk Management Framework and the ICC Stress Testing Framework

August 8, 2017.

I. Introduction

On June 28, 2017, ICE Clear Credit LLC (''ICC'' or ''ICE Clear Credit'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change (SR–ICC–2017–011) to revise the ICC Liquidity Risk Management Framework and the ICC Stress Testing Framework. The proposed rule change was published for comment in the **Federal Register** on July 12, 2017.[3] The Commission did not receive comments regarding the proposed changes. For the reasons discussed below, the Commission is approving the proposed rule change on an accelerated basis.

II. Description of the Proposed Rule Change

ICC stated that the proposed revisions to its Liquidity Risk Management Framework and Stress Testing Framework are for the purpose of revising its liquidity monitoring program to enhance compliance with U.S. Commodity Futures Trading Commission (''CFTC'') regulations, including Regulations 39.11, 39.33, and 39.36.[4] ICC represented that the proposed revisions will also facilitate the prompt and accurate clearance and settlement of securities transactions and derivative agreements, contracts, and transactions for which it is responsible. These revisions would not require any changes to the ICC Clearing Rules (''Rules'').

A. Liquidity Risk Management Framework

ICC proposed to reorganize the format of the Liquidity Risk Management Framework to consist of three elements: Liquidity Risk Management Model; Measurement and Monitoring; and Governance. The Regulatory Requirements element, previously included as an element of the framework, would be deleted; however, the regulatory requirements applicable to liquidity risk management would still be referenced in the framework.

1. Liquidity Risk Management Model

ICC proposed to enhance the description of several components of its Liquidity Risk Management Model. As revised, the Liquidity Risk Management Model now includes, but is not limited to, the following components: Currency-Specific Risk Requirements; Acceptable Collateral; Liquidity Requirements; Collateral Valuation Methodology; Investment Strategy; Clearing Participant (''CP'') Deposits as a Liquidity Pool, Liquidity Facilities (including committed repo facilities and committed foreign exchange (''FX'') facilities); and Liquidity Waterfall.

For the Currency-Specific Risk Requirements component, ICC proposed to add language to cross reference ICC's current policy of maintaining cash and collateral assets posted by CPs (on behalf of themselves and/or their clients) to meet currency-specific Initial Margin (''IM'') and Guaranty Fund (''GF'') requirements, to ensure ICC has sufficient total resources in the required currencies of denomination.

With respect to the Liquidity Requirements component,[5] ICC proposed to add a cross reference to ICC's requirement that each CP contribute to the GF a minimum of 20 million wholly in U.S. Dollars (''USD''), which is not a change but rather a restatement of ICC's current rules.[6] Further, ICC proposed revisions to extend ICC's margin risk horizon up to 6-days in order to account for the risk associated with clearing Asia Pacific products. This change would apply throughout the framework.

With respect to the Liquidity Facilities component, ICC proposed revisions to add reference to its committed repurchase facility, consisting of committed repo lines from multiple financial institutions (as opposed to committed repurchase agreements as before), and its recently instituted committed FX facilities for converting USD cash to EUR cash. ICC also proposed removing reference to FX Swaps and Immediate FX Spot Transactions because these arrangements are not committed and therefore are not ''qualifying liquidity resources'' under CFTC Regulation 39.33, according to ICC.[7] ICC also proposed removing reference to the Intercontinental Exchange, Inc. committed line of credit because ICC no longer participates in the arrangement.

In the Liquidity Waterfall component, ICC proposed revisions to its definition of Available Liquidity Resources (''ALR'') to note that ALR consists of the available deposits currently in cash of the required currency of denomination and the cash equivalent of the available deposits in collateral types that ICC can convert to cash, in the required currency of denomination, using all sources of liquidity available to it. For reference, the Liquidity Waterfall classifies ALR on any given day into four levels. Level One includes the House IM and GF cash deposits of the defaulting CP. Level Two includes GF cash deposits of ICC and non-defaulting CPs. Level Three includes House IM cash deposits of the non-defaulting CPs. Level Four includes committed repo facilities and FX facilities, as described above in the changes to the Liquidity Facilities component.

A few of the Liquidity Risk Management Model components would remain the same or substantially the same. The Acceptable Collateral component would remain the same and will note that CPs may post IM and GF deposits that meet ICC's acceptable collateral criteria as described in ICC's Treasury Operations Policies and Procedures and Schedule 401 of the ICC Rules. The Investment Strategy component would remain substantially the same and was proposed to be revised to note that, when beneficial, ICC diversifies its cash investments across multiple depository institutions to reduce its liquidity exposure to any single depository. The CP Deposits as a Liquidity Pool and Collateral Valuation Methodology components also would remain substantially the same.

2. Measurement and Monitoring

With respect to the Measurement and Monitoring element of the Liquidity Risk Management Framework, ICC

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Exchange Act Release No. 34–81132 (July 12, 2017), 82 FR 32895 (July 18, 2017) (SR–ICC–2017–011) (''Notice'').

[4] 17 CFR 39.11; 17 CFR 39.33; 17 CFR 39.36.

[5] The Liquidity Requirements component also reflects the changes to ICC's liquidity thresholds for Euro (''EUR'') denominated products approved by the Commission in rule filing ICC–2017–002. *See* Exchange Act Release No. 34–80324 (Mar. 28, 2017), 82 FR 16244 (Apr. 3, 2017).

[6] *See* Schedule 401 of the ICC Rules.

[7] 17 CFR 39.33.

proposed changes to the Methodology section to change the calculation for ALR. In response to CFTC feedback to ensure consistency with CFTC Regulation 39.33,[8] ICC proposed replacing the estimation of minimum ALR based on risk requirements with the observation of cash and collateral on deposit (excluding cash that will be unavailable by the applicable ICC Payout Deadline because it has been invested by ICC). Accordingly, ICC proposed removing the section from the Liquidity Risk Management Framework which described the process for computing the estimation of minimum ALR. In addition, ICC proposed removing other references throughout the framework related to the estimation of minimum ALR. Thus, under its revised approach, ICC proposed executing stress test analysis by using the amount of liquid assets currently on deposit.

ICC proposed additional changes to the Methodology section. Among other things, the proposed revisions clarify that ICC's measurement and monitoring methodology assesses the adequacy of ICC's established liquidity resources in response to historically observed and hypothetically created (forward looking) scenarios with risk horizons up to and including 6-days. The analyzed scenarios feature assumptions that directly impact the ability of ICC to meet its payment obligations. Based on available IM and GF collateral on deposit on the day of the considered default(s), the analysis determines currency-specific ALR by liquidity waterfall level, and compares these ALRs to the currency-specific Liquidity Obligations resulting from the analyzed scenarios on each day of the considered time horizon. According to ICC, to be conservative, the analysis assumes no client-related ALR and that only the day-1 ALR are available throughout the considered time horizon (*i.e.,* the analysis does not consider ICC's ability during the considered time horizon to liquefy non-cash collateral on deposit or transform the currency of cash on deposit).

In addition, ICC proposed changes to the Historical Analysis section of the Measurement and Monitoring element of the Liquidity Risk Management Framework. ICC proposed adding language to note that, as part of its historical liquidity analysis, ICC analyzes historical data sets to assess the level of liquidity coverage achieved for each currency. Under the revised framework, ICC would continue to conduct a historical liquidity analysis on both an individual affiliate group (''AG'') basis and a cover-2 basis.

ICC also proposed the use of the Basel Traffic Light System[9] to determine if the minimum cash component of its risk requirements truly covers historically observed 1-day liquidity obligations with a 99% level of confidence. ICC's risk requirements are designed to meet at least a 99% N-day VaR equivalent level of coverage. CPs must meet their IM and GF requirements with a minimum cash component equivalent to the 1-day portion of the N-day requirement, computed using the square-root-of-time approach.[10]

ICC proposed additional enhancements to consider the simultaneous default of the two worst-case AGs of CPs, rather than the two worst-case CPs, which, according to ICC, is consistent with CFTC regulations, including CFTC Regulation 39.33(c)(1)(ii).[11] Under the revised framework, when computing a CP's combined house and client origin liquidity obligation for the purposes of selecting which AGs are considered to be in a state of default, ICC proposed to eliminate the application of house origin gains against client origin losses, or house origin losses against client origin gains. This analysis is designed to demonstrate to what extent the liquidity resources available to ICC were sufficient to meet historical single and multi-day cover-2 Liquidity Obligations, consistent with CFTC Regulation 39.33(c)(1)(ii), according to ICC.[12]

ICC also proposed enhancements to note that, for each day of its historical analysis and on a currency specific basis, its Risk Department explores predefined cover-2 scenarios considering the default of the CPs within two AGs creating the largest remaining Liquidity Obligation after applying the IM and GF cash deposits of each constituent CP to that CP's Liquidity Obligation.[13]

ICC proposed clarifying changes to note that the prices considered for historical analysis purposes are ''dirty'' prices as they include riskless (deterministic) payments (*e.g.,* upfront fees, coupon payments, credit event payments, interest on mark-to-market margin). ICC proposed adding explanatory language regarding its calculation of the N-day worst-case cumulative (combined house and client origin) liquidity obligations. ICC also proposed removing a measurement and monitoring framework diagram, representing that the diagram was no longer relevant or necessary in light of the larger changes to the framework.

Finally, ICC proposed revisions to note that ICC reports cover-2 results from the observed immediate liquidity obligation scenarios and the worst-case five-day liquidity obligation scenarios to various audiences, depending on the results. ICC notes that the results should exhibit no deficiencies of the combined resources in Levels One through Four of the Liquidity Waterfall.

ICC proposed changes to the Stress Testing Analysis section of the Measurement and Monitoring element of the Liquidity Risk Management Framework. ICC proposed re-categorizing and adding to the stress testing scenarios. Under the revised approach, ICC would enhance its description of its historically observed extreme but plausible market scenarios to note that the scenarios define spread or price shocks based on observations during specific historical events. The historical data set from which ICC derives the proposed scenarios will continue to begin on April 1, 2007 and include periods of extreme market events such as the Bear Stearns collapse, the Lehman Brothers default, the 2009 Credit Crisis, the US ''Flash Crash'' event, and the European Sovereign Crisis. The scenarios are similar to the stress testing currently performed under the financial resources Stress Testing Framework.

ICC proposed eliminating all scenarios not expected to be realized as market outcomes (*i.e.,* those considered extreme and not plausible). Under the revised approach, ICC would continue to have the ability to execute liquidity analyses based on extreme but not plausible scenarios on an ad-hoc basis. Further, ICC proposed to add 1-day, 2-day, and N-day analogues in place of existing 5-day scenarios. Under the revised framework, each historically observed scenario would have three analogues: one representing a 1-day horizon, one representing a 2-day horizon, and one representing an N-day horizon. Previously, only analogues representing an N-day horizon were considered. The addition of the 1-day analogue would demonstrate ICC's ability to meet its immediate payment obligations over a one-day period (*e.g.,* intraday and same-day obligations),

[8] 17 CFR 39.33.

[9] *See* Basel Committee on Banking Supervision (''BCBS''), Supervisory Framework for the use of ''Backtesting'' in Conjunction with the Internal Models Approach to Market Risk Capital Requirements (Jan. 1996).

[10] *See* BCBS, Amendment to the Capital Accord to Incorporate Market Risk (Jan. 1996).

[11] 17 CFR 39.33(c)(1)(ii).

[12] *Id.*

[13] ICC's cover-2 analysis considers the liquidity resources provided by the defaulting CPs, the GF, IM liquidity resources provided by the non-defaulting CPs and ICC, and any externally available liquidity resources.

while the 2-day and N-day analogues would demonstrate ICC's ability to meet its payment obligations over a multiday period.

ICC also proposed adding a number of hypothetically constructed (forward looking) extreme but plausible market scenarios comprised of a given historically observed extreme but plausible market scenario and additional stress enhancements representing forward looking hypothetical adverse market events. Specifically, two sets of hypothetically constructed (forward looking) extreme but plausible market scenarios were proposed: loss-given default scenarios and one-service-provider-down scenarios. The loss-given default scenarios consider the addition of up to three adverse credit events including the holder of the considered portfolio, one additional CP name, and one additional non-CP name. The one-service-provider-down scenarios consider a reduction in ALR designed to represent ICC's worst-case exposure to a single service provider at which it maintains cash deposits or investments, due to ICC's potential inability to access those deposits and/or investments when required. ICC proposed that the reduction in ALR used in the one-service-provider-down scenarios is based on ICC's analysis of the diversification of its deposits and investments across its multiple service providers. Additionally, ICC proposed revisions to further describe its analysis under the above referenced scenarios.

ICC proposed revisions to consider the simultaneous default of the two worst-case AGs of CPs, rather than the two worst-case CPs, to conform with CFTC regulations, including CFTC Regulation 39.33(c)(1)(ii), as ICC interprets such regulations.[14] Under the proposed revisions, ICC would perform cover-2 analysis in which, for each scenario, it determines the two AGs creating the largest remaining Liquidity Obligation after applying the IM and GF cash deposits of each constituent CP to its own Liquidity Obligation. ICC would compare the remaining Liquidity Obligation of the AG to the remaining liquidity resources to determine if there are sufficient resources to meet the obligation.

ICC proposed enhancements to describe its cover-N analysis in which, for each scenario, it first considers the default of one AG, then the defaults of two AGs, then three AGs, and so forth. The sequence of selecting AGs is based on the remaining Liquidity Obligation associated with the constituent CP's portfolios after applying the IM and GF cash deposits of each constituent CP to its own Liquidity Obligation. AGs are sequenced from largest to smallest remaining Liquidity Obligation. For each set of AGs considered to be in a state of default (1 AG, 2 AGs, 3 AGs, etc.), ICC compares the total remaining Liquidity Obligation to the remaining liquidity resources to determine if there are sufficient resources to meet the obligation. In this way, ICC determines how many AGs it would require to be in a state of default to consume all available liquidity resources.

To determine the Liquidity Obligations in the above analysis, ICC applies the stress scenarios to actual cleared portfolios to determine a currency-specific profit/loss for each CP, representing the largest cumulative loss over the specified risk horizon. The considered profit/loss in the analysis is the sum of the upfront fee changes corresponding to the clean prices associated with the hypothetical scenarios, and excluding the riskless (deterministic) payments.

To determine ICC's liquidity needs for each scenario, ICC's Risk Department computes Liquidity Obligations for futures commission merchant and broker-dealer CPs by combining the net payments for house and client origin accounts. For the purposes of selecting defaulting AGs, ICC's Risk Department does not offset client origin losses with house origin gains, or offset house origin losses with client origin gains.

3. Governance

With respect to the Governance element of the Liquidity Risk Management Framework, the Required Analysis and Interpretation of Results and Potential Actions sections would remain substantially the same. The Model Validation section would be revised to note that the Liquidity Risk Management Framework is under the purview of the Model Validation Framework and subject to initial validations.

In the Materiality and Reporting Framework section, ICC proposed a change that would note that, at each ICC Risk Committee meeting, ICC's Risk Department would provide a summary of historical liquidity analysis and liquidity stress testing analysis intended to demonstrate the adequacy of ICC's liquidity resources to cover Liquidity Obligations over N-days. Such analyses would also include any instance where Level Three resources were required to meet Liquidity Obligations in response to any of the considered historical liquidity or liquidity stress testing scenarios.

Further, ICC proposed revisions to note that, when exceedances of funded and/or unfunded resources are identified, ICC's Risk Department would be required to report them to the senior management team and the ICC Risk Committee, and (i) demonstrate that the breaches do not highlight a significant liquidity risk management weaknesses or (ii) recommend specific liquidity risk management model enhancements that produce an adequate increase in funded and/or unfunded liquidity resources under the identified scenario(s). In addition to the reporting described above, ICC's Risk Department would also report to the ICC Risk Committee any instances where the Basel Traffic Light System categorizes the number of observed exceedances in its individual AG historical analysis as being in the predefined ''red zone.'' In these instances, ICC's Risk Department would discuss with ICC's Risk Committee the appropriateness of its liquidity thresholds, and if appropriate, make revisions.

B. Stress Testing Framework

ICC proposed revisions to its Stress Testing Framework to unify the stress testing scenarios with the liquidity stress testing scenarios set forth in the Liquidity Risk Management Framework. ICC operates its stress testing and liquidity stress testing on a unified set of stress testing scenarios and systems. As such, revisions to the stress testing scenarios are necessary to ensure scenario unification following changes to the Liquidity Risk Management Framework. The proposed revisions are described in detail as follows.

ICC proposed to introduce Risk Factor specific scenarios for all stress test scenarios. Previously, corporate single names were considered at the sector level, as opposed to the Risk Factor level. This change would be reflected throughout the framework.

ICC also proposed to add clarifying language to note that the predefined stress testing scenarios set forth in its Stress Testing Framework would be applied to all cleared instruments, and that name-specific scenarios would be applied to all sovereign and corporate reference entities.

ICC proposed revisions to extend ICC's margin risk horizon up to 6-days, to account for the risk associated with clearing Asia Pacific products. This change would apply throughout the framework.

ICC also proposed to revise its description of the Historically Observed Extreme but Plausible Market Scenarios section to note that the stress spread changes considered as part of each

[14] 17 CFR 39.33(c)(1)(ii).

scenario are extracted from the market history of the most actively traded instrument for the considered Risk Factors.

ICC proposed to revise the Hypothetically Constructed (Forward Looking) Extreme but Plausible Market Scenarios section to ensure consistency with the loss-given default stress scenario set forth in the Liquidity Risk Management Framework, which combines a given historically observed extreme but plausible market scenario with explicit Jump-to-Default events. The proposed revisions specify that there would be up to two reference entities selected for a hypothetical adverse credit event.

Finally, ICC proposed to revise the description of the discordant scenarios (*i.e.,* scenarios under which selected risk factors move in opposite directions) in the Stress Testing Framework to reflect the introduction of Risk Factor specific scenarios. According to ICC, the discordant scenarios are designed to reproduce significant discordant market outcomes observed during the considered historical period. ICC creates discordant scenarios for North American corporate single names and indices; European corporate single names and indices; and sovereign reference entities.

III. Discussion and Commission Findings

Section 19(b)(2)(C) of the Exchange Act directs the Commission to approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of the Exchange Act and the rules and regulations thereunder applicable to such organization.[15] Section 17A(b)(3)(F) of the Exchange Act requires, among other things, that the rules of a registered clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions.[16] Rule 17Ad–22(d)(11) requires, in relevant part, that a registered clearing agency establish default procedures that ensure that the clearing agency can take timely action to contain losses and liquidity pressures and to continue meeting its obligations in the event of a participant default.

The Commission finds that the proposed rule change, which revises ICC's Liquidity Risk Management Framework and makes conforming changes to ICC's Stress Testing Framework, is consistent with Section 17A of the Exchange Act and Rule 17Ad–22(d)(11) thereunder. As represented by ICC, the various elements set forth in the Liquidity Risk Management Framework, and described above, ensure that ICC has sufficient liquidity resources to effectively measure, monitor, and manage its liquidity risk. Further, ICC represented the Liquidity Risk Management Framework supports ICC's ability to maintain sufficient liquid resources in all relevant currencies to effect same-day and, where appropriate, intraday and multiday settlement of payment obligations with a high degree of confidence under a wide range of potential stress scenarios. ICC represented that changes to the Stress Testing Framework were necessary following recent changes to the Liquidity Risk Management Framework, as ICC operates its stress testing and liquidity stress testing on a unified set of stress testing scenarios and systems. ICC stated that its stress testing practices will continue to ensure the adequacy of systemic risk protections. ICC represented that the revised stress test scenarios set forth in the Stress Testing Framework will continue to ensure that ICC maintains sufficient financial resources to withstand a default by the CP family to which it has the largest exposure in extreme but plausible market conditions. The Commission therefore believes that the proposed revisions to the ICC Liquidity Risk Management Framework and Stress Testing Framework are designed to promote the prompt and accurate settlement of securities transactions, derivatives agreements, contracts, and transactions for which ICC is responsible, consistent with Section 17A(b)(3)(F) of the Exchange Act. Furthermore, for similar reasons, the Commission finds that the proposed revisions are consistent with the requirements of Rule 17Ad–22(d)(11).

Section 19(b)(2)(C)(iii) of the Exchange Act allows the Commission to approve a proposed rule change earlier than 30 days after the date of publication of the notice of the proposed rule change in the **Federal Register** where the Commission finds good cause for so doing and publishes the reason for the finding.[17] In its filing, ICC requested that the Commission approve the proposed rule change on an accelerated basis for good cause shown. ICC represented that the amendments to ICC's Liquidity Risk Management Framework and Stress Testing Framework set forth in the proposed rule change further ICC's compliance with CFTC regulations. The Commission also notes that the CFTC is the supervisory agency for ICC under Section 803(8)(A)(ii) of the Payment, Clearing, and Settlement Supervision Act of 2010.[18] Based on the foregoing, the Commission finds that good cause exists to approve the proposed rule change on an accelerated basis pursuant to Section 19(b)(2)(C)(iii) of the Exchange Act.

IV. Conclusion

It is therefore ordered pursuant to Section 19(b)(2) of the Exchange Act that the proposed rule change (SR–ICC–2017–011) be, and hereby is, approved on an accelerated basis.[19]

For the Commission by the Division of Trading and Markets, pursuant to delegated authority.[20]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–17052 Filed 8–11–17; 8:45 am]

BILLING CODE 8011–01–P

[15] 15 U.S.C. 78s(b)(2)(C).

[16] 15 U.S.C. 78q–1(b)(3)(F).

[17] 15 U.S.C. 78s(b)(2)(C)(iii).

[18] 12 U.S.C. 5462(8)(A)(ii).

[19] In approving the proposed rule change, the Commission considered the proposal's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[20] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81351; File No. SR–BOX–2017–25]

Self-Regulatory Organizations; BOX Options Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend BOX Rule 7170 (Nullification and Adjustment of Options Transactions Including Obvious Errors)

August 8, 2017.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 3, 2017, BOX Options Exchange LLC (the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend BOX Rule 7170 (Nullification and Adjustment of Options Transactions including Obvious Errors). The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's Internet Web site at *http://boxexchange.com*.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange and other options exchanges recently adopted a new, harmonized rule related to the adjustment and nullification of erroneous options transactions, including a specific provision related to coordination in connection with large-scale events involving erroneous options transactions.[3] The Exchange believes that the changes the options exchanges implemented with the new, harmonized rule have led to increased transparency and finality with respect to the adjustment and nullification of erroneous options transactions. However, as part of the initial initiative, the Exchange and other options exchanges deferred a few specific matters for further discussion. Specifically, as described in the Initial Filing, the Exchange and all other options exchanges have been working to further improve the review of potentially erroneous transactions as well as their subsequent adjustment by creating an objective and universal way to determine Theoretical Price in the event a reliable NBBO is not available. Because this initiative required additional exchange and industry discussion as well as additional time for development and implementation, the Exchange and the other options exchanges determined to proceed with the Initial Filing and to undergo a secondary initiative to complete any additional improvements to the applicable rule. In this filing, the Exchange proposes to adopt procedures that will lead to a more objective and uniform way to determine Theoretical Price in the event a reliable NBBO is not available. In addition to this change, the Exchange has proposed two additional minor changes to its rules. The Exchange's proposal mirrors that of Bats BZX, which the Commission approved on July 6, 2017,[4] and those that the other options exchanges intend to file, except that it omits the section of the proposal that pertains to trading halts due to the fact that IM–7080–3 already includes the applicable language.

Calculation of Theoretical Price Using a Third Party Provider

Under the harmonized rule, when reviewing a transaction as potentially erroneous, the Exchange needs to first determine the ''Theoretical Price'' of the option, *i.e.,* the Exchange's estimate of the correct market price for the option. Pursuant to Rule 7170, if the applicable option series is traded on at least one other options exchange, then the Theoretical Price of an option series is the last national best bid (''NBB'') just prior to the trade in question with respect to an erroneous sell transaction or the last national best offer (''NBO'') just prior to the trade in question with respect to an erroneous buy transaction unless one of the exceptions described below exists. Thus, whenever the Exchange has a reliable NBB or NBO, as applicable, just prior to the transaction, then the Exchange uses this NBB or NBO as the Theoretical Price.

The Rule also contains various provisions governing specific situations where the NBB or NBO is not available or may not be reliable. Specifically, the Rule specifies situations in which there are no quotes or no valid quotes for comparison purposes, when the national best bid or offer (''NBBO'') is determined to be too wide to be reliable, and at the open of trading on each trading day. In each of these circumstances, in turn, because the NBB or NBO is not available or is deemed to be unreliable, the Exchange determines Theoretical Price. Under the current Rule, when determining Theoretical Price, Exchange personnel generally consult and refer to data such as the prices of related series, especially the closest strikes in the option in question. Exchange personnel may also take into account the price of the underlying security and the volatility characteristics of the option as well as historical pricing of the option and/or similar options. Although the Rule is administered by experienced personnel and the Exchange believes the process is currently appropriate, the Exchange recognizes that it is also subjective and could lead to disparate results for a transaction that spans multiple options exchanges.

The Exchange proposes to adopt IM–7170–5 to specify how the Exchange will determine Theoretical Price when required by sub-paragraphs (b)(1)–(3) of the Rule (*i.e.,* at the open, when there are no valid quotes or when there is a wide quote). In particular, the Exchange has been working with other options exchanges to identify and select a reliable third party vendor (''TP Provider'') that would provide Theoretical Price to the Exchange whenever one or more transactions is under review pursuant to Rule 7170 and the NBBO is unavailable or deemed unreliable pursuant to Rule 7170(b). The Exchange and other options exchanges have selected CBOE Livevol, LLC (''Livevol'') as the TP Provider, as described below. As further described below, proposed IM–7170–5 would codify the use of the TP Provider as well as limited exceptions where the Exchange would be able to deviate from the Theoretical Price given by the TP Provider.

Pursuant to proposed IM–7170–5, when the Exchange must determine Theoretical Price pursuant to the sub-paragraphs (b)(1)–(3) of the Rule, the Exchange will request Theoretical Price from the third party vendor to which the Exchange and all other options exchanges have subscribed. Thus, as set forth in this proposed language, Theoretical Price would be provided to the Exchange by the TP Provider on request and not through a streaming data feed.[5] This language also makes clear that the Exchange and all other options exchanges will use the same TP Provider.

[3] *See* Securities Exchange Act Release No. 74556 (March 20, 2015), 80 FR 16031 (March 26, 2015) (SR–BATS–2014–067); *see also* Securities Exchange Act Release No. 73884 (December 18, 2014), 79 FR 77557 (December 24, 2014) (the ''Initial Filing'').

[4] *See* Securities Exchange Act Release No. 34–81084 (July 6, 2017) (granting approval of Bats BZX proposal), 82 FR 32216 (July 12, 2017); 82 FR 23684 (May 23, 2017) (SR–BatsBZX–2017–035) (notice of filing of Bats BZX proposal).

[5] Though the Exchange and other options exchanges considered a streaming feed, it was determined that it would be more feasible to develop and implement an on demand service and that such a service would satisfy the goals of the initiative.

As noted above, the proposed TP Provider selected by the Exchange and other options exchanges is Livevol. The Exchange proposes to codify this selection in proposed paragraph (d) to IM–7170–5. As such, the Exchange would file a rule proposal and would provide notice to the options industry of any proposed change to the TP Provider.

The Exchange and other options exchanges have selected Livevol as the proposed TP Provider after diligence into various alternatives. Livevol has, since 2009, been the options industry leader in providing equity and index options market data and analytics services.[6] The Exchange believes that Livevol has established itself within the options industry as a trusted provider of such services and notes that it and all other options exchanges already subscribe to various Livevol services. In connection with this proposal, Livevol will develop a new tool based on its existing technology and services that will supply Theoretical Price to the Exchange and other options exchanges upon request. The Theoretical Price tool will leverage current market data and surrounding strikes to assist in a relative value pricing approach to generating a Theoretical Price. When relative value methods are incapable of generating a valid Theoretical Price, the Theoretical Price tool will utilize historical trade and quote data to calculate Theoretical Price.

Because the purpose of the proposal is to move away from a subjective determination by Exchange personnel when the NBBO is unavailable or unreliable, the Exchange intends to use the Theoretical Price provided by the TP Provider in all such circumstances. However, the Exchange believes it is necessary to retain the ability to contact the TP Provider if it believes that the Theoretical Price provided is fundamentally incorrect and to determine the Theoretical Price in the limited circumstance of a systems issue experienced by the TP Provider, as described below.

As proposed, to the extent an Official[7] of the Exchange believes that the Theoretical Price provided by the TP Provider is fundamentally incorrect and cannot be used consistent with the maintenance of a fair and orderly market, the Official shall contact the TP Provider to notify the TP Provider of the reason the Official believes such Theoretical Price is inaccurate and to request a review and correction of the calculated Theoretical Price. For example, if an Official received from the TP Provider a Theoretical Price of $80 in a series that the Official might expect to be instead in the range of $8 to $10 because of a recent corporate action in the underlying, the Official would request that the TP Provider review and confirm its calculation and determine whether it had appropriately accounted for the corporate action. In order to ensure that other options exchanges that may potentially be relying on the same Theoretical Price that, in turn, the Official believes to be fundamentally incorrect, the Exchange also proposes to promptly provide notice to other options exchanges that the TP Provider has been contacted to review and correct the calculated Theoretical Price at issue and to include a brief explanation of the reason for the request.[8] Although not directly addressed by the proposed Rule, the Exchange expects that all other options exchanges once in receipt of this notification would await the determination of the TP Provider and would use the corrected price as soon as it is available. The Exchange further notes that it expects the TP Provider to cooperate with, but to be independent of, the Exchange and other options exchanges.[9]

The Exchange believes that the proposed provision to allow an Official to contact the TP Provider if he or she believes the provided Theoretical Price is fundamentally incorrect is necessary, particularly because the Exchange and other options exchanges will be using the new process for the first time. Although the exchanges have conducted thorough diligence with respect to Livevol as the selected TP Provider and would do so with any potential replacement TP Provider, the Exchange is concerned that certain scenarios could arise where the Theoretical Price generated by the TP Provider does not take into account relevant factors and would result in an unfair result for market participants involved in a transaction. The Exchange notes that if such situations do indeed arise, to the extent practicable the Exchange will also work with the TP Provider and other options exchanges to improve the TP Provider's calculation of Theoretical Price in future situations. For instance, if the Exchange determines that a particular type of corporate action is not being appropriately captured by the TP Provider when such provider is generating Theoretical Price, while the Exchange believes that it needs the ability to request a review and correction of the Theoretical Price in connection with a specific review in order to provide a timely decision to market participants, the Exchange would share information regarding the specific situation with the TP Provider and other options exchanges in an effort to improve the Theoretical Price service for future use. The Exchange notes that it does not anticipate needing to rely on this provision frequently, if at all, but believes the provision is necessary nonetheless to best prepare for all potential circumstances. Further, the Theoretical Price used by the Exchange in connection with its rulings will always be that received from the TP Provider and the Exchange has not proposed the ability to deviate from such price.[10]

Pursuant to proposed paragraph (c) of IM–7170–5, an Official of the Exchange may determine the Theoretical Price if the TP Provider has experienced a systems issue that has rendered its services unavailable to accurately calculate Theoretical Price and such issue cannot be corrected in a timely manner. The Exchange notes that it does not anticipate needing to rely on this provision frequently, if at all, but believes the provision is necessary nonetheless to best prepare for all potential circumstances. Further, consistent with existing text in Rule 7170(e)(4), the Exchange has not proposed a specific time by which the service must be available in order to be considered timely.[11] The Exchange expects that it would await the TP Provider's services becoming available again so long as the Exchange was able to obtain information regarding the issue and the TP Provider had a reasonable expectation of being able to

[6] The Exchange notes that in 2015, Livevol was acquired by CBOE Holdings, Inc., the ultimate parent company of the Chicago Board Options Exchange (''CBOE'') and C2 Options Exchange (''C2'').

[7] For purposes of the Rule, an Official is an Officer of the Exchange or such other employee designee of the Exchange that is trained in the application of Rule 7170.

[8] *See* proposed paragraph (b) to IM–7170–5.

[9] The Exchange expects any TP Provider selected by the Exchange and other options exchanges to act independently in its determination and calculation of Theoretical Price. With respect to Livevol specifically, the Exchange again notes that Livevol is a subsidiary of CBOE Holdings, Inc., which is also the ultimate parent company of multiple options exchanges. The Exchange expects Livevol to calculate Theoretical Price independent of its affiliated exchanges in the same way it will calculate Theoretical Price independent of non-affiliated exchanges.

[10] To the extent the TP Provider has been contacted by an Official of the Exchange, reviews the Theoretical Price provided but disagrees that there has been any error, then the Exchange would be bound to use the Theoretical Price provided by the TP Provider.

[11] In the context of a Significant Market Event, the Exchange may determine, ''in consultation with other options exchanges . . . that timely adjustment is not feasible due to the extraordinary nature of the situation.'' *See* Rule 7170(e)(4).

resume normal operations within the next several hours based on communications with the TP Provider. More specifically with respect to Livevol, Livevol has business continuity and disaster recovery procedures that will help to ensure that the Theoretical Price tool remains available or, in the event of an outage, that service is restored in a timely manner.

The Exchange also notes that if a wide-scale event occurred, even if such event did not qualify as a ''Significant Market Event'' pursuant to Rule 7170(e), and the TP Provider was unavailable or otherwise experiencing difficulty, the Exchange believes that it and other options exchanges would seek to coordinate to the extent possible. In particular, the Exchange and other options exchanges now have a process, administered by the Options Clearing Corporation, to invoke a discussion amongst all options exchanges in the event of any widespread or significant market events. The Exchange believes that this process could be used in the event necessary if there were an issue with the TP Provider.

The Exchange also proposes to adopt language in paragraph (d) of IM–7170–5 to disclaim the liability of the Exchange and the TP Provider in connection with the proposed Rule, the TP Provider's calculation of Theoretical Price, and the Exchange's use of such Theoretical Price. Specifically, the proposed rule would state that neither the Exchange, the TP Provider, nor any affiliate of the TP Provider (the TP Provider and its affiliates are referred to collectively as the ''TP Provider''), makes any warranty, express or implied, as to the results to be obtained by any person or entity from the use of the TP Provider pursuant to IM–7170–5. The proposed rule would further state that the TP Provider does not guarantee the accuracy or completeness of the calculated Theoretical Price and that the TP Provider disclaims all warranties of merchantability or fitness for a particular purpose or use with respect to such Theoretical Price. Finally, the proposed Rule would state that neither the Exchange nor the TP Provider shall have any liability for any damages, claims, losses (including any indirect or consequential losses), expenses, or delays, whether direct or indirect, foreseen or unforeseen, suffered by any person arising out of any circumstance or occurrence relating to the use of such Theoretical Price or arising out of any errors or delays in calculating such Theoretical Price. This proposed language is modeled after existing language in Exchange Rules regarding ''reporting authorities'' that calculate indices.[12]

In connection with the proposed change described above, the Exchange proposes to modify Rule 7170 to state that the Exchange will rely on paragraph (b) and IM–7170–5 when determining Theoretical Price.

No Valid Quotes—Market Participant Quoting on Multiple Exchanges

As described above, one of the times where the NBB or NBO is deemed to be unreliable for purposes of Theoretical Price is when there are no quotes or no valid quotes for the affected series. In addition to when there are no quotes, the Exchange does not consider the following to be valid quotes: (i) All quotes in the applicable option series published at a time where the last NBB is higher than the last NBO in such series (a ''crossed market''); (ii) quotes published by the Exchange that were submitted by either party to the transaction in question; and (iii) quotes published by another options exchange against which the Exchange has declared self-help. In recognition of today's market structure where certain participants actively provide liquidity on multiple exchanges simultaneously, the Exchange proposes to add an additional category of invalid quotes. Specifically, in order to avoid a situation where a market participant has established the market at an erroneous price on multiple exchanges, the Exchange proposes to consider as invalid the quotes in a series published by another options exchange if either party to the transaction in question submitted the quotes in the series representing such options exchange's best bid or offer. Thus, similar to being able to ignore for purposes of the Rule the quotes published by the Exchange if submitted by either party to the transaction in question, the Exchange would be able to ignore for purposes of the rule quotations on other options exchanges by that same market participant.

In order to continue to apply the Rule in a timely and organized fashion, however, the Exchange proposes to initially limit the scope of this proposed provision in two ways. First, because the process will take considerable coordination with other options exchanges to confirm that the quotations in question on an away options exchange were indeed submitted by a party to a transaction on the Exchange, the Exchange proposes to limit this provision to apply to up to twenty-five (25) total options series (*i.e.,* whether such series all relate to the same underlying security or multiple underlying securities). Second, the Exchange proposes to require the party that believes it established the best bid or offer on one or more other options exchanges to identify to the Exchange the quotes which were submitted by such party and published by other options exchanges. In other words, as proposed, the burden will be on the party seeking that the Exchange disregard their quotations on other options exchanges to identify such quotations. In turn, the Exchange will verify with such other options exchanges that such quotations were indeed submitted by such party.

Below are examples of both the current rule and the rule as proposed to be amended.

Example 1—Current Rule, Participant Erroneously Quotes on One Exchange

Assumptions

For purposes of this example, assume the following:

- A Participant acting as a Market Maker on the Exchange (''Market Maker A'') is quoting in twenty series of options underlying security ABCD on the Exchange (and only the Exchange).
- Market Maker A makes an error in calculating the market for options on ABCD, and publishes quotes in all twenty series to buy options at $1.00 and to sell options at $1.05.
- In fact, options on ABCD in these series are nearly worthless and no other market participant is quoting in such series.
- Therefore, the NBBO in the twenty series at issue is $1.00 × $1.05 (with the Exchange representing the NBBO based on Market Maker A's quotes).
- Assume Participant A immediately enters sell orders and executes against Market Maker A's quotes at $1.00.
- Assume Market Maker A submits to the Exchange a timely request for review of the trades with Participant A as potentially erroneous transactions to buy.

Result

- Based on the Exchange's current rules, the Exchange would identify Market Maker A as a participant to the trades at issue and would consider Market Maker A's quotations invalid pursuant to Rule 7170(b)(2).
- As there were no other valid quotes to use as a reference price, the Exchange would then determine Theoretical Price.
- Assume the Exchange determines a Theoretical Price of $0.05.

[12] *See, e.g.,* Rule 6110, which relates to index options potentially listed and traded on the Exchange and disclaims liability for a reporting authority and their affiliates.

○ The execution price of $1.00 exceeds the $0.25 minimum amount set forth in the Exchange's table to determine whether an obvious error has occurred (*i.e.,* $0.05 + $0.25 = $0.30) so any execution at or above this price is an obvious error.

○ Accordingly, the executions in all series would be adjusted by the Exchange to executions at $0.20 per contract (Theoretical Price of $0.05 plus $0.15) to the extent the incoming orders submitted by Participant A were non-Customer orders.

○ The executions in all series would be nullified to the extent the incoming orders submitted by Participant A were Customer orders.

Example 2—Current Rule, Participant Erroneously Quotes on Multiple Exchanges

Assumptions

For purposes of this example, assume the following:

• A Participant acting as a Market Maker on the Exchange (''Market Maker A'') is quoting in twenty series of options underlying security ABCD on the Exchange and on a second exchange (''Away Exchange'').

• Market Maker A makes an error in calculating the market for options on ABCD, and publishes quotes on both the Exchange and the Away Exchange in all twenty series to buy options at $1.00 and to sell options at $1.05.

• In fact, options on ABCD in these series are nearly worthless and no other market participant is quoting in such series.

• Therefore, the NBBO in the twenty series at issue is $1.00 × $1.05 (with the Exchange and the Away Exchange representing the NBBO based on Market Maker A's quotes).

• Assume Participant A immediately enters sell orders and executes against Market Maker A's quotes at $1.00.

• Assume Market Maker A submits to the Exchange and to the Away Exchange timely requests for review of the trades with Participant A as potentially erroneous transactions to buy.

Result

• Based on the Exchange's current rules, the Exchange would identify Market Maker A as a participant to the trades at issue and would consider Market Maker A's quotations on the Exchange invalid pursuant to Rule 7170(b)(2). The Exchange, however, would view the Away Exchange's quotations as valid, and would thus determine Theoretical Price to be $1.05 (*i.e.,* the NBO in the case of a potentially erroneous buy transaction).

• The execution price of $1.00 does not exceed the $0.25 minimum amount set forth in the Exchange's table to determine whether an obvious error has occurred (*i.e.,* $1.05 + $0.25 = $1.30) so any execution at or above this price is an obvious error.

• The transactions on the Exchange would not be nullified or adjusted.

• As the Exchange and all other options exchanges have identical rules with respect to the process described above, the transactions on the Away Exchange would not be nullified or adjusted.

Example 3—Proposed Rule, Participant Erroneously Quotes on Multiple Exchanges [13]

Assumptions

For purposes of this example, assume the following:

• A Participant acting as a Market Maker on the Exchange (''Market Maker A'') is quoting in twenty series of options underlying security ABCD on the Exchange and on a second exchange (''Away Exchange'').[14]

• Market Maker A makes an error in calculating the market for options on ABCD, and publishes quotes on both the Exchange and the Away Exchange in all twenty series to buy options at $1.00 and to sell options at $1.05.

• In fact, options on ABCD in these series are nearly worthless and no other market participant is quoting in such series.

• Therefore, the NBBO in the twenty series at issue is $1.00 × $1.05 (with the Exchange and the Away Exchange representing the NBBO based on Market Maker A's quotes).

• Assume Participant A immediately enters sell orders and executes against Market Maker A's quotes at $1.00.

• Assume Market Maker A submits to the Exchange and to the Away Exchange timely requests for review of the trades with Participant A as potentially erroneous transactions to buy. At the time of submitting the requests for review to the Exchange and the Away Exchange, Market Maker A identifies to the Exchange the quotes on the Away Exchange as quotes also represented by Market Maker A (and to the Away Exchange, the quotes on the Exchange as quotes also represented by Market Maker A).

Result

• Based on the proposed rules, the Exchange would identify Market Maker A as a participant to the trades at issue and would consider Market Maker A's quotations on the Exchange invalid pursuant to Rule 7170(b)(2).

• The Exchange and the Away Exchange would also coordinate to confirm that the quotations identified by Market Maker A on the other exchange were indeed Market Maker A's quotations. Once confirmed, each of the Exchange and the Away Exchange would also consider invalid the quotations published on the other exchange.

• As there were no other valid quotes to use as a reference price, the Exchange would then determine Theoretical Price.

• Assume the Exchange determines a Theoretical Price of $0.05.

○ The execution price of $1.00 exceeds the $0.25 minimum amount set forth in the Exchange's table to determine whether an obvious error has occurred (*i.e.,* $0.05 + $0.25 = $0.30) so any execution at or above this price is an obvious error.

○ Accordingly, the executions in all series would be adjusted by the Exchange to executions at $0.20 per contract (Theoretical Price of $0.05 plus $0.15) to the extent the incoming orders submitted by Participant A were non-Customer orders.

○ The executions in all series would be nullified to the extent the incoming orders submitted by Participant A were Customer orders.

• As the Exchange and all other options exchanges would have identical rules with respect to the process described above, as other options exchanges intend to adopt the same rule if the proposed rule is approved, the transactions on the Away Exchange would also be nullified or adjusted as set forth above.

• If this example was instead modified such that Market Maker A was quoting in 200 series rather than 20, the Exchange notes that Market Maker A could only request that the Exchange consider as invalid their quotations in 25 of those series on other exchanges. As noted above, the Exchange has proposed to limit the proposed rule to 25 series in order to continue to process requests for review in a timely and organized fashion in order to provide certainty to market participants. This is due to the amount of coordination that will be necessary in such a scenario to confirm that the quotations in question on an away options exchange were indeed submitted by a party to a transaction on the Exchange.

[13] The Exchange notes that its proposed rule will not impact the proposed handling of a request for review where a market participant is quoting only on the Exchange, thus, the Exchange has not included a separate example for such a fact-pattern.

[14] The Exchange notes that the proposed rule would operate the same if Market Maker A was quoting on more than two exchanges. The Exchange has limited the example to two exchanges for simplicity.

Implementation Date

The Exchange proposes to delay the operative date of this proposal to a date within ninety (90) days after the Commission approved the Bats BZX proposal on July 6, 2017. The Exchange will announce the operative date in a Regulatory Circular made available to its Participants.

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[15] in general, and Section 6(b)(5) of the Act,[16] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. In particular, the Exchange believes that the proposal to utilize a TP Provider in the event the NBBO is unavailable or unreliable will provide greater transparency and clarity with respect to the adjustment and nullification of erroneous options transactions. Particularly, the proposed changes seek to achieve consistent results for participants across U.S. options exchanges while maintaining a fair and orderly market, protecting investors and protecting the public interest. Thus, the Exchange believes that the proposal is consistent with Section 6(b)(5) of the Act[17] in that the proposed Rule will foster cooperation and coordination with persons engaged in regulating and facilitating transactions.

The Exchange again reiterates that it has retained the standard of the current rule for most reviews of options transactions pursuant to Rule 7170, which is to rely on the NBBO to determine Theoretical Price if such NBBO can reasonably be relied upon. The proposal to use a TP Provider when the NBBO is unavailable or unreliable is consistent with Section 6(b)(5) of the Act[18] in that the proposed Rule will foster cooperation and coordination with persons engaged in regulating and facilitating transactions by further reducing the possibility of disparate results between options exchanges and increasing the objectivity of the application of Rule 7170. Further, the Exchange believes that the proposed Rule is transparent with respect to the limited circumstances under which the Exchange will request a review and correction of Theoretical Price from the TP Provider, and has sought to limit such circumstances as much as possible. The Exchange notes that under the current Rule, Exchange personnel are required to determine Theoretical Price in certain circumstances and yet rarely do so because such circumstances have already been significantly limited under the harmonized rule (for example, because the wide quote provision of the harmonized rule only applies if the quote was narrower and then gapped but does not apply if the quote had been persistently wide). Thus, the Exchange believes it will need to request Theoretical Price from the TP Provider only in very rare circumstances and in turn, the Exchange anticipates that the need to contact the TP Provider for additional review of the Theoretical Price provided by the TP Provider will be even rarer. Similarly, the Exchange believes it is unlikely that an Exchange Official will ever be required to determine Theoretical Price, as such circumstance would only be in the event of a systems issue that has rendered the TP Provider's services unavailable and such issue cannot be corrected in a timely manner.

The Exchange also believes its proposal to adopt language in paragraph (d) of IM–7170–5 to disclaim the liability of the Exchange and the TP Provider in connection with the proposed Rule, the TP Provider's calculation of Theoretical Price, and the Exchange's use of such Theoretical Price is consistent with the Act. As noted above, this proposed language is modeled after existing language in Exchange Rules regarding ''reporting authorities'' that calculate indices,[19] and is consistent with Section 6(b)(5) of the Act[20] in that the proposed Rule will foster cooperation and coordination with persons engaged in regulating and facilitating transactions.

As described above, the Exchange proposes a modification to the valid quotes provision to also exclude quotes in a series published by another options exchange if either party to the transaction in question submitted the orders or quotes in the series representing such options exchange's best bid or offer. The Exchange believes this proposal is consistent with Section 6(b)(5) of the Act[21] because the application of the rule will foster cooperation and coordination with persons engaged in regulating and facilitating transactions by allowing the Exchange to coordinate with other options exchanges to determine whether a market participant that is party to a potentially erroneous transaction on the Exchange established the market in an option on other options exchanges; to the extent this can be established, the Exchange believes such participant's quotes should be excluded in the same way such quotes are excluded on the Exchange. The Exchange also believes it is reasonable to limit the scope of this provision to twenty-five (25) series and to require the party that believes it established the best bid or offer on one or more other options exchanges to identify to the Exchange the quotes which were submitted by that party and published by other options exchanges. The Exchange believes these limitations are consistent with Section 6(b)(5) of the Act[22] because they will ensure that the Exchange is able to continue to apply the Rule in a timely and organized fashion, thus fostering cooperation and coordination with persons engaged in regulating and facilitating transactions and also removing impediments to and perfecting the mechanism of a free and open market and a national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act as explained below.

Importantly, the Exchange does not believe that the proposal will impose a burden on intermarket competition but rather that it will alleviate any burden on competition because it is the result of a collaborative effort by all options exchanges to further harmonize and improve the process related to the adjustment and nullification of erroneous options transactions. The Exchange does not believe that the rules applicable to such process is an area where options exchanges should compete, but rather, that all options exchanges should have consistent rules to the extent possible. Particularly where a market participant trades on several different exchanges and an erroneous trade may occur on multiple markets nearly simultaneously, the Exchange believes that a participant should have a consistent experience with respect to the nullification or

[15] 15 U.S.C. 78f(b).

[16] 15 U.S.C. 78f(b)(5).

[17] *Id.*

[18] *Id.*

[19] *See supra,* note 12.

[20] 15 U.S.C. 78f(b)(5).

[21] 15 U.S.C. 78f(b)(5).

[22] 15 U.S.C. 78f(b)(5).

adjustment of transactions. To that end, the selection and implementation of a TP Provider utilized by all options exchanges will further reduce the possibility that participants with potentially erroneous transactions that span multiple options exchanges are handled differently on such exchanges. Similarly, the proposed ability to consider quotations invalid on another options exchange if ultimately originating from a party to a potentially erroneous transaction on the Exchange represents a proposal intended to further foster cooperation by the options exchanges with respect to market events. The Exchange understands that all other options exchanges intend to file proposals that are substantially similar to this proposal.

The Exchange does not believe that the proposed rule change imposes a burden on intramarket competition because the proposed provisions apply to all market participants equally.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act [23] and Rule 19b–4(f)(6) [24] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BOX–2017–25 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BOX–2017–25. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BOX–2017–25, and should be submitted on or before September 5, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–17066 Filed 8–11–17; 8:45 am]

BILLING CODE 8011–01–P

[23] 15 U.S.C. 78s(b)(3)(A).

[24] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[25] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81353; File No. SR–MRX–2017–16]

Self-Regulatory Organizations; Nasdaq MRX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 720, Nullification and Adjustment of Options Transactions Including Obvious Errors

August 8, 2017.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 3, 2017, Nasdaq MRX, LLC (''MRX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 720, Nullification and Adjustment of Options Transactions including Obvious Errors.

While these amendments are effective upon filing, the Exchange has designated the proposed amendments to be operative on a date that is within ninety (90) days after the Commission approved a similar proposal filed by Bats BZX on July 6, 2017.

The text of the proposed rule change is available on the Exchange's Web site at *www.ise.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange and other options exchanges recently adopted a new, harmonized rule related to the adjustment and nullification of erroneous options transactions, including a specific provision related to coordination in connection with large-scale events involving erroneous options transactions.[3] The Exchange believes that the changes the options exchanges implemented with the new, harmonized rule have led to increased transparency and finality with respect to the adjustment and nullification of erroneous options transactions. However, as part of the initial initiative, the Exchange and other options exchanges deferred a few specific matters for further discussion. Specifically, as described in the Initial Filing, the Exchange and all other options exchanges have been working to further improve the review of potentially erroneous transactions as well as their subsequent adjustment by creating an objective and universal way to determine Theoretical Price in the event a reliable NBBO is not available. Because this initiative required additional exchange and industry discussion as well as additional time for development and implementation, the Exchange and the other options exchanges determined to proceed with the Initial Filing and to undergo a secondary initiative to complete any additional improvements to the applicable rule. In this filing, the Exchange proposes to adopt procedures that will lead to a more objective and uniform way to determine Theoretical Price in the event a reliable NBBO is not available. In addition to this change, the Exchange has proposed two additional minor changes to its rules. The Exchange's proposal mirrors that of Bats BZX, which the Exchange [sic] approved on July 6, 2017,[4] and those that the other options exchanges intend to file, except that it omits the section of the proposal that pertains to trading halts due to the fact that the Supplementary Material to Exchange Rule 702 already includes the applicable language.

Calculation of Theoretical Price Using a Third Party Provider

Under the harmonized rule, when reviewing a transaction as potentially erroneous, the Exchange needs to first determine the ''Theoretical Price'' of the option, *i.e.,* the Exchange's estimate of the correct market price for the option. Pursuant to Rule 720, if the applicable option series is traded on at least one other options exchange, then the Theoretical Price of an option series is the last national best bid (''NBB'') just prior to the trade in question with respect to an erroneous sell transaction or the last national best offer (''NBO'') just prior to the trade in question with respect to an erroneous buy transaction unless one of the exceptions described below exists. Thus, whenever the Exchange has a reliable NBB or NBO, as applicable, just prior to the transaction, then the Exchange uses this NBB or NBO as the Theoretical Price.

The Rule also contains various provisions governing specific situations where the NBB or NBO is not available or may not be reliable. Specifically, the Rule specifies situations in which there are no quotes or no valid quotes for comparison purposes, when the national best bid or offer (''NBBO'') is determined to be too wide to be reliable, and at the open of trading on each trading day. In each of these circumstances, in turn, because the NBB or NBO is not available or is deemed to be unreliable, the Exchange determines Theoretical Price. Under the current Rule, when determining Theoretical Price, Exchange personnel generally consult and refer to data such as the prices of related series, especially the closest strikes in the option in question. Exchange personnel may also take into account the price of the underlying security and the volatility characteristics of the option as well as historical pricing of the option and/or similar options. Although the Rule is administered by experienced personnel and the Exchange believes the process is currently appropriate, the Exchange recognizes that it is also subjective and could lead to disparate results for a transaction that spans multiple options exchanges.

The Exchange proposes to adopt Supplementary Material to Rule 720, Item .04 to specify how the Exchange will determine Theoretical Price when required by sub-paragraphs (b)(1)–(3) of the Rule (*i.e.,* at the open, when there are no valid quotes or when there is a wide quote). In particular, the Exchange has been working with other options exchanges to identify and select a reliable third party vendor (''TP Provider'') that would provide Theoretical Price to the Exchange whenever one or more transactions is under review pursuant to Rule 720 and the NBBO is unavailable or deemed unreliable pursuant to Rule 720(b). The Exchange and other options exchanges have selected CBOE Livevol, LLC (''Livevol'') as the TP Provider, as described below. As further described below, proposed Supplementary Material to Rule 720, Item .04 would codify the use of the TP Provider as well as limited exceptions where the Exchange would be able to deviate from the Theoretical Price given by the TP Provider.

Pursuant to proposed Supplementary Material to Rule 720, Item .04, when the Exchange must determine Theoretical Price pursuant to the sub-paragraphs (b)(1)–(3) of the Rule, the Exchange will request Theoretical Price from the third party vendor to which the Exchange and all other options exchanges have subscribed. Thus, as set forth in this proposed language, Theoretical Price would be provided to the Exchange by the TP Provider on request and not through a streaming data feed.[5] This language also makes clear that the Exchange and all other options exchanges will use the same TP Provider.

As noted above, the proposed TP Provider selected by the Exchange and other options exchanges is Livevol. The Exchange proposes to codify this selection in proposed paragraph (d) to Supplementary Material to Rule 720, Item .04. As such, the Exchange would file a rule proposal and would provide notice to the options industry of any proposed change to the TP Provider.

The Exchange and other options exchanges have selected Livevol as the proposed TP Provider after diligence into various alternatives. Livevol has, since 2009, been the options industry

[3] The Exchange's application for registration as a national securities exchange, ss [sic] approved by the Commission, incorporated the changes made previously by the other options exchanges. *See* Securities Exchange Act Release No. 34–76998 (January 29, 2016); 81 FR 6066 (Feb. 4, 2016) (the ''Initial Filing'').

[4] *See* Securities Exchange Act Release No. 34–81084 (July 6, 2017) (granting approval of Bats BZX proposal), 82 FR 32216 (July 12, 2017); 82 FR 23684 (May 23, 2017) (SR–BatsBZX–2017–035) (notice of filing of Bats BZX proposal).

[5] Though the Exchange and other options exchanges considered a streaming feed, it was determined that it would be more feasible to develop and implement an on demand service and that such a service would satisfy the goals of the initiative.

leader in providing equity and index options market data and analytics services.[6] The Exchange believes that Livevol has established itself within the options industry as a trusted provider of such services and notes that it and all other options exchanges already subscribe to various Livevol services. In connection with this proposal, Livevol will develop a new tool based on its existing technology and services that will supply Theoretical Price to the Exchange and other options exchanges upon request. The Theoretical Price tool will leverage current market data and surrounding strikes to assist in a relative value pricing approach to generating a Theoretical Price. When relative value methods are incapable of generating a valid Theoretical Price, the Theoretical Price tool will utilize historical trade and quote data to calculate Theoretical Price.

Because the purpose of the proposal is to move away from a subjective determination by Exchange personnel when the NBBO is unavailable or unreliable, the Exchange intends to use the Theoretical Price provided by the TP Provider in all such circumstances. However, the Exchange believes it is necessary to retain the ability to contact the TP Provider if it believes that the Theoretical Price provided is fundamentally incorrect and to determine the Theoretical Price in the limited circumstance of a systems issue experienced by the TP Provider, as described below.

As proposed, to the extent an Official[7] of the Exchange believes that the Theoretical Price provided by the TP Provider is fundamentally incorrect and cannot be used consistent with the maintenance of a fair and orderly market, the Official shall contact the TP Provider to notify the TP Provider of the reason the Official believes such Theoretical Price is inaccurate and to request a review and correction of the calculated Theoretical Price. For example, if an Official received from the TP Provider a Theoretical Price of $80 in a series that the Official might expect to be instead in the range of $8 to $10 because of a recent corporate action in the underlying, the Official would request that the TP Provider review and confirm its calculation and determine whether it had appropriately accounted for the corporate action. In order to ensure that other options exchanges that may potentially be relying on the same Theoretical Price that, in turn, the Official believes to be fundamentally incorrect, the Exchange also proposes to promptly provide notice to other options exchanges that the TP Provider has been contacted to review and correct the calculated Theoretical Price at issue and to include a brief explanation of the reason for the request.[8] Although not directly addressed by the proposed Rule, the Exchange expects that all other options exchanges once in receipt of this notification would await the determination of the TP Provider and would use the corrected price as soon as it is available. The Exchange further notes that it expects the TP Provider to cooperate with, but to be independent of, the Exchange and other options exchanges.[9]

The Exchange believes that the proposed provision to allow an Official to contact the TP Provider if he or she believes the provided Theoretical Price is fundamentally incorrect is necessary, particularly because the Exchange and other options exchanges will be using the new process for the first time. Although the exchanges have conducted thorough diligence with respect to Livevol as the selected TP Provider and would do so with any potential replacement TP Provider, the Exchange is concerned that certain scenarios could arise where the Theoretical Price generated by the TP Provider does not take into account relevant factors and would result in an unfair result for market participants involved in a transaction. The Exchange notes that if such situations do indeed arise, to the extent practicable the Exchange will also work with the TP Provider and other options exchanges to improve the TP Provider's calculation of Theoretical Price in future situations. For instance, if the Exchange determines that a particular type of corporate action is not being appropriately captured by the TP Provider when such provider is generating Theoretical Price, while the Exchange believes that it needs the ability to request a review and correction of the Theoretical Price in connection with a specific review in order to provide a timely decision to market participants, the Exchange would share information regarding the specific situation with the TP Provider and other options exchanges in an effort to improve the Theoretical Price service for future use. The Exchange notes that it does not anticipate needing to rely on this provision frequently, if at all, but believes the provision is necessary nonetheless to best prepare for all potential circumstances. Further, the Theoretical Price used by the Exchange in connection with its rulings will always be that received from the TP Provider and the Exchange has not proposed the ability to deviate from such price.[10]

Pursuant to proposed paragraph (c) to Supplementary Material to Rule 720, Item .04, an Official of the Exchange may determine the Theoretical Price if the TP Provider has experienced a systems issue that has rendered its services unavailable to accurately calculate Theoretical Price and such issue cannot be corrected in a timely manner. The Exchange notes that it does not anticipate needing to rely on this provision frequently, if at all, but believes the provision is necessary nonetheless to best prepare for all potential circumstances. Further, consistent with existing text in Rule 720(e)(4), the Exchange has not proposed a specific time by which the service must be available in order to be considered timely.[11] The Exchange expects that it would await the TP Provider's services becoming available again so long as the Exchange was able to obtain information regarding the issue and the TP Provider had a reasonable expectation of being able to resume normal operations within the next several hours based on communications with the TP Provider. More specifically with respect to Livevol, Livevol has business continuity and disaster recovery procedures that will help to ensure that the Theoretical Price tool remains available or, in the event of an outage, that service is restored in a timely manner.

The Exchange also notes that if a wide-scale event occurred, even if such

[6] The Exchange notes that in 2015, Livevol was acquired by CBOE Holdings, Inc., the ultimate parent company of the Chicago Board Options Exchange (''CBOE'') and C2 Options Exchange (''C2'').

[7] For purposes of the Rule, an Official is an Officer of the Exchange or such other employee designee of the Exchange that is trained in the application of this Rule. *See* Rule 720(a)(3).

[8] *See* proposed paragraph (b) to Supplementary Material to Rule 720, Item .04.

[9] The Exchange expects any TP Provider selected by the Exchange and other options exchanges to act independently in its determination and calculation of Theoretical Price. With respect to Livevol specifically, the Exchange again notes that Livevol is a subsidiary of CBOE Holdings, Inc., which is also the ultimate parent company of multiple options exchanges. The Exchange expects Livevol to calculate Theoretical Price independent of its affiliated exchanges in the same way it will calculate Theoretical Price independent of non-affiliated exchanges.

[10] To the extent the TP Provider has been contacted by an Official of the Exchange, reviews the Theoretical Price provided but disagrees that there has been any error, then the Exchange would be bound to use the Theoretical Price provided by the TP Provider.

[11] In the context of a Significant Market Event, the Exchange may determine, ''in consultation with other options exchanges . . . that timely adjustment is not feasible due to the extraordinary nature of the situation.'' *See* Rule 720(e)(4).

event did not qualify as a ''Significant Market Event'' pursuant to Rule 720(e), and the TP Provider was unavailable or otherwise experiencing difficulty, the Exchange believes that it and other options exchanges would seek to coordinate to the extent possible. In particular, the Exchange and other options exchanges now have a process, administered by the Options Clearing Corporation, to invoke a discussion amongst all options exchanges in the event of any widespread or significant market events. The Exchange believes that this process could be used in the event necessary if there were an issue with the TP Provider.

The Exchange also proposes to adopt language in paragraph (d) of Supplementary Material to Rule 720, Item .04 to Rule 720 to disclaim the liability of the Exchange and the TP Provider in connection with the proposed Rule, the TP Provider's calculation of Theoretical Price, and the Exchange's use of such Theoretical Price. Specifically, the proposed rule would state that neither the Exchange, the TP Provider, nor any affiliate of the TP Provider (the TP Provider and its affiliates are referred to collectively as the ''TP Provider''), makes any warranty, express or implied, as to the results to be obtained by any person or entity from the use of the TP Provider pursuant to Supplementary Material to Rule 720, Item .04. The proposed rule would further state that the TP Provider does not guarantee the accuracy or completeness of the calculated Theoretical Price and that the TP Provider disclaims all warranties of merchantability or fitness for a particular purpose or use with respect to such Theoretical Price. Finally, the proposed Rule would state that neither the Exchange nor the TP Provider shall have any liability for any damages, claims, losses (including any indirect or consequential losses), expenses, or delays, whether direct or indirect, foreseen or unforeseen, suffered by any person arising out of any circumstance or occurrence relating to the use of such Theoretical Price or arising out of any errors or delays in calculating such Theoretical Price. This proposed language is modeled after existing language in Exchange Rules regarding ''reporting authorities'' that calculate indices.[12]

In connection with the proposed change described above, the Exchange proposes to modify Rule 720 to state that the Exchange will rely on paragraph (b) and Supplementary Material to Rule 720, Item .04 when determining Theoretical Price.

No Valid Quotes—Market Participant Quoting on Multiple Exchanges

As described above, one of the times where the NBB or NBO is deemed to be unreliable for purposes of Theoretical Price is when there are no quotes or no valid quotes for the affected series. In addition to when there are no quotes, the Exchange does not consider the following to be valid quotes: (i) All quotes in the applicable option series published at a time where the last NBB is higher than the last NBO in such series (a ''crossed market''); (ii) quotes published by the Exchange that were submitted by either party to the transaction in question; and (iii) quotes published by another options exchange against which the Exchange has declared self-help. In recognition of today's market structure where certain participants actively provide liquidity on multiple exchanges simultaneously, the Exchange proposes to add an additional category of invalid quotes. Specifically, in order to avoid a situation where a market participant has established the market at an erroneous price on multiple exchanges, the Exchange proposes to consider as invalid the quotes in a series published by another options exchange if either party to the transaction in question submitted the quotes in the series representing such options exchange's best bid or offer. Thus, similar to being able to ignore for purposes of the Rule the quotes published by the Exchange if submitted by either party to the transaction in question, the Exchange would be able to ignore for purposes of the rule quotations on other options exchanges by that same market participant.

In order to continue to apply the Rule in a timely and organized fashion, however, the Exchange proposes to initially limit the scope of this proposed provision in two ways. First, because the process will take considerable coordination with other options exchanges to confirm that the quotations in question on an away options exchange were indeed submitted by a party to a transaction on the Exchange, the Exchange proposes to limit this provision to apply to up to twenty-five (25) total options series (*i.e.,* whether such series all relate to the same underlying security or multiple underlying securities). Second, the Exchange proposes to require the party that believes it established the best bid or offer on one or more other options exchanges to identify to the Exchange the quotes which were submitted by such party and published by other options exchanges. In other words, as proposed, the burden will be on the party seeking that the Exchange disregard their quotations on other options exchanges to identify such quotations. In turn, the Exchange will verify with such other options exchanges that such quotations were indeed submitted by such party.

Below are examples of both the current rule and the rule as proposed to be amended.

Example 1—Current Rule, Member Erroneously Quotes on One Exchange

Assumptions

For purposes of this example, assume the following:

- A Member acting as a Market Maker on the Exchange (''Market Maker A'') is quoting in twenty series of options underlying security ABCD on the Exchange (and only the Exchange).
- Market Maker A makes an error in calculating the market for options on ABCD, and publishes quotes in all twenty series to buy options at $1.00 and to sell options at $1.05.
- In fact, options on ABCD in these series are nearly worthless and no other market participant is quoting in such series.
- Therefore, the NBBO in the twenty series at issue is $1.00 × $1.05 (with the Exchange representing the NBBO based on Market Maker A's quotes).
- Assume Member A immediately enters sell orders and executes against Market Maker A's quotes at $1.00.
- Assume Market Maker A submits to the Exchange a timely request for review of the trades with Member A as potentially erroneous transactions to buy.

Result

- Based on the Exchange's current rules, the Exchange would identify Market Maker A as a participant to the trades at issue and would consider Market Maker A's quotations invalid pursuant to Rule 720(b)(2).
- As there were no other valid quotes to use as a reference price, the Exchange would then determine Theoretical Price.
- Assume the Exchange determines a Theoretical Price of $0.05.
- The execution price of $1.00 exceeds the $0.25 minimum amount set forth in the Exchange's table to determine whether an obvious error has occurred (*i.e.,* $0.05 + $0.25 = $0.30) so any execution at or above this price is an obvious error.
- Accordingly, the executions in all series would be adjusted by the

[12] *See, e.g.,* ISE Rule 2011, which is incorporated by reference into the MRX rules and which relates to index options potentially listed and traded on the Exchange and disclaim [sic] liability for a reporting authority and their affiliates.

Exchange to executions at $0.20 per contract (Theoretical Price of $0.05 plus $0.15) to the extent the incoming orders submitted by Member A were non-Customer orders.

• The executions in all series would be nullified to the extent the incoming orders submitted by Member A were Customer orders.

Example 2—Current Rule, Member Erroneously Quotes on Multiple Exchanges

Assumptions

For purposes of this example, assume the following:

• A Member acting as a Market Maker on the Exchange (''Market Maker A'') is quoting in twenty series of options underlying security ABCD on the Exchange and on a second exchange (''Away Exchange'').

• Market Maker A makes an error in calculating the market for options on ABCD, and publishes quotes on both the Exchange and the Away Exchange in all twenty series to buy options at $1.00 and to sell options at $1.05.

• In fact, options on ABCD in these series are nearly worthless and no other market participant is quoting in such series.

• Therefore, the NBBO in the twenty series at issue is $1.00 × $1.05 (with the Exchange and the Away Exchange representing the NBBO based on Market Maker A's quotes).

• Assume Member A immediately enters sell orders and executes against Market Maker A's quotes at $1.00.

• Assume Market Maker A submits to the Exchange and to the Away Exchange timely requests for review of the trades with Member A as potentially erroneous transactions to buy.

Result

• Based on the Exchange's current rules, the Exchange would identify Market Maker A as a participant to the trades at issue and would consider Market Maker A's quotations on the Exchange invalid pursuant to Rule 720(b)(2). The Exchange, however, would view the Away Exchange's quotations as valid, and would thus determine Theoretical Price to be $1.05 (*i.e.,* the NBO in the case of a potentially erroneous buy transaction).

• The execution price of $1.00 does not exceed the $0.25 minimum amount set forth in the Exchange's table to determine whether an obvious error has occurred (*i.e.,* $1.05 + $0.25 = $1.30) so any execution at or above this price is an obvious error.

• The transactions on the Exchange would not be nullified or adjusted.

• As the Exchange and all other options exchanges have identical rules with respect to the process described above, the transactions on the Away Exchange would not be nullified or adjusted.

Example 3—Proposed Rule, Member Erroneously Quotes on Multiple Exchanges [13]

Assumptions

For purposes of this example, assume the following:

• A Member acting as a Market Maker on the Exchange (''Market Maker A'') is quoting in twenty series of options underlying security ABCD on the Exchange and on a second exchange (''Away Exchange'').[14]

• Market Maker A makes an error in calculating the market for options on ABCD, and publishes quotes on both the Exchange and the Away Exchange in all twenty series to buy options at $1.00 and to sell options at $1.05.

• In fact, options on ABCD in these series are nearly worthless and no other market participant is quoting in such series.

• Therefore, the NBBO in the twenty series at issue is $1.00 × $1.05 (with the Exchange and the Away Exchange representing the NBBO based on Market Maker A's quotes).

• Assume Member A immediately enters sell orders and executes against Market Maker A's quotes at $1.00.

• Assume Market Maker A submits to the Exchange and to the Away Exchange timely requests for review of the trades with Member A as potentially erroneous transactions to buy. At the time of submitting the requests for review to the Exchange and the Away Exchange, Market Maker A identifies to the Exchange the quotes on the Away Exchange as quotes also represented by Market Maker A (and to the Away Exchange, the quotes on the Exchange as quotes also represented by Market Maker A).

Result

• Based on the proposed rules, the Exchange would identify Market Maker A as a participant to the trades at issue and would consider Market Maker A's quotations on the Exchange invalid pursuant to Rule 720(b)(2).

• The Exchange and the Away Exchange would also coordinate to confirm that the quotations identified by Market Maker A on the other exchange were indeed Market Maker A's quotations. Once confirmed, each of the Exchange and the Away Exchange would also consider invalid the quotations published on the other exchange.

• As there were no other valid quotes to use as a reference price, the Exchange would then determine Theoretical Price.

• Assume the Exchange determines a Theoretical Price of $0.05.

• The execution price of $1.00 exceeds the $0.25 minimum amount set forth in the Exchange's table to determine whether an obvious error has occurred (*i.e.,* $0.05 + $0.25 = $0.30) so any execution at or above this price is an obvious error.

• Accordingly, the executions in all series would be adjusted by the Exchange to executions at $0.20 per contract (Theoretical Price of $0.05 plus $0.15) to the extent the incoming orders submitted by Member A were non-Customer orders.

• The executions in all series would be nullified to the extent the incoming orders submitted by Member A were Customer orders.

• As the Exchange and all other options exchanges would have identical rules with respect to the process described above, as other options exchanges intend to adopt the same rule if the proposed rule is approved, the transactions on the Away Exchange would also be nullified or adjusted as set forth above.

• If this example was instead modified such that Market Maker A was quoting in 200 series rather than 20, the Exchange notes that Market Maker A could only request that the Exchange consider as invalid their quotations in 25 of those series on other exchanges. As noted above, the Exchange has proposed to limit the proposed rule to 25 series in order to continue to process requests for review in a timely and organized fashion in order to provide certainty to market participants. This is due to the amount of coordination that will be necessary in such a scenario to confirm that the quotations in question on an away options exchange were indeed submitted by a party to a transaction on the Exchange.

Implementation Date

The Exchange proposes to delay the operative date of this proposal to a date within ninety (90) days after the Commission approved the Bats BZX proposal on July 6, 2017. The Exchange will announce the operative date in a

[13] The Exchange notes that its proposed rule will not impact the proposed handling of a request for review where a market participant is quoting only on the Exchange, thus, the Exchange has not included a separate example for such a fact pattern.

[14] The Exchange notes that the proposed rule would operate the same if Market Maker A was quoting on more than two exchanges. The Exchange has limited the example to two exchanges for simplicity.

Regulatory Alert made available to its Members.

2. Statutory Basis

The Exchange believes that its proposal is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.[15] Specifically, the proposal is consistent with Section 6(b)(5) of the Act[16] because it would promote just and equitable principles of trade, remove impediments to, and perfect the mechanism of, a free and open market and a national market system, and, in general, protect investors and the public interest.

As described above, the Exchange and other options exchanges are seeking to further modify their harmonized rules related to the adjustment and nullification of erroneous options transactions. The Exchange believes that the proposal to utilize a TP Provider in the event the NBBO is unavailable or unreliable will provide greater transparency and clarity with respect to the adjustment and nullification of erroneous options transactions. Particularly, the proposed changes seek to achieve consistent results for participants across U.S. options exchanges while maintaining a fair and orderly market, protecting investors and protecting the public interest. Thus, the Exchange believes that the proposal is consistent with Section 6(b)(5) of the Act[17] in that the proposed Rule will foster cooperation and coordination with persons engaged in regulating and facilitating transactions.

The Exchange again reiterates that it has retained the standard of the current rule for most reviews of options transactions pursuant to Rule 720, which is to rely on the NBBO to determine Theoretical Price if such NBBO can reasonably be relied upon. The proposal to use a TP Provider when the NBBO is unavailable or unreliable is consistent with Section 6(b)(5) of the Act[18] in that the proposed Rule will foster cooperation and coordination with persons engaged in regulating and facilitating transactions by further reducing the possibility of disparate results between options exchanges and increasing the objectivity of the application of Rule 720. Further, the Exchange believes that the proposed Rule is transparent with respect to the limited circumstances under which the Exchange will request a review and correction of Theoretical Price from the TP Provider, and has sought to limit such circumstances as much as possible. The Exchange notes that under the current Rule, Exchange personnel are required to determine Theoretical Price in certain circumstances and yet rarely do so because such circumstances have already been significantly limited under the harmonized rule (for example, because the wide quote provision of the harmonized rule only applies if the quote was narrower and then gapped but does not apply if the quote had been persistently wide). Thus, the Exchange believes it will need to request Theoretical Price from the TP Provider only in very rare circumstances and in turn, the Exchange anticipates that the need to contact the TP Provider for additional review of the Theoretical Price provided by the TP Provider will be even rarer. Similarly, the Exchange believes it is unlikely that an Exchange Official will ever be required to determine Theoretical Price, as such circumstance would only be in the event of a systems issue that has rendered the TP Provider's services unavailable and such issue cannot be corrected in a timely manner.

The Exchange also believes its proposal to adopt language in paragraph (d) of Supplementary Material to Rule 720, Item .04 to Rule 720 to disclaim the liability of the Exchange and the TP Provider in connection with the proposed Rule, the TP Provider's calculation of Theoretical Price, and the Exchange's use of such Theoretical Price is consistent with the Act. As noted above, this proposed language is modeled after existing language in Exchange Rules regarding ''reporting authorities'' that calculate indices,[19] and is consistent with Section 6(b)(5) of the Act[20] in that the proposed Rule will foster cooperation and coordination with persons engaged in regulating and facilitating transactions.

As described above, the Exchange proposes a modification to the valid quotes provision to also exclude quotes in a series published by another options exchange if either party to the transaction in question submitted the orders or quotes in the series representing such options exchange's best bid or offer. The Exchange believes this proposal is consistent with Section 6(b)(5) of the Act[21] because the application of the rule will foster cooperation and coordination with persons engaged in regulating and facilitating transactions by allowing the Exchange to coordinate with other options exchanges to determine whether a market participant that is party to a potentially erroneous transaction on the Exchange established the market in an option on other options exchanges; to the extent this can be established, the Exchange believes such participant's quotes should be excluded in the same way such quotes are excluded on the Exchange. The Exchange also believes it is reasonable to limit the scope of this provision to twenty-five (25) series and to require the party that believes it established the best bid or offer on one or more other options exchanges to identify to the Exchange the quotes which were submitted by that party and published by other options exchanges. The Exchange believes these limitations are consistent with Section 6(b)(5) of the Act[22] because they will ensure that the Exchange is able to continue to apply the Rule in a timely and organized fashion, thus fostering cooperation and coordination with persons engaged in regulating and facilitating transactions and also removing impediments to and perfecting the mechanism of a free and open market and a national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes the entire proposal is consistent with Section 6(b)(8) of the Act[23] in that it does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act as explained below.

Importantly, the Exchange does not believe that the proposal will impose a burden on intermarket competition but rather that it will alleviate any burden on competition because it is the result of a collaborative effort by all options exchanges to further harmonize and improve the process related to the adjustment and nullification o [sic] erroneous options transactions. The Exchange does not believe that the rules applicable to such process is an area where options exchanges should compete, but rather, that all options exchanges should have consistent rules to the extent possible. Particularly where a market participant trades on several different exchanges and an erroneous trade may occur on multiple markets nearly simultaneously, the Exchange believes that a participant should have a consistent experience with respect to the nullification or

[15] 15 U.S.C. 78f(b).

[16] 15 U.S.C. 78f(b)(5).

[17] *Id.*

[18] *Id.*

[19] *See supra,* note 12.

[20] 15 U.S.C. 78f(b)(5).

[21] 15 U.S.C. 78f(b)(5).

[22] *Id.*

[23] 15 U.S.C. 78f(b)(8).

adjustment of transactions. To that end, the selection and implementation of a TP Provider utilized by all options exchanges will further reduce the possibility that participants with potentially erroneous transactions that span multiple options exchanges are handled differently on such exchanges. Similarly, the proposed ability to consider quotations invalid on another options exchange if ultimately originating from a party to a potentially erroneous transaction on the Exchange represents a proposal intended to further foster cooperation by the options exchanges with respect to market events. The Exchange understands that all other options exchanges either have or they intend to file proposals that are substantially similar to this proposal.

The Exchange does not believe that the proposed rule change imposes a burden on intramarket competition because the proposed provisions apply to all market participants equally.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act [24] and subparagraph (f)(6) of Rule 19b–4 thereunder.[25]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MRX–2017–16 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–MRX–2017–16. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MRX–2017–16, and should be submitted on or before September 5, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–17068 Filed 8–11–17; 8:45 am]

BILLING CODE 8011–01–P

[24] 15 U.S.C. 78s(b)(3)(A)(iii).

[25] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[26] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81339; File No. SR–NSCC–2017–011]

Self-Regulatory Organizations; National Securities Clearing Corporation; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Make Certain Adjustments, Clarifications and Corrections to the Fee Provisions for Insurance and Retirement Processing Services

August 8, 2017.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 3, 2017, National Securities Clearing Corporation (''NSCC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the clearing agency. NSCC filed the proposed rule change pursuant to Section 19(b)(3)(A) [3] of the Act and subparagraphs (f)(2) [4] and (f)(4) [5] of Rule 19b–4 thereunder so that the proposal was effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change would make certain adjustments, clarifications and corrections to the fee provisions for NSCC's Insurance and Retirement Processing Services (''I&RS'') set forth in Addendum A (Fee Structure) (''Addendum A'') of NSCC's Rules & Procedures (''Rules''), as described below.[6]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(2).

[5] 17 CFR 240.19b–4(f)(4).

[6] Capitalized terms not defined herein are defined in the Rules, available at *http://www.dtcc.com/~/media/Files/Downloads/legal/rules/nscc_rules.pdf.*

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

NSCC is proposing to make adjustments, clarifications and corrections to the fee provisions for I&RS set forth in Addendum A, as described below, in order to (i) align the fees charged more closely with the costs of providing the associated products and services to Members and Limited Members of NSCC (collectively, ''NSCC Members''); (ii) allocate those fees equitably among NSCC Members; and (iii) make the Rules more consistent and clear with respect to these fees.

(i) Proposed Changes to Fees

NSCC is proposing to make the following changes to fees set forth in Section IV.K. of Addendum A:

A. Proposed Change to Fees for Multiple Destination Files

NSCC currently charges NSCC Members an additional monthly fee for directing NSCC to deliver I&RS files to more than two destinations.[7] NSCC added the additional monthly fees for multiple destinations in 2016 to align the fees charged with the cost of providing products and services to NSCC Members with multiple file destinations.[8] Currently, the Rules state that NSCC charges an additional $50 per month for delivering files to three to four destinations and an additional $100 per month for delivering files to five or more destinations.[9] NSCC has determined that charging an additional $50 monthly fee for NSCC Members that send files to five destinations is sufficient to allow NSCC to recover costs to NSCC of delivering files to such multiple destinations. Therefore, NSCC is proposing to amend its fee structure so that NSCC Members that direct NSCC to deliver files to five destinations would be charged an additional $50 per month rather than an additional $100 per month. As such, NSCC is proposing to change the additional fees charged for delivering files to multiple destinations, as described in Section IV.K. of Addendum A, to charge an additional $50 per month for delivering files to three to five destinations, and an additional $100 per month for delivering files to more than five destinations.

B. Proposed Change to Fees for Positions for Retirement Plans Files

NSCC is proposing to add a fee for the Positions for Retirement Plans file type into the billing tier for the Positions and Valuations service (''Positions'') in Section IV.K. of Addendum A.[10] Pursuant to Section 5 of Rule 57, NSCC Members can send four file types using Positions—Positions Full, Positions New, Positions for Retirement Plans, and Positions Focused.[11] In 2009, NSCC created two billing tiers for Positions, with one fee for Positions Full and Positions New, and a reduced fee charged for Positions Focused.[12] The fees charged for processing Positions Focused file types are lower because these files include less data than other Positions file types.[13] In 2015, NSCC introduced a new file type for Positions—Positions for Retirement Plans. This file type is a full data file type, similar to the Positions Full and Positions New file types.

Therefore, NSCC is now proposing to amend Addendum A to add a fee for the Positions for Retirement Plans file type that is identical to the fee for the Positions Full and Positions New file types. NSCC believes this proposed change would align the fees for processing the Positions for Retirement Plans file type with the costs of delivering this service because the costs of processing the Positions for Retirement Plans file type are similar to the cost of processing the Positions Full and Positions New file types.

C. Proposed Change to Fees for Positions Focused

As stated above, NSCC amended Addendum A in the 2009 Fee Filing to change the fees to be charged for processing the Positions Full, Positions New, and Positions Focused file types.[14] The 2009 Fee Filing incorrectly amended Addendum A to state that NSCC would charge $1.50 per 1,000 items for processing Positions Focused files from 2,000,001 to 4,000,000 items per month.[15] NSCC management had previously determined that, in order to align the fee charged with the cost of providing this service, the fee for processing Positions Focused files from 2,000,001 to 4,000,000 items per month should be $1.00 per 1,000 items.[16] Therefore, NSCC is proposing to correct this error and amend Addendum A to provide that NSCC would charge $1.00 per 1,000 items for processing Positions Focused files from 2,000,001 to 4,000,000 items per month.

D. Proposed Change to Fees for APP Non-Settlement Tiers

NSCC is proposing to modify the fee structure for the Initial Application Information feature of I&RS (''APP'') in order to align the fees charged to settling NSCC Members with the fees charged to non-settling NSCC Members. In 2003, NSCC established two categories for the fee structure for APP—a category for settling NSCC Members and a separate category for non-settling NSCC Members.[17] When the fee structure was implemented in 2003, the fees charged to settling NSCC Members were higher than the fees charged to non-settling NSCC Members and the category for settling NSCC Members contained three tiers while the category for non-settling NSCC Members contained two tiers.[18] In the 2009 Fee Filing, NSCC reduced the fees applicable to settling NSCC Members for APP resulting in the fees in the first two tiers being identical to the fees in the tiers for the non-settling

[7] Note 6 to Section IV.K. of Addendum A, *supra* note 6.

[8] Securities Exchange Act Release No. 76787 (December 29, 2015), 81 FR 283 (January 5, 2016) (File No. SR–NSCC–2015–009).

[9] Note 6 to Section IV.K. of Addendum A, *supra* note 6.

[10] Section IV.K. of Addendum A, *supra* note 6.

[11] Rule 57, *supra* note 6.

[12] Securities Exchange Act Release No. 59285 (January 23, 2009), 74 FR 5875 (February 2, 2009) (File No. SR–NSCC–2008–13) (''2009 Fee Filing'').

[13] Subsection 2.a.(ii), Section IV.K. of Addendum A, *supra* note 6.

[14] 2009 Fee Filing, *supra* note 12.

[15] Subsection 2.a.(ii), Section IV.K. of Addendum A, *supra* note 6. NSCC's Important Notice announcing the 2009 fee changes identified the intended price for this tier at $1.00 per 1,000 items. *See* NSCC Important Notice, ''2009 Fee Revisions,'' A# 6766, P&S# 6336, dated December 31, 2008, *available at http://www.dtcc.com/~/media/Files/pdf/2008/12/31/a6766.pdf.*

[16] A fee of $1.00 per 1,000 items for processing Positions Focused files from 2,000,001 to 4,000,000 items per month was approved by the NSCC Core Services Operations and Planning Committee on November 13, 2008.

[17] *See* Securities Exchange Act Release No. 48284 (August 5, 2003), 68 FR 48430 (August 13, 2003) (File No. SR–NSCC–2003–13).

[18] *See id.* The fees for settling NSCC Members contained three tiers: (1) 0–1,999 items per month, (2) 2,000–3,499 items per month and (3) more than 3,499 per month. The fees for non-settling NSCC Members contained only two tiers: (1) 0–1,999 items per month, and (2) more than 1,999 items per month.

NSCC Members.[19] In addition, in the 2009 Fee Filing, NSCC reduced the fees in the third tier for settling NSCC Members. The result of these changes is that currently, settling NSCC Members that process more than 3,499 items a month receive a discount per item while non-settling NSCC Members do not.[20]

NSCC believes the discount tier for processing more than 3,499 items a month was not added in the category for non-settling NSCC Members because these firms are unlikely to process transactions with more than 1,999 items per month and a tier for processing more items per month above 1,999 was unnecessary. Although NSCC believes it is unlikely that non-settling NSCC Members will process more than 1,999 items per month, NSCC is proposing to remove the separate fee categories for settling and non-settling NSCC Members in order to provide that the same fees apply to both settling NSCC Members and non-settling NSCC Members. The cost to NSCC for processing APP files for settling NSCC Members and non-settling NSCC Members is the same. Therefore, NSCC proposes to amend subsection 2.d. of Section IV.K of Addendum A to provide non-settling NSCC Members with the same discount that settling NSCC Members receive if they process more than 3,499 items per month.

(ii) Proposed Changes to the Organization of Addendum A

NSCC is also proposing to make the following changes to the organization of Section IV.K. of Addendum A, as described below:

A. Proposed Change to Location of Fees for Producer Management Portal

NSCC is proposing to revise Addendum A, Section IV.K., by deleting subsection 4. and moving the fees under the heading ''Batch Service Fees'' in that subsection to subsection 2.h.[21] These fees would be renamed ''Distributor Batch Service Fees.'' These fees are charged in connection with use of the Producer Management Portal and are only charged to NSCC Members that are distributors, which include broker-dealers, banks and insurance agencies that act as intermediaries for insurance companies. The proposed change would include these fees with the other fees charged for use of the Producer Management Portal, so such fees are identified in one section, and would further clarify that these fees are only charged to distributors. This proposed change would clarify this section of Addendum A, and would not change the fees charged for any services or products.

B. Proposed Change to Location of Fees Listed Under TIER 6

NSCC is proposing to revise Addendum A, Section IV.K., subsection 3., by deleting TIER 6, and moving each of the fees listed under this TIER into TIERS 3 and 5 based on the fees being charged.[22] As a result of the proposed change, each product would be listed together with other products for which the same fee is being charged under one TIER.[23] The proposed rule change would move fees for ''Values Inquiry'' and ''Policy Administration Inquiry'' to TIER 3 and move fees for ''Policy Administration Request,'' ''Death Notification Request,'' ''Fund Transfer,'' ''Withdrawals,'' and ''Arrangements'' to TIER 5. Each of the fees moved from TIER 6 would be identified as being subject to the ''In Force Transaction Chart,'' which is currently set forth at the end of subsection 3., and would continue to apply to these fees. This proposed change would clarify this subsection of Addendum A, and would not change the fees charged for any services or products.

2. Statutory Basis

Section 17A(b)(3)(D) of the Act requires, in part, that the Rules provide for the equitable allocation of reasonable dues, fees, and other charges among its participants.[24]

The proposed changes to Addendum A set forth in item II(A)(1)(i)(A) above are consistent with 17A(b)(3)(D) of the Act[25] because the proposed fees would be equitably allocated among NSCC Members based on each NSCC Member's utilization of directing NSCC to send files to multiple destinations. In addition, NSCC believes that the proposed fee changes are reasonable because the proposed $50 additional fee is less than the $100 additional fee currently charged for delivering to five destinations, while continuing to allow NSCC to recover the costs associated with delivering to five destinations. Therefore, NSCC believes the proposed fee modifications set forth in item II(A)(1)(i)(A) above are consistent with the requirements of Section 17A(b)(3)(D) of the Act.[26]

The proposed changes to Addendum A set forth in items II(A)(1)(i)(B) and (D) above are consistent with 17A(b)(3)(D) of the Act[27] because the proposed fees would be allocated equitably among the NSCC Members that subscribe for those services based on each NSCC Member's use of such services. In addition, NSCC believes that the proposed fees are reasonable because they would enable NSCC to better align its revenue with the costs and expenses required for NSCC to provide the services to NSCC Members. Specifically, with respect to II(A)(1)(i)(B), the costs of processing the Positions for Retirement Plans file type are similar to the cost of processing other full data file types and NSCC has determined that charging the same fee as is charged for other full data file types would enable it to recover its costs for processing the Positions for Retirement Plans file type. With respect to II(A)(1)(i)(D), the cost to NSCC of processing over 3,499 items per month in APP is the same for settling NSCC Members and non-settling NSCC Members and therefore the fees for settling NSCC Members and non-settling NSCC Members for APP should be the same. Therefore, by establishing fees that align with the cost of delivery of these products and services and allocating those fees equitably among the subscribing NSCC Members, the proposed changes to Addendum A set forth in items II(A)(1)(i)(B) and (D) are consistent with the requirements of Section 17A(b)(3)(D) of the Act.[28]

NSCC believes the proposed fees set forth in item II(A)(1)(i)(C) above are also consistent with the requirements of 17A(b)(3)(D) of the Act.[29] Specifically, the proposed fees would be equitably allocated among NSCC Members that choose to process the file type for Positions Focused. NSCC also believes the proposed fees set forth in item II(A)(1)(i)(C) above are reasonable because the proposed fee for processing Position Focused files from 2,000,001 to 4,000,000 items per month is less than the fee currently charged, while continuing to allow NSCC to recover the costs associated with processing such items. In addition, the proposed fee changes were previously approved by NSCC management,[30] and NSCC Members were previously notified of the

[19] 2009 Fee Filing, *supra* note 12.

[20] Subsection 2.d. Section IV.K. of Addendum A, *supra* note 6 (provides that settling NSCC Members that process more than 3,499 items per month in APP are charged $0.50 per item compared to $1.00 per item for processing 2,000 to 3,499 items per month).

[21] Subsections 2. and 4., Section IV.K. of Addendum A, *supra* note 6.

[22] Subsection 3., Section IV.K. of Addendum A of the Rules, *supra* note 6.

[23] TIER 6, subsection 3., Section IV.K. of Addendum A of the Rules, *supra* note 6.

[24] 15 U.S.C. 78q–1(b)(3)(D).

[25] *Id.*

[26] *Id.*

[27] *Id.*

[28] *Id.*

[29] *Id.*

[30] See *supra,* note 16.

fee changes,[31] at the time the fee changes were originally contemplated for 2009. Therefore, NSCC believes the proposed fee modifications are consistent with the requirements of Section 17A(b)(3)(D) of the Act.[32]

Section 17A(b)(3)(F) of the Act requires, in part, that the Rules promote the prompt and accurate clearance and settlement of securities transactions.[33] The proposed changes to Addendum A set forth in item II(A)(1)(ii) above would enhance NSCC Members' ability to understand the fees associated with the I&RS services. Specifically, the proposed rule change relating to Addendum A described above in item II(A)(1)(ii) would clarify the meaning of certain provisions of Addendum A relating to the fees and enhance clarity and consistency in the Rules in this regard. As such, the proposed rule change would allow NSCC Members to have a better understanding of the Rules in relation to their I&RS activity, and thereby assist in promoting the prompt and accurate clearance and settlement of securities transactions, consistent with the requirements of Section 17A(b)(3)(F) of the Act.[34]

Rule 17Ad–22(e)(23)(i) under the Act requires, in part, that NSCC establish, implement, maintain and enforce written policies and procedures reasonably designed to provide for publicly disclosing all relevant rules and material procedures.[35] Rule 17Ad–22(e)(23)(ii) under the Act requires, in part, that NSCC establish, implement, maintain and enforce written policies and procedures reasonably designed to provide for providing sufficient information to enable participants to identify and evaluate the risks, fees, and other material costs they incur by participating in NSCC.[36] The proposed rule change set forth in item II(A)(1)(ii) above would enhance clarity and consistency with respect to the fees described herein. In this way, the proposed rule change would provide for the public disclosure of these fees through the proposed changes to Addendum A. The proposed rule change would allow NSCC to further provide its participants with sufficient information to enable those participants to identify and evaluate the fees incurred through their participation in NSCC. As such, NSCC believes the proposed rule change is consistent with both Rule 17Ad–22(e)(23)(i) and (ii) under the Act.[37]

(B) Clearing Agency's Statement on Burden on Competition

NSCC does not believe that the proposed changes to Addendum A set forth in items II(A)(1)(i)(A), (C) and (D) above would have an adverse impact, or impose any burden, on competition because, in each case, the proposed fee changes would be a reduction in fees as currently set forth in the Rules that would not disproportionally impact any NSCC Members. As a reduction to the fees currently in the Addendum A for these services, the proposed changes would not impede any NSCC Members from engaging in the services or have an adverse impact on any NSCC Members.

Moreover, the proposed rule changes may promote competition because, in each case, the proposed fee modifications would allow NSCC Members to engage in a greater number of transactions with lower fee costs than they would incur today for the same number of transactions. For instance, the proposed changes in item II(A)(1)(i)(A) above would allow NSCC Members that are currently sending to three or four destinations to begin to send to five destinations without incurring a higher fee than if files were sent to only three or four destinations because, as a result of the proposed rule change, the additional fee incurred by NSCC Members to send to five destinations would be the same as the additional fee to send to three or four destinations. Similarly, the proposed changes in item II(A)(1)(i)(C) above could result in NSCC Members that are currently sending 500,001 to 2,000,000 items per month to begin to send 2,000,001 to 4,000,000 items per month in order to take advantage of the proposed stated fee of $1.00 per 1,000 items rather than $1.50 per 1,000 items which is the current fee. In addition, the proposed change in item II(A)(1)(i)(D) above could result in non-settling NSCC Members that are currently sending less than 3,499 items per month to be more likely to send more than 3,499 items per month in order to take advantage of the proposed stated fee of $0.50 per item rather than $1.00 per item which is the current fee for non-settling NSCC Members. NSCC Members sending data to more destinations and sending additional data items relating to Positions and APP products and services would enhance participation in the marketplace by providing NSCC Members and their counterparties with more data. Finally, as discussed above, NSCC believes that the proposed fee changes are appropriate in light of the expenses incurred by NSCC in providing its services.

NSCC believes that the proposed changes to Addendum A set forth in item II(A)(1)(i)(B), could have an impact on competition because NSCC Members would need to pay the fees for a full file type in order to deliver Positions for Retirement Plan file types similar to Positions Full and Position New file types rather than paying the reduced fee that NSCC Members pay to deliver the Positions Focused file type. The higher fee may make it less likely for some NSCC Members to deliver the Position for Retirement Plan file type rather than the Position Focused file type. NSCC believes, however, that any burden on competition that would be created by the proposed rule change would be necessary and appropriate in furtherance of the Act. Specifically, the proposed rule change is necessary to align the fees charged for sending the Positions for Retirement Plans file type feature with the costs and expenses required for NSCC to process that file type. As stated above, NSCC believes the costs of processing the Positions for Retirement Plans file type for NSCC are similar to the cost of processing the Positions Full and the Positions New file types. As such, NSCC believes that the fee for processing the Positions Full and the Positions for Retirement Plans file type should be the same as the fee for processing the Positions Full and Positions New file types and is appropriate given the costs to NSCC of delivering the full data file types.

NSCC does not believe that the proposed changes to Addendum A set forth in item II(A)(1)(ii) above would have any impact on competition because such changes are clarifications of the Rules which would not affect the rights or obligations of NSCC Members. Moreover, the proposed changes set forth in item II(A)(1)(ii) are revenue neutral and would not affect one set of NSCC Members in favor of another.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments relating to the proposed rule change have not yet been solicited or received. NSCC will notify the Commission of any written comments received by NSCC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section

[31] *See supra,* note 15.

[32] 15 U.S.C. 78q–1(b)(3)(D).

[33] 15 U.S.C. 78q–1(b)(3)(F).

[34] *Id.*

[35] 17 CFR 240.17Ad–22(e)(23)(i).

[36] 17 CFR 240.17Ad–22(e)(23)(ii).

[37] 17 CFR 240.17Ad–22(e)(23)(i), (ii).

19(b)(3)(A)[38] of the Act and subparagraphs (f)(2)[39] and (f)(4)[40] of Rule 19b–4 thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NSCC–2017–011 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NSCC–2017–011. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of NSCC and on DTCC's Web site (*http://dtcc.com/legal/sec-rule-filings.aspx*). All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NSCC–2017–011 and should be submitted on or before September 5, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[41]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–17044 Filed 8–11–17; 8:45 am]

BILLING CODE 8011–01–P

[38] 15 U.S.C 78s(b)(3)(A).

[39] 17 CFR 240.19b–4(f)(2).

[40] 17 CFR 240.19b–4(f)(4).

[41] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81340; File No. SR–NYSEAMER–2017–03]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Supplementary Material .01 and .02 to NYSE American Rule 5.2E(j)(3) To Provide for the Inclusion of Cash in an Index Underlying a Series of Investment Company Units

August 8, 2017.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on July 27, 2017, NYSE American LLC (the ''Exchange'' or ''NYSE American'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Supplementary Material .01 and .02 to NYSE American Rule 5.2E(j)(3) to provide for the inclusion of cash in an index underlying a series of Investment Company Units, which amendments conform to amendments to NYSE Arca Equities Rule 5.2(j)(3) previously approved by the Commission. The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes (1) to amend Supplementary Material .01 and .02 to NYSE American Rule 5.2E(j)(3) to provide for the inclusion of cash in an index underlying a series of Investment Company Units (''Units''), which amendments conform to amendments to NYSE Arca Equities Rule 5.2(j)(3) previously approved by the Commission.[4]

Amendments to NYSE American Rule 5.2E(j)(3)

NYSE American Rule 5.2E(j)(3) permits the trading of Units pursuant to unlisted trading privileges (''UTP''). The Exchange proposes to amend Commentaries .01 and .02 to NYSE American Rule 5.2E(j)(3) to permit trading of Units based on an index or portfolio that includes cash as a component. While Units, like mutual funds, will generally hold an amount of cash, NYSE American Rule 5.2E(j)(3) currently provides that components of an index or portfolio underlying a series of Units consist of securities—namely, US Component Stocks, Non-US Component Stocks, Fixed Income Securities or a combination thereof. As described below, the proposed amendments to Supplementary Material .01 and .02 to Rule 5.2E(j)(3) would

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 80777 (May 25, 2017) (SR–NYSEArca–2017–30) (order approving amendments to Commentary .01 and Commentary .02 to NYSE Arca Equities Rule 5.2(j)(3) to provide for the inclusion of cash in an index underlying a series of Investment Company Units).

permit inclusion of cash as an index or portfolio component.

Currently, Supplementary Material .01(a)(A) to NYSE American Rule 5.2E(j)(3) provides that an underlying index or portfolio of US Component Stocks [5] must meet specified criteria. The Exchange proposes to amend Supplementary Material .01(a)(A) to provide that the components of an index or portfolio underlying a series of Units may also include cash. In addition, the percentage weighting criteria in Supplementary Material .01(a)(A)(1) through (4) each would be amended to make clear that such criteria would be applied only to the US Component Stocks portion of an index or portfolio. For example, in applying the criteria in proposed Supplementary Material .01(a)(A)(1),[6] if 85% of the weight of an index consists of US Component Stocks and 15% of the index weight is cash, the requirement that component stocks (excluding Exchange Traded Products) that in the aggregate account for at least 90% of the weight of the US Component Stocks portion of the index or portfolio (excluding such Exchange Traded Products) each will have a minimum market value of $75 million minimum would be applied only to the 85% portion consisting of US Component Stocks.

Supplementary Material .01 (a)(B) to NYSE American Rule 5.2E(j)(3), which relates to international or global indexes or portfolios, would be amended to provide that components of an index or portfolio underlying a series of Units may consist of (a) only Non-US Component Stocks, (b) Non-US Component Stocks and cash, (c) both US Component Stocks and Non-US Component Stocks, or (d) US Component Stocks, Non-US Component Stocks and cash. In addition, the percentage weighting criteria in Supplementary Material .01(a)(B)(1) through (4) each would be amended to make clear that such criteria would be applied only to the combined US and Non-US Component Stocks portions of an index or portfolio.

Supplementary Material .02 to NYSE American Rule 5.2E(j)(3) provides generic criteria applicable to trading of Units whose underlying index or portfolio includes Fixed Income Securities.[7] Currently, Commentary .02(a)(1) provides that an underlying index or portfolio must consist of Fixed Income Securities. The Exchange proposes to amend Commentary .02(a)(1) to provide that the index or portfolio may also include cash. In addition, the percentage weighting criteria in Supplementary Material .02(a)(2), (a)(4) and (a)(6) each would be amended to make clear that such criteria would be applied only to the Fixed Income Securities portion of an index or portfolio. For example, in applying the criteria in proposed Supplementary Material .02(a)(2),[8] if 90% of the weight of an index or portfolio consists of Fixed Income Securities and 10% of the index weight is cash, the requirement that Fixed Income Security components accounting for at least 75% of the Fixed Income Securities portion of the weight of the index or portfolio each will have a minimum original principal amount outstanding of $100 million would be applied only to the 90% portion consisting of Fixed Income Securities.

The Exchange notes that the Commission has previously approved NYSE Arca rules allowing portfolios held by issues of Managed Fund Shares (actively-managed exchange-traded funds) under Commentary .01 to NYSE Arca Equities Rule 8.600 to include cash.[9] Like the provision in Supplementary Material .01(c) to Exchange Rule 8.600E (which is similar to Commentary .01(c) to NYSE Arca Equities Rule 8.600), which states that there is no limit to cash holdings by an issue of Managed Fund Shares traded under Supplementary Material .01 to Exchange Rule 8.600E, there is no proposed limit to the weighting of cash in an index underlying a series of Units. The Exchange believes this is appropriate in that cash does not, in itself, impose investment or market risk.

The Exchange also proposes to make a non-substantive change to Supplementary Material .02 to Exchange Rule 5.2E(j)(3) to change ''shall'' to ''will'' in one place to conform to other usages in Rule 5.2E(j)(3).

The Exchange believes the proposed amendments, by permitting inclusion of cash as a component of indexes underlying series of Units, would provide issuers of Units with additional choice in indexes permitted to underlie Units that are permitted to trade on the Exchange pursuant to the Rule 19b–4(e), which would enhance competition among market participants, to the benefit of investors and the marketplace. In addition, the proposed amendments would provide investors with greater ability to hold Units based on underlying indexes that may accord more closely with an investor's assessment of market risk, in that some investors may view cash as a desirable component of an underlying index under certain market conditions.

2. Statutory Basis

The basis under the Act for this proposed rule change is the requirement under Section 6(b)(5) [10] that an exchange have rules that are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest.

The proposed rule changes are designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest. The basis under the Exchange Act for this proposed rule change is the requirement under Section 6(b)(5) that an exchange have rules that are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest.

With respect to the proposed amendments to Supplementary Material .01(a)(B)(1) through (4) to Rule 5.2E(j)(3), as described above, the percentage weighting criteria in Supplementary Material .01(a)(B)(1) through (4) to Rule 5.2E(j)(3) each would be amended to make clear that such criteria would be applied only to the combined US and Non-US Component Stocks portions of an index or portfolio. The percentage weighting criteria in Supplementary Material

[5] Rule 5.2E(j)(3) defines ''US Component Stock'' as an equity security that is registered under Sections 12(b) or 12(g) of the Act or an American Depositary Receipt, the underlying equity security of which is registered under Sections 12(b) or 12(g) of the Act.

[6] Supplementary Material .01(a)(A)(1) provides that component stocks (excluding Units and securities defined in Section 2 of Rule 8E, collectively, ''Exchange Traded Products'') that in the aggregate account for at least 90% of the weight of the US Component Stocks portion of the index or portfolio (excluding such Exchange Traded Products) each shall have a minimum market value of at least $75 million.

[7] As defined in Supplementary Material .02 to NYSE American Rule 5.2E(j)(3), Fixed Income Securities are debt securities that are notes, bonds, debentures or evidence of indebtedness that include, but are not limited to, U.S. Department of Treasury securities (''Treasury Securities''), government-sponsored entity securities (''GSE Securities''), municipal securities, trust preferred securities, supranational debt and debt of a foreign country or a subdivision thereof.

[8] Supplementary Material .02(a)(2) provides that Fixed Income Security components that in aggregate account for at least 75% of the Fixed Income Securities portion of the weight of the index or portfolio each shall have a minimum original principal amount outstanding of $100 million or more.

[9] *See* Commentary .01(c) to NYSE Arca Equities Rule 8.600.

[10] 15 U.S.C. 78f(b)(5).

.02(a)(2), (a)(4) and (a)(6) to Rule 5.2E(j)(3) each would be amended to make clear that such criteria would be applied only to the Fixed Income Securities portion of an index or portfolio. Such applications of the proposed amendments would assure that the weighting requirements in Supplementary Material .01 and .02 would continue to be applied only to securities in an index or portfolio, and would not be diluted as a result of inclusion of a cash component. In addition, the addition of cash as a permitted component of indexes underlying Units traded on the Exchange pursuant to Rule 19b–4(e) does not raise regulatory issues because cash does not, in itself, impose investment or market risk and is not susceptible to manipulation. The non-substantive change to Supplementary Material .02 to Exchange Rule 5.2E(j)(3) to change ''shall'' to ''will'' conforms to other usages in Rule 5.2E(j)(3).

The Exchange believes these proposed amendments, by permitting inclusion of cash as a component of indexes underlying series of Units, would provide issuers of Units with additional choice in indexes permitted to underlie Units that are permitted to trade on the Exchange pursuant to UTP, which would enhance competition among market participants, to the benefit of investors and the marketplace. In addition, the proposed amendments would provide investors with greater ability to hold Units based on underlying indexes that may accord more closely with an investor's assessment of market risk.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purpose of the Act. The Exchange believes the proposed rule change will enhance intermarket competition by allowing trading on the Exchange pursuant to UTP of the above-described securities pursuant to rules that have been previously approved by the Commission for NYSE Arca, Inc.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [11] and Rule 19b–4(f)(6) thereunder.[12]

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative prior to 30 days after the date of filing. However, Rule 19b–4(f)(6)(iii)T [13] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. As noted above, the Exchange believes that the proposed rule change would provide additional choices to issuers of Units and investors in Units. The Exchange also noted that the amendments it is proposing to Rule 5.2E(j)(3) conform to amendments to NYSE Arca Equities Rule 5.2(j)(3) that the Commission previously approved,[14] and that this proposed rule change may enhance competition between the exchanges. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the 30-day operative delay and designates the proposed rule change to be operative upon filing.[15]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEAMER–2017–03 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEAMER–2017–03. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEAMER–2017–03 and should be submitted on or before September 5, 2017.

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(6). As required under Rule 19b–4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

[13] 17 CFR 240.19b–4(f)(6)(iii).

[14] *See supra* note 4.

[15] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–17045 Filed 8–11–17; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81345; File No. SR–ISE–2017–71]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend ISE's Schedule of Fees With Respect to the Options Regulatory Fee

August 8, 2017.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 26, 2017, Nasdaq ISE, LLC (''ISE'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to revise ISE's Schedule of Fees to: (i) Make adjustments to the amount of the Options Regulatory Fee (''ORF''); (ii) more closely reflect the manner in which ISE assesses and collects its ORF; and (iii) remove rule text related to the timing when the Exchange may increase or decrease the amount of the ORF.

While the changes proposed herein are effective upon filing, the Exchange has designated the amendments [sic] become operative on August 1, 2017.

The text of the proposed rule change is available on the Exchange's Web site at *www.ise.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

ISE initially filed to establish its ORF in 2010.[3] The Exchange has amended its ORF several times since the inception of this fee.[4] At this time, the Exchange proposes to: (i) Amend the amount of its ORF; (ii) more closely reflect the manner in which ISE assesses and collects its ORF; and (iii) remove rule text related to the timing when the Exchange may increase or decrease the amount of its ORF.

The Exchange supports a common approach for the assessment and collection of ORF among the various options exchanges that assess such a fee. Furthermore, the Exchange supports guidance from the Commission regarding regulatory cost structures to ensure equal knowledge and treatment among options markets assessing ORF.

Proposal 1—Amend the Amount of the ORF

The Exchange assesses an ORF of $0.0039 per contract side. The Exchange proposes to decrease the ORF from $0.0039 per contract side to $0.0016 per contract side as of August 1, 2017 to account for synergies which resulted from Nasdaq's acquisition of the Exchange. On June 30, 2016, Nasdaq completed its acquisition of the International Securities Exchange, which included acquiring three electronic options exchanges.[5] With the acquisition, ISE [sic] regulatory program has been examined and conformed to certain best practices which exist today on NASDAQ PHLX LLC, The NASDAQ Options Market LLC and NASDAQ BX, Inc. (collectively ''Nasdaq Markets'') and Nasdaq GEMX, LLC. These synergies in combination with conforming the expense and revenue review of ISE to that of the Nasdaq Markets has resulted in a projected decreased in regulatory expenses for ISE and therefore ISE is decreasing the amount of its ORF. The Exchange believes that this decreased number reflects efficiencies in the regulatory program today within the Nasdaq Markets.

The Exchange's proposed change to the ORF should balance the Exchange's regulatory cost [sic] against the anticipated revenue. The Exchange regularly reviews its ORF to ensure that the ORF, in combination with its other regulatory fees and fines, does not exceed regulatory costs. The Exchange believes this adjustment will permit the Exchange to cover a material portion of its regulatory costs, while not exceeding regulatory costs.

The Exchange notified members of this ORF adjustment thirty (30) calendar days prior to the proposed operative date.[6]

Proposal 2—Reflect the Manner in Which ISE Assesses and Collects its ORF

Currently, ISE assesses its ORF for each customer option transaction that is either: (1) Executed by a member on ISE; or (2) cleared by a ISE member at The Options Clearing Corporation (''OCC'') in the customer range,[7] even if the transaction was executed by a non-member of ISE, regardless of the exchange on which the transaction occurs.[8] If the OCC clearing member is a ISE member, ORF is assessed and collected on all cleared customer contracts (after adjustment for CMTA [9]); and (2) if the OCC clearing member is not a ISE member, ORF is collected only on the cleared customer contracts executed at ISE, taking into account any

[16] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release Nos. 61154 (December 11, 2009), 74 FR 67278 (December 18, 2009) (SR–ISE–2009–105) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to the Registered Representative Fee and an Options Regulatory Fee).

[4] *See* Securities Exchange Act Release Nos. 62012 (April 30, 2010), 75 FR 25306 (May 7, 2010) (SR–ISE–2010–36); 67087 (May 31, 2012), 77 FR 33535 (June 6, 2012) (SR–ISE–2012–43); and 70859 (November 13, 2013), 78 FR 69501 (November 19, 2013) (SR–ISE–2014–54).

[5] On June 30, 2016, Nasdaq, Inc. acquired all of the capital stock of U.S. Exchange Holdings, Inc., the ISE's indirect parent company. As a result, ISE in addition to its affiliates, which are now known as Nasdaq GEMX, LLC and Nasdaq MRX, LLC, became a wholly-owned subsidiary of Nasdaq, Inc. *See* Securities Exchange Act Release No. 78119 (June 21, 2016), 81 FR 41611 (June 27, 2016) (SR–ISE–2016–11).

[6] *See* Options Trader Alert #2017–54.

[7] Members must record the appropriate account origin code on all orders at the time of entry in order. The Exchange represents that it has surveillances in place to verify that members mark orders with the correct account origin code.

[8] The Exchange uses reports from OCC when assessing and collecting the ORF.

[9] CMTA or Clearing Member Trade Assignment is a form of ''give-up'' whereby the position will be assigned to a specific clearing firm at OCC.

CMTA instructions which may result in collecting the ORF from a non-member.

By way of example, if Broker A, an ISE member, routes a customer order to CBOE and the transaction executes on CBOE and clears in Broker A's OCC Clearing account, ORF will be collected by ISE from Broker A's clearing account at OCC via direct debit. While this transaction was executed on a market other than ISE, it was cleared by an ISE member in the member's OCC clearing account in the customer range, therefore there is a regulatory nexus between ISE and the transaction. If Broker A was not an ISE member, then no ORF should be assessed and collected because there is no nexus; the transaction did not execute on ISE nor was it cleared by an ISE member.

In the case where a member both executes a transaction and clears the transaction, the ORF is assessed to and collected from the member only once. In the case where a member executes a transaction and a different member clears the transaction, the ORF is assessed to and collected from the member who clears the transaction and not the member who executes the transaction. In the case where a non-member executes a transaction at an away market and a member clears the transaction, the ORF is assessed to and collected from the member who clears the transaction. In the case where a member executes a transaction on ISE and a non-member clears the transaction, the ORF is assessed to the member that executed the transaction and collected from the non-member who cleared the transaction. In the case where a member executes a transaction at an away market and a non-member clears the transaction, the ORF is not assessed to the member who executed the transaction or collected from the non-member who cleared the transaction because the Exchange does not have access to the data to make absolutely certain that ORF should apply. Further, the data does not allow the Exchange to identify the member executing the trade at an away market.

ORF Revenue and Monitoring of ORF

The Exchange monitors the amount of revenue collected from the ORF to ensure that it, in combination with other regulatory fees and fines, does not exceed regulatory costs. In determining whether an expense is considered a regulatory cost, the Exchange reviews all costs and makes determinations if there is a nexus between the expense and a regulatory function. The Exchange notes that fines collected by the Exchange in connection with a disciplinary manner offset ORF.

The ORF is designed to recover a material portion of the costs to the Exchange of the supervision and regulation of its members, including performing routine surveillances, investigations, examinations, financial monitoring, and policy, rulemaking, interpretive, and enforcement activities.

The Exchange believes that revenue generated from the ORF, when combined with all of the Exchange's other regulatory fees, will cover a material portion, but not all, of the Exchange's regulatory costs. The Exchange will continue to monitor the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory fees and fines, does not exceed regulatory costs. If the Exchange determines regulatory revenues exceed regulatory costs, the Exchange will adjust the ORF by submitting a fee change filing to the Commission.

Finally, the Exchange notes that it is amending ISE's Schedule of Fees to remove certain rule text and include new rule text to make clear the manner in which ORF is assessed and collected on ISE.

Proposal 3—Semi-Annual Changes to ORF

The Exchange's current ORF rule text provides that, ''The Exchange may only increase or decrease the Options Regulatory Fee semi-annually, and any such fee change will be effective on the first business day of February or August.'' The Exchange is proposing to eliminate the requirement that its ORF may be only increased or decreased semi-annually because the Exchange believes it requires the flexibility to amend its ORF as needed to meet its regulatory requirements and adjust its ORF to account for the regulatory revenue that it receives and the costs that it incurs. While the Exchange is eliminating the requirement to adjust only semi-annually, it will continue to submit a rule proposal with the Commission for each modification to the ORF and notify participants via an Options Trader Alert of any proposed change in the amount of the fee at least thirty (30) calendar days prior to the effective date. The Exchange believes that the prior notification to market participants will provide guidance on the timing of any changes to the ORF and ensure market participants are prepared to configure their systems to properly account for the ORF.

The Exchange also notes it now issues Options Trader Alerts instead of circulars to provide notification to members. The Exchange is amending the rule text to reflect this change.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act [10] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act [11] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using its facility and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes the proposed clarifications in the Fee Schedule to the ORF further the objectives of Section 6(b)(4) of the Act and are equitable and reasonable since they expressly describe the Exchange's existing practices regarding the manner in which the Exchange assesses and collects its ORF.

Proposal 1—Amend the Amount of the ORF

The Exchange believes that decreasing the ORF from $0.0039 per contract side to $0.0016 per contract side as of August 1, 2017 is reasonable because the Exchange's collection of ORF needs to be balanced against the amount of regulatory cost collected [sic] by the Exchange. The decrease is a result of synergies among the Nasdaq owned self-regulatory organizations. The synergies in combination with conforming the expense and revenue review of ISE to that of the Nasdaq Markets has resulted in a decreased ORF for ISE. The Exchange believes that this decreased number reflects efficiencies in the regulatory program today within the Nasdaq Markets. The Exchange's proposed change to the ORF should balance the Exchange's regulatory cost against the anticipated regulatory revenue. The Exchange regularly reviews its ORF to ensure that the ORF, in combination with its other regulatory fees and fines, does not exceed regulatory costs.

The Exchange believes that decreasing the ORF from $0.0039 per contract side to $0.0016 per contract side as of August 1, 2017 is equitable and not unfairly discriminatory because this decrease will serve to balance the Exchange's regulatory revenue against the anticipated regulatory costs in light of recent synergies experienced from the merger described herein. The ORF seeks to recover the costs of supervising and regulating members, including performing routine surveillances, investigations, examinations, financial monitoring, and policy, rulemaking, interpretive, and enforcement activities.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(4) and (5).

Moreover, the Exchange believes the ORF ensures fairness by assessing fees to those members that are directly based on the amount of customer options business they conduct. Regulating customer trading activity is much more labor intensive and requires greater expenditure of human and technical resources than regulating non-customer trading activity, which tends to be more automated and less labor-intensive. As a result, the costs associated with administering the customer component of the Exchange's overall regulatory program are materially higher than the costs associated with administering the non-customer component (*e.g.* member proprietary transactions) of its regulatory program.

The ORF is designed to recover a material portion of the costs of supervising and regulating member's customer options business including performing routine surveillances, investigations, examinations, financial monitoring, and policy, rulemaking, interpretive, and enforcement activities. The Exchange will monitor the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory fees and fines, does not exceed the Exchange's total regulatory costs. The Exchange has designed the ORF to generate revenues that, when combined with all of the Exchange's other regulatory fees, will be less than or equal to the Exchange's regulatory costs, which is consistent with the Commission's view that regulatory fees be used for regulatory purposes and not to support the Exchange's business side. In this regard, the Exchange believes that the proposed amount of the fee is reasonable.

Proposal 2—Reflect the Manner in Which ISE Assesses and Collects Its ORF

The Exchange believes it is reasonable and appropriate for the Exchange to charge the ORF for options transactions regardless of the exchange on which the transactions occur. The Exchange has a statutory obligation to enforce compliance by members and their associated persons under the Act and the rules of the Exchange and to surveil for other manipulative conduct by market participants (including non-members) trading on the Exchange. The Exchange cannot effectively surveil for such conduct without looking at and evaluating activity across all options markets. Many of the Exchange's market surveillance programs require the Exchange to look at and evaluate activity across all options markets, such as surveillance for position limit violations, manipulation, front-running and contrary exercise advice violations/expiring exercise declarations. The Exchange, because it lacks access to information on the identity of the entering firm for executions that occur on away markets, believes it is appropriate to assess the ORF on its member's clearing activity, based on information the Exchange receives from OCC, including for away market activity. Among other reasons, doing so better and more accurately captures activity that occurs away from the Exchange over which the Exchange has a degree of regulatory responsibility. In so doing, the Exchange believes that assessing ORF on member clearing firms in certain instances equitably distributes the collection of ORF in a fair and reasonable manner. Also, the Exchange and the other options exchanges are required to populate a consolidated options audit trail (''COATS'') [12] system in order to surveil a member's activities across markets.[13]

The Exchange believes that assessing the ORF to each Exchange member for options transactions cleared by OCC in the customer range where the execution occurs on another exchange and is cleared by a ISE Member is an equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities. The ORF is collected by OCC on behalf of ISE from Exchange clearing members for all customer transactions they clear or from non-Members for all customer transactions they clear that were executed on ISE. The Exchange believes that this collection practice is reasonable and appropriate because higher fees are assessed to those Members that require more Exchange regulatory services based on the amount of customer options business they conduct.

Regulating customer trading activity is more labor intensive and requires greater expenditure of human and technical resources than regulating non-customer trading activity, which tends to be more automated and less labor intensive. As a result, the costs associated with administering the customer component of the Exchange's overall regulatory program are anticipated to be typically higher than the costs associated with administering the non-customer component of its regulatory program. The Exchange proposes assessing higher fees to those members that will require more Exchange regulatory services based on the amount of customer options business they conduct. Additionally, the dues and fees paid by members go into the general funds of the Exchange, a portion of which is used to help pay the costs of regulation. The Exchange has in place a regulatory structure to surveil, conduct examinations and monitor the marketplace for violations of Exchange Rules. The ORF assists the Exchange to fund the cost of this regulation of the marketplace.

Proposal 3—Semi-Annual Changes to ORF

The Exchange believes that the proposed rule change to remove the limit to amend the ORF only semi-annually, with advance notice, is reasonable because the Exchange will continue to provide market participants with thirty (30) days advance notice of amending the amount of the ORF. Also, the Exchange is required to monitor the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory fees and fines, do not exceed regulatory costs. Therefore, the Exchange believes it is reasonable to remove the semi-annual limit to amend its ORF in order to permit the Exchange to make amendments to its ORF as necessary to comply with the Exchange's obligations. This proposed change would conform this rule with that of NASDAQ PHLX LLC (''Phlx''), The NASDAQ Options Market LLC (''NOM'') and NASDAQ BX, Inc. (''BX'').[14]

The Exchange believes that the proposed rule change to remove the limit to amend the ORF only semi-annually, with advance notice, is equitable and not unfairly discriminatory because it will apply in the same manner to all members that are subject to the ORF. The Exchange has in place a regulatory structure to surveil for, conduct examinations and monitor

[12] COATS effectively enhances intermarket options surveillance by enabling the options exchanges to reconstruct the market promptly to effectively surveil certain rules.

[13] In addition to its own surveillance programs, the Exchange works with other SROs and exchanges on intermarket surveillance related issues. Through its participation in the Intermarket Surveillance Group (''ISG''), the Exchange shares information and coordinates inquiries and investigations with other exchanges designed to address potential intermarket manipulation and trading abuses. The Exchange's participation in ISG helps it to satisfy the requirement that it has coordinated surveillance with markets on which security futures are traded and markets on which any security underlying security futures are traded to detect manipulation and insider trading. *See* Section 6(h)(3)(I) of the Act. ISG is an industry organization formed in 1983 to coordinate intermarket surveillance among the SROs by co-operatively sharing regulatory information pursuant to a written agreement between the parties. The goal of the ISG's information sharing is to coordinate regulatory efforts to address potential intermarket trading abuses and manipulations.

[14] *See* Phlx's Pricing Schedule and NOM and BX Rules at Chapter XV, Sections 5.

the marketplace for violations of Exchange Rules. The ORF assists the Exchange to fund the cost of this regulation of the marketplace.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The ORF is not intended to have any impact on competition. Rather, it is designed to enable the Exchange to recover a material portion of the Exchange's cost related to its regulatory activities. The Exchange is obligated to ensure that the amount of regulatory revenue collected from the ORF, in combination with its other regulatory fees and fines, does not exceed regulatory costs.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[15] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–ISE–2017–71 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–ISE–2017–71. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–ISE–2017–71, and should be submitted on or before September 5, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–17050 Filed 8–11–17; 8:45 am]

BILLING CODE 8011–01–P

[15] 15 U.S.C. 78s(b)(3)(A)(ii).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81338; File Nos. SR–DTC–2017–014; SR–FICC–2017–017; SR–NSCC–2017–013]

Self-Regulatory Organizations; The Depository Trust Company; Fixed Income Clearing Corporation; National Securities Clearing Corporation; Notice of Filings of Proposed Rule Changes To Adopt the Clearing Agency Operational Risk Management Framework

DATE: August 8, 2017.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934, as amended (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 25, 2017, The Depository Trust Company (''DTC''), Fixed Income Clearing Corporation (''FICC''), and National Securities Clearing Corporation (''NSCC,'' and together with DTC and FICC, the ''Clearing Agencies'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule changes as described in Items I and II below, which Items have been prepared primarily by the Clearing Agencies. The Commission is publishing this notice to solicit comments on the proposed rule changes from interested persons.

I. Clearing Agencies' Statement of the Terms of Substance of the Proposed Rule Changes

The proposed rule changes would adopt the Clearing Agency Operational Risk Management Framework (''Framework'') of the Clearing Agencies, described below. The Framework would apply to both of FICC's divisions, the Government Securities Division (''GSD'') and the Mortgage-Backed Securities Division (''MBSD''). The Framework would be maintained by the Clearing Agencies to support their compliance with Rule 17Ad–22(e)(17) under the Act, as described below.[3]

Although the Clearing Agencies would consider the Framework to be a rule, the proposed rule changes do not require any changes to the Rules, By-laws and Organization Certificate of DTC (''DTC Rules''), the Rulebook of GSD (''GSD Rules''), the Clearing Rules of MBSD (''MBSD Rules''), or the Rules & Procedures of NSCC (''NSCC Rules''), as the Framework would be a standalone document.[4]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.17Ad–22(e)(17).

[4] Capitalized terms not defined herein are defined in the DTC Rules, GSD Rules, MBSD Rules, or

II. Clearing Agencies' Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Changes

In their filings with the Commission, the Clearing Agencies included statements concerning the purpose of and basis for the proposed rule changes and discussed any comments they received on the proposed rule changes. The text of these statements may be examined at the places specified in Item IV below. The Clearing Agencies have prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agencies' Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Changes

1. Purpose

The Clearing Agencies are proposing to adopt the Framework, which would describe the manner in which each of the Clearing Agencies manages operational risk, which is defined by the Clearing Agencies in the Framework as the risk of direct or indirect loss or reputational harm resulting from an event, internal or external, that is the result of inadequate or failed processes, people, and systems (''Operational Risk''). As described in more detail below, the Framework would set forth the manner in which the Clearing Agencies (1) generally manage Operational Risk; (2) more specifically manage their information technology risks; and (3) more specifically manage their business continuity risks. The processes and systems described in the Framework, and any policies, procedures or other documents created to support those processes, support the Clearing Agencies' compliance with the requirements of Rule 17Ad–22(e)(17).[5] The Framework would be maintained by the DTCC Operational Risk Management group (''ORM''), on behalf of the Clearing Agencies.[6]

Operational Risk Management

The Framework would describe how the Clearing Agencies generally manage their Operational Risks. The Framework would describe how ORM is specifically charged with establishing appropriate systems, policies, procedures, and controls to enable management to identify plausible sources of Operational Risk in order to mitigate their impact to the Clearing Agencies, including through the Risk Tolerance Statements and Risk Profiles, as described below.

The Framework would describe how the Clearing Agencies identify key risks and set metrics to categorize such risks (from ''no impact'' to ''severe impact'') through ''Risk Tolerance Statements.'' The Framework would describe how the Risk Tolerance Statements document the overall risk reduction or mitigation objectives for the Clearing Agencies with respect to identified risks to the Clearing Agencies. The Framework would also describe how the Risk Tolerance Statements document the risk controls and other measures used to manage such identified risks, including escalation requirements in the event of risk metric breaches. The Framework would state that each Risk Tolerance Statement is reviewed, revised, updated, and/or created, as necessary, by ORM on an annual basis.

The Framework would also describe how the Clearing Agencies monitor key risks, including Operational Risk, through ''Risk Profiles,'' which document the assessment of risk for each of the Clearing Agencies' businesses and support areas (each a ''Clearing Agency Business'' and/or ''Clearing Agency Support Area''). The risk assessment documented in these profiles includes (1) identification and assessment of inherent risk, which is risk without any mitigating controls; (2) identification of existing controls, and, as appropriate, any new additional controls, and evaluation of the same risk against the strength of such controls; and (3) identification of any residual risk and a determination to either further mitigate such risk or accept such risk by the applicable Clearing Agency Business or Clearing Agency Support Area.

The Framework would also provide a description of the responsibilities of ORM, which is a part of the second line of defense within the Clearing Agencies' Three Lines of Defense approach to risk management.[7] The Framework would identify some of those responsibilities as including, for example, management of the Risk Tolerance Statements and working with the Clearing Agency Businesses and Clearing Agency Support Areas to create and monitor Risk Profiles.

Information Technology Risk

The Framework would describe how the Clearing Agencies address information technology risks. The Framework would state that the DTCC Technology Risk Management group (''TRM''), on behalf of the Clearing Agencies, is responsible for establishing appropriate programs, policies, procedures, and controls with respect to the Clearing Agencies' information technology risks to help management ensure that systems have a high degree of security, resiliency, operational reliability, and adequate, scalable capacity. The Framework would identify some of the recognized information technology standards that may be used by TRM, as applicable, in support of executing its responsibilities.

The Framework would also identify some of TRM's responsibilities, which include, for example, (1) performing risk assessments to, among other things, facilitate the determination of the Clearing Agencies' investment and remediation priorities; (2) facilitating annual mandatory and periodic information security awareness, education, training, and communication to personnel of Clearing Agency Businesses and Clearing Agency Support Areas and relevant external parties; and (3) creating, implementing, and managing certain programs, including programs that (i) address information security throughout a system's lifecycle, (ii) facilitate compliance with evolving and established regulatory rules and guidelines that govern protection of the information assets of the Clearing Agencies and their participants, (iii) identify, prioritize, and manage the level of cyber threats to the Clearing Agencies, and (iv) assure that access to Clearing Agency information assets is appropriately authorized and authenticated based on current business need.

The Framework would state that TRM's risk strategy is closely aligned to the Clearing Agencies' business drivers and future strategic direction, such that efforts to achieve information security threat mitigation objectives, resiliency of infrastructure supporting Clearing Agency critical business applications,

NSCC Rules, as applicable, *available at http://dtcc.com/legal/rules-and-procedures.*

[5] 17 CFR 240.17Ad–22(e)(17).

[6] The parent company of the Clearing Agencies is The Depository Trust & Clearing Corporation (''DTCC''). DTCC operates on a shared services model with respect to the Clearing Agencies. Most corporate functions are established and managed on an enterprise-wide basis pursuant to intercompany agreements under which it is generally DTCC that provides a relevant service to a Clearing Agency.

[7] The Three Lines of Defense approach to risk management identifies the roles and responsibilities of different Clearing Agency Businesses or Clearing Agency Support Areas in identifying, assessing, measuring, monitoring, mitigating, and reporting certain key risks faced by the Clearing Agencies. The Three Lines of Defense approach is more fully described in a separate framework, the Clearing Agency Risk Management Framework, maintained by the DTCC General Counsel's Office. *See* SR–DTC–2017–013, SR–FICC–2017–016, SR–NSCC–2017–012, which was filed with the Commission but has not yet been published in the **Federal Register**. A copy of these proposed rule change filings is *available at http://www.dtcc.com/legal/sec-rule-filings.*

and operational reliability are prioritized. The Framework would state this is also accomplished through TRM's early and consistent involvement in initiatives to develop new products and systems. The Framework would state that, by involving TRM from the initial planning phase, through the design, build and operative phases of those initiatives, resiliency, operational effectiveness, reliability, and availability requirements are addressed and incorporated into design and execution from both a technology and cyber security perspective.

The Framework would also describe the Clearing Agencies' security strategy and defense, and would state that the Clearing Agencies' network security framework and preventive controls are designed to support a reliable and robust tiered security strategy and defense. These controls include modern and technically advanced security firewalls, intrusion detection, system and data monitoring, and data protection tools. The Framework would describe the Clearing Agencies' enhanced security features and the standards they use to assess vulnerabilities and potential threats.

Business Continuity Risk

Finally, the Framework would describe how the Clearing Agencies have established and maintain business continuity plans to address events that may pose a significant risk of disrupting their operations. The Framework would describe how the business continuity process for each Clearing Agency Business and Clearing Agency Support Area is ranked within a range of tiers, from 0 to 5, based on criticality to each applicable Clearing Agency's operations (each a ''Tier''), where Tier 0 equates to critical operations or support of such operations for which virtually no downtime is permitted under applicable regulatory standards, and Tier 5 equates to non-essential operations or support of such operations for which recovery times of greater than five days is permitted.

The Framework would state that, on an annual basis, each Clearing Agency Business and Clearing Agency Support Area updates its own business continuity plan and reviews and ratifies its business impact analysis. These analyses are used by the DTCC Business Continuity Management department (''BCM''), on behalf of the Clearing Agencies, to validate that business' or area's current Tier ranking. The Framework would identify the key elements of these business impact analyses, which include (1) an assessment of the criticality of the applicable Clearing Agency Business or Clearing Agency Support Area, based on potential impact to the Clearing Agency; (2) an estimation of the maximum allowable downtime for the applicable Clearing Agency Business or Clearing Agency Support Area; and (3) the identification of dependencies, and ranking such dependencies to align with the process criticality for recovery, of the applicable Clearing Agency Business or Clearing Agency Support Area.

The Framework would describe the Clearing Agencies' multiple data centers, and the emergency monitoring and back up systems available at each site. The Framework would describe the capacity of the various data centers. The Framework would also describe the Clearing Agencies' operating centers, and would describe how each Clearing Agency Business and Clearing Agency Support Area creates and deploys its own work area recovery strategy to mitigate the loss of primary workspace and/or associated desktop technology, as well as for purposes of social distancing among personnel. The Framework would describe how each of these work area recovery strategies is developed and executed, based on the applicable Clearing Agency Business' and Clearing Agency Support Area's current Tier ranking, as described above.

The Framework would describe the responsibilities of BCM in managing a disruptive business event, which includes coordination with a team of representatives from each Clearing Agency Business and Clearing Agency Support Area. Finally, the Framework would describe how the Clearing Agencies conduct regular exercises used to simulate loss of Clearing Agency locations, and would describe some of the preventive measures the Clearing Agencies take with respect to business continuity risk management.

2. Statutory Basis

The Clearing Agencies believe that the proposed rule changes are consistent with the requirements of the Act and the rules and regulations thereunder applicable to a registered clearing agency. In particular, the Clearing Agencies believe that the Framework is consistent with Section 17A(b)(3)(F) of the Act [8] and the subsections cited below of Rule 17Ad–22(e)(17),[9] promulgated under the Act, for the reasons described below.

Section 17A(b)(3)(F) of the Act requires, in part, that the rules of a registered clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions, and to assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible.[10] As described above, the Framework would describe how the Clearing Agencies manage their Operational Risk, technology and information security risks, and their business continuity risks. The processes, systems, and controls used by the Clearing Agencies to identify, manage, and mitigate these risks, as described in the Framework, and the policies and procedures that support these activities, assist the Clearing Agencies to continue the prompt and accurate clearance and settlement of securities transactions and continue to assure the safeguarding of securities and funds which are in their custody or control or for which they are responsible notwithstanding the realization of these risks. Therefore, the Clearing Agencies believe the Framework is consistent with the requirements of Section 17A(b)(3)(F) of the Act.[11]

The Clearing Agencies believe that the Framework is consistent with the requirements of each of the subsections of Rule 17Ad–22(e)(17),[12] cited below, for the reasons described below.

Rule 17Ad–22(e)(17)(i) under the Act requires, in part, that each covered clearing agency establish, implement, maintain and enforce written policies and procedures reasonably designed to manage the covered clearing agency's operational risks by identifying the plausible sources of operational risk, both internal and external, and mitigating their impact through the use of appropriate systems, policies, procedures, and controls.[13] The Framework would describe how the Risk Tolerance Statements and the Risk Profiles both assist the Clearing Agencies to identify the plausible sources of Operational Risk, both internal and external. As described above, the Risk Tolerance Statements identify both internal and external Clearing Agency risks, categorize the respective Clearing Agencies' tolerance for those risks, and then identify governance process applicable to any breach of those tolerances. In this way, the Risk Tolerance Statements allow the Clearing Agencies to identify and manage the risks they face. As described above, the Risk Profiles serve a similar

[8] 15 U.S.C. 78q–1(b)(3)(F).

[9] 17 CFR 240.17Ad–22(e)(17).

[10] 15 U.S.C. 78q–1(b)(3)(F).

[11] *Id.*

[12] 17 CFR 240.17Ad–22(e)(17).

[13] 17 CFR 240.17Ad–22(e)(17)(i).

function, by serving as a tool for identifying and assessing inherent risks, and evaluating the controls around those risks. The Framework also describes the role of ORM, which includes oversight of the Risk Tolerance Statements and Risk Profiles. By describing the functions of the Risk Tolerance Statements and Risk Profiles, which, together, assist the Clearing Agencies in effectively managing their operational risks by identifying the plausible sources of operational risk, both internal and external, and by assisting the Clearing Agencies in mitigating the impact of those risks, and by describing the role of ORM in facilitating these tools, the Clearing Agencies believe the Framework is consistent with the requirements of Rule 17Ad–22(e)(17)(i).[14]

Rule 17Ad–22(e)(17)(ii) under the Act requires, in part, that each covered clearing agency establish, implement, maintain and enforce written policies and procedures reasonably designed to manage the covered clearing agency's operational risks by ensuring that systems have a high degree of security, resiliency, operational reliability, and adequate, scalable capacity.[15] The Framework would describe the role, and some of the responsibilities, of TRM, in managing the Clearing Agencies' information technology risks and in helping the Clearing Agencies maintain systems with a high degree of security, resiliency, operational reliability, and adequate, scalable capacity. The Framework would also describe the programs, systems, and controls used by TRM in performing this function, and would identify some of the standards on information technology risk management that may be used by TRM in support of its responsibilities. The Framework would also describe TRM's role in product and project initiatives to address security issues through the lifecycle of an initiative. Therefore, by describing the role and responsibilities of TRM in managing the Clearing Agencies' information technology risks and in helping the Clearing Agencies maintain systems with a high degree of security, resiliency, operational reliability, and adequate, scalable capacity, the Clearing Agencies believe the Framework is consistent with the requirements of Rule 17Ad–22(e)(17)(ii).[16]

Rule 17Ad–22(e)(17)(iii) under the Act requires, in part, that each covered clearing agency establish, implement, maintain and enforce written policies and procedures reasonably designed to manage the covered clearing agency's operational risks by establishing and maintaining a business continuity plan that addresses events posing a significant risk of disrupting operations.[17] The Framework would describe how the Clearing Agencies have established and maintain business continuity plans, and would describe the critical features of those plans to demonstrate how such plans address events posing a significant risk of disrupting the Clearing Agencies' operations. The Framework would also describe how each Clearing Agency Business and Clearing Agency Support Area reviews and ratifies its respective plan and its business impact analysis, relative to its assigned Tier. Therefore, through this description of the establishment, management and maintenance of the business continuity plans of the Clearing Agencies, the Clearing Agencies believe the Framework is consistent with the requirements of Rule 17Ad–22(e)(17)(iii).[18]

(B) Clearing Agencies' Statement on Burden on Competition

None of the Clearing Agencies believe that the Framework would have any impact, or impose any burden, on competition because the proposed rule changes reflect some of the existing methods by which the Clearing Agencies manage Operational Risk, including their management of information technology and business continuity risks, and would not effectuate any changes to the Clearing Agencies' processes described therein as they currently apply to their respective participants.

(C) Clearing Agencies' Statement on Comments on the Proposed Rule Changes Received From Members, Participants, or Others

The Clearing Agencies have not solicited or received any written comments relating to this proposal. The Clearing Agencies will notify the Commission of any written comments received by the Clearing Agencies.

III. Date of Effectiveness of the Proposed Rule Changes, and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the clearing agency consents, the Commission will:

(A) By order approve or disapprove such proposed rule changes, or

(B) institute proceedings to determine whether the proposed rule changes should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule changes are consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–DTC–2017–014, SR–FICC–2017–017, or SR–NSCC–2017–013 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549.

All submissions should refer to File Number SR–DTC–2017–014, SR–FICC–2017–017, or SR–NSCC–2017–013. One of these file numbers should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule changes that are filed with the Commission, and all written communications relating to the proposed rule changes between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Clearing Agencies and on DTCC's Web site (*http://dtcc.com/legal/sec-rule-filings.aspx*). All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only

[14] *Id.*

[15] 17 CFR 240.17Ad–22(e)(17)(ii).

[16] *Id.*

[17] 17 CFR 240.17Ad–22(e)(17)(iii).

[18] *Id.*

information that you wish to make available publicly. All submissions should refer to File Number SR–DTC–2017–014, SR–FICC–2017–017, or SR–NSCC–2017–013 and should be submitted on or before September 5, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–17043 Filed 8–11–17; 8:45 am]

BILLING CODE 8011–01–P

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81341; File No. SR–BX–2017–032]

Self-Regulatory Organizations; NASDAQ BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Revise the Rules Regarding the Exchange's Options Regulatory Fee

DATES: August 8, 2017.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1], and Rule 19b–4 thereunder,[2] notice is hereby given that on July 26, 2017, NASDAQ BX, Inc. (''BX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to revise BX Rules at Chapter XV, Section 5 to: (i) Make adjustments to the amount of its Options Regulatory Fee (''ORF''); and (ii) more closely reflect the manner in which BX assesses and collects its ORF.

While the changes proposed herein are effective upon filing, the Exchange has designated the amendments [sic] become operative on August 1, 2017.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqbx.cchwallstreet.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

BX initially filed to establish its ORF in 2016.[3] The Exchange has amended its ORF several times since the inception of this fee.[4] At this time, the Exchange proposes to: (i) Amend the amount of its ORF; and (ii) revise BX Rules at Chapter XV, Section 5 to more closely reflect the manner in which BX assesses and collects its ORF.

The Exchange supports a common approach for the assessment and collection of ORF among the various options exchanges that assess such a fee. Furthermore, the Exchange supports guidance from the Commission regarding regulatory cost structures to ensure equal knowledge and treatment among options markets assessing ORF.

Proposal 1—Amend the Amount of the ORF

The Exchange assesses an ORF of $0.0004 per contract side. The Exchange proposes to increase the ORF from $0.0004 per contract side to $0.0005 per contract side as of August 1, 2017 to account for a reduction in market volume. The Exchange's proposed change to the ORF should balance the Exchange's regulatory cost [sic] against the anticipated revenue. The Exchange regularly reviews its ORF to ensure that the ORF, in combination with its other regulatory fees and fines, does not exceed regulatory costs. The Exchange believes this adjustment will permit the Exchange to cover a material portion of its regulatory costs, while not exceeding regulatory costs.

The Exchange notified its Participants of this ORF adjustment thirty (30) calendar days prior to the proposed operative date.[5]

Proposal 2—Reflect the Manner in Which BX Assesses and Collects its ORF

Currently, BX assesses its ORF for each Customer option transaction that is either: (1) Executed by a Participant on BX; or (2) cleared by a BX Participant at The Options Clearing Corporation (''OCC'') in the Customer range,[6] even if the transaction was executed by a non-member of BX, regardless of the exchange on which the transaction occurs.[7] If the OCC clearing member is a BX Participant, ORF is assessed and collected on all cleared Customer contracts (after adjustment for CMTA [8]); and (2) if the OCC clearing member is not a BX Participant, ORF is collected only on the cleared Customer contracts executed at BX, taking into account any CMTA instructions which may result in collecting the ORF from a non-member.

By way of example, if Broker A, a BX Participant, routes a Customer order to CBOE and the transaction executes on CBOE and clears in Broker A's OCC Clearing account, ORF will be collected by BX from Broker A's clearing account at OCC via direct debit. While this transaction was executed on a market other than BX, it was cleared by a BX Participant in the Participant's OCC clearing account in the Customer range, therefore there is a regulatory nexus between BX and the transaction. If Broker A was not a BX Participant, then no ORF should be assessed and collected because there is no nexus; the transaction did not execute on BX nor was it cleared by a BX Participant.

In the case where a Participant both executes a transaction and clears the transaction, the ORF is assessed to and collected from the Participant only once. In the case where a Participant executes a transaction and a different Participant clears the transaction, the ORF is assessed to and collected from the Participant who clears the transaction and not the Participant who executes the transaction. In the case

[3] *See* Securities Exchange Act Release Nos. 77053 (February 4, 3016), 81 FR 7163 (February 10, 2016) (SR–BX–2016–007); (Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating To Adopt an Options Regulatory Fee).

[4] *See* Securities Exchange Act Release No. 78361 (July 19, 2016), 81 FR 48485 (July 25, 2016) (SR–BX–2016–043).

[5] *See* Options Trader Alert #2017–54.

[6] Exchange Rules require each member to record the appropriate account origin code on all orders at the time of entry in order to allow the Exchange to properly prioritize and route orders and assess transaction fees pursuant to the Rules of the Exchange and report resulting transactions to OCC.

[7] The Exchange uses reports from OCC to determine the identity of the executing clearing firm and ultimate clearing firm.

[8] CMTA or Clearing Member Trade Assignment is a form of ''give-up'' whereby the position will be assigned to a specific clearing firm at OCC.

where a non-member executes a transaction at an away market and a Participant clears the transaction, the ORF is assessed to and collected from the Participant who clears the transaction. In the case where a Participant executes a transaction on BX and a non-member clears the transaction, the ORF is assessed to the Participant that executed the transaction and collected from the non-member who cleared the transaction. In the case where a Participant executes a transaction at an away market and a non-member clears the transaction, the ORF is not assessed to the Participant who executed the transaction or collected from the non-member who cleared the transaction because the Exchange does not have access to the data to make absolutely certain that ORF should apply. Further, the data does not allow the Exchange to identify the Participant executing the trade at an away market.

ORF Revenue and Monitoring of ORF

The Exchange monitors the amount of revenue collected from the ORF to ensure that it, in combination with other regulatory fees and fines, does not exceed regulatory costs. In determining whether an expense is considered a regulatory cost, the Exchange reviews all costs and makes determinations if there is a nexus between the expense and a regulatory function. For example, a cost related to BX's equity platform, would not be considered an expense that is compared to ORF revenue. An options surveillance employee's cost, however would be an expense that is compared to ORF revenue. The Exchange notes that fines collected by the Exchange in connection with a disciplinary manner offset ORF.

The ORF is designed to recover a material portion of the costs to the Exchange of the supervision and regulation of its Participants, including performing routine surveillances, investigations, examinations, financial monitoring, and policy, rulemaking, interpretive, and enforcement activities.

The Exchange believes that revenue generated from the ORF, when combined with all of the Exchange's other regulatory fees, will cover a material portion, but not all, of the Exchange's regulatory costs. The Exchange will continue to monitor the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory fees and fines, does not exceed regulatory costs. If the Exchange determines regulatory revenues exceed regulatory costs, the Exchange will adjust the ORF by submitting a fee change filing to the Commission.

Finally, the Exchange notes that it is amending its rule text at Chapter XV, Section 5 to remove certain rule text and include new text to make clear the manner in which ORF is assessed and collected on BX.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act [9] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act [10] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using its facility and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes the proposed clarifications in the Fee Schedule to the ORF further the objectives of Section 6(b)(4) of the Act and are equitable and reasonable since they expressly describe the Exchange's existing practices regarding the manner in which the Exchange assesses and collects its ORF.

Proposal 1—Amend the Amount of the ORF

The Exchange believes that increasing the ORF from $0.0004 per contract side to $0.0005 per contract side as of August 1, 2017 is reasonable because the Exchange's collection of ORF needs to be balanced against the amount of regulatory cost collected [sic] by the Exchange. The Exchange believes that the proposed adjustments noted herein will serve to balance the Exchange's regulatory cost against the anticipated regulatory revenue. The Exchange regularly reviews its ORF to ensure that the ORF, in combination with its other regulatory fees and fines, does not exceed regulatory costs.

The Exchange believes that increasing the ORF from $0.0004 per contract side to $0.0005 per contract side as of August 1, 2017 is equitable and not unfairly discriminatory because this modest increase will serve to balance the Exchange's regulatory revenue against the anticipated regulatory costs. The ORF seeks to recover the costs of supervising and regulating members, including performing routine surveillances, investigations, examinations, financial monitoring, and policy, rulemaking, interpretive, and enforcement activities. Moreover, the Exchange believes the ORF ensures fairness by assessing fees to those Participants that are directly based on the amount of Customer options business they conduct. Regulating Customer trading activity is much more labor intensive and requires greater expenditure of human and technical resources than regulating non-customer trading activity, which tends to be more automated and less labor-intensive. As a result, the costs associated with administering the Customer component of the Exchange's overall regulatory program are materially higher than the costs associated with administering the non-Customer component (*e.g.* Participant proprietary transactions) of its regulatory program.

The ORF is designed to recover a material portion of the costs of supervising and regulating Participants' Customer options business including performing routine surveillances, investigations, examinations, financial monitoring, and policy, rulemaking, interpretive, and enforcement activities. The Exchange will monitor the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory fees and fines, does not exceed the Exchange's total regulatory costs. The Exchange has designed the ORF to generate revenues that, when combined with all of the Exchange's other regulatory fees, will be less than or equal to the Exchange's regulatory costs, which is consistent with the Commission's view that regulatory fees be used for regulatory purposes and not to support the Exchange's business side. In this regard, the Exchange believes that the proposed amount of the fee is reasonable.

Proposal 2—Reflect the Manner in Which BX Assesses and Collects Its ORF

The Exchange believes it is reasonable and appropriate for the Exchange to charge the ORF for options transactions regardless of the exchange on which the transactions occur. The Exchange has a statutory obligation to enforce compliance by Participants and their associated persons under the Act and the rules of the Exchange and to surveil for other manipulative conduct by market participants (including non-members) trading on the Exchange. The Exchange cannot effectively surveil for such conduct without looking at and evaluating activity across all options markets. Many of the Exchange's market surveillance programs require the Exchange to look at and evaluate activity across all options markets, such as surveillance for position limit violations, manipulation, front-running and contrary exercise advice violations/expiring exercise declarations. The Exchange, because it lacks access to

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(4) and (5).

information on the identity of the entering firm for executions that occur on away markets, believes it is appropriate to assess the ORF on its Participant's clearing activity, based on information the Exchange receives from OCC, including for away market activity. Among other reasons, doing so better and more accurately captures activity that occurs away from the Exchange over which the Exchange has a degree of regulatory responsibility. In so doing, the Exchange believes that assessing ORF on Participant clearing firms in certain instances equitably distributes the collection of ORF in a fair and reasonable manner. Also, the Exchange and the other options exchanges are required to populate a consolidated options audit trail (''COATS'') [11] system in order to surveil a Participant's activities across markets.[12]

The Exchange believes that assessing the ORF to each Exchange member for options transactions cleared by OCC in the Customer range where the execution occurs on another exchange and is cleared by a BX member is an equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities. The ORF is collected by OCC on behalf of BX from Exchange clearing members for all Customer transactions they clear or from non-members for all Customer transactions they clear that were executed on BX. The Exchange believes that this collection practice is reasonable and appropriate because higher fees are assessed to those members that require more Exchange regulatory services based on the amount of Customer options business they conduct.

Regulating Customer trading activity is more labor intensive and requires greater expenditure of human and technical resources than regulating non-Customer trading activity. Surveillance, regulation and examination of non-Customer trading activity generally tends to be more automated and less labor intensive. As a result, the costs associated with administering the Customer component of the Exchange's overall regulatory program are anticipated to be typically higher than the costs associated with administering the non-Customer component of its regulatory program. The Exchange proposes assessing higher fees to those members that will require more Exchange regulatory services based on the amount of Customer options business they conduct. Additionally, the dues and fees paid by members go into the general funds of the Exchange, a portion of which is used to help pay the costs of regulation. The Exchange has in place a regulatory structure to surveil, conduct examinations and monitor the marketplace for violations of Exchange Rules. The ORF assists the Exchange to fund the cost of this regulation of the marketplace.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The ORF is not intended to have any impact on competition. Rather, it is designed to enable the Exchange to recover a material portion of the Exchange's cost related to its regulatory activities. The Exchange is obligated to ensure that the amount of regulatory revenue collected from the ORF, in combination with its other regulatory fees and fines, does not exceed regulatory costs.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[13]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–BX–2017–032 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–BX–2017–032. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–BX–2017–032, and should be submitted on or before September 5, 2017.

[11] COATS effectively enhances intermarket options surveillance by enabling the options exchanges to reconstruct the market promptly to effectively surveil certain rules.

[12] In addition to its own surveillance programs, the Exchange works with other SROs and exchanges on intermarket surveillance related issues. Through its participation in the Intermarket Surveillance Group (''ISG''), the Exchange shares information and coordinates inquiries and investigations with other exchanges designed to address potential intermarket manipulation and trading abuses. The Exchange's participation in ISG helps it to satisfy the requirement that it has coordinated surveillance with markets on which security futures are traded and markets on which any security underlying security futures are traded to detect manipulation and insider trading. *See* Section 6(h)(3)(I) of the Act. ISG is an industry organization formed in 1983 to coordinate intermarket surveillance among the SROs by co-operatively sharing regulatory information pursuant to a written agreement between the parties. The goal of the ISG's information sharing is to coordinate regulatory efforts to address potential intermarket trading abuses and manipulations.

[13] 15 U.S.C. 78s(b)(3)(A)(ii).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–17046 Filed 8–11–17; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81352; File No. SR–Phlx–2017–66]

Self-Regulatory Organizations; NASDAQ PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 1092, Nullification and Adjustment of Options Transactions Including Obvious Errors

August 8, 2017.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 3, 2017, NASDAQ PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 1092, Nullification and Adjustment of Options Transactions including Obvious Errors.

While these amendments are effective upon filing, the Exchange has designated the proposed amendments to be operative on a date that is within ninety (90) days after the Commission approved a similar proposal filed by Bats BZX on July 6, 2017.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqphlx.cchwallstreet.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange and other options exchanges recently adopted a new, harmonized rule related to the adjustment and nullification of erroneous options transactions, including a specific provision related to coordination in connection with large-scale events involving erroneous options transactions.[3] The Exchange believes that the changes the options exchanges implemented with the new, harmonized rule have led to increased transparency and finality with respect to the adjustment and nullification of erroneous options transactions. However, as part of the initial initiative, the Exchange and other options exchanges deferred a few specific matters for further discussion. Specifically, as described in the Initial Filing, the Exchange and all other options exchanges have been working to further improve the review of potentially erroneous transactions as well as their subsequent adjustment by creating an objective and universal way to determine Theoretical Price in the event a reliable NBBO is not available. Because this initiative required additional exchange and industry discussion as well as additional time for development and implementation, the Exchange and the other options exchanges determined to proceed with the Initial Filing and to undergo a secondary initiative to complete any additional improvements to the applicable rule. In this filing, the Exchange proposes to adopt procedures that will lead to a more objective and uniform way to determine Theoretical Price in the event a reliable NBBO is not available. In addition to this change, the Exchange has proposed two additional minor changes to its rules. The Exchange's proposal mirrors that of Bats BZX, which the Commission approved on July 6, 2017,[4] and those that the other options exchanges intend to file.

Calculation of Theoretical Price Using a Third Party Provider

Under the harmonized rule, when reviewing a transaction as potentially erroneous, the Exchange needs to first determine the ''Theoretical Price'' of the option, *i.e.,* the Exchange's estimate of the correct market price for the option. Pursuant to Rule 1092, if the applicable option series is traded on at least one other options exchange, then the Theoretical Price of an option series is the last national best bid (''NBB'') just prior to the trade in question with respect to an erroneous sell transaction or the last national best offer (''NBO'') just prior to the trade in question with respect to an erroneous buy transaction unless one of the exceptions described below exists. Thus, whenever the Exchange has a reliable NBB or NBO, as applicable, just prior to the transaction, then the Exchange uses this NBB or NBO as the Theoretical Price.

The Rule also contains various provisions governing specific situations where the NBB or NBO is not available or may not be reliable. Specifically, the Rule specifies situations in which there are no quotes or no valid quotes for comparison purposes, when the national best bid or offer (''NBBO'') is determined to be too wide to be reliable, and at the open of trading on each trading day. In each of these circumstances, in turn, because the NBB or NBO is not available or is deemed to be unreliable, the Exchange determines Theoretical Price. Under the current Rule, when determining Theoretical Price, Exchange personnel generally consult and refer to data such as the prices of related series, especially the closest strikes in the option in question. Exchange personnel may also take into account the price of the underlying security and the volatility characteristics of the option as well as historical pricing of the option and/or similar options. Although the Rule is administered by experienced personnel and the Exchange believes the process is currently appropriate, the Exchange recognizes that it is also subjective and could lead to disparate results for a transaction that spans multiple options exchanges.

The Exchange proposes to adopt Commentary .05 to specify how the Exchange will determine Theoretical Price when required by sub-paragraphs

[14] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 34–74919 (May 8, 2015); 80 FR 27766 (May 14, 2015) (SR–PHLX–2015–43) (the ''Initial Filing'').

[4] *See* Securities Exchange Act Release No. 34–81084 (July 6, 2017) (granting approval of Bats BZX proposal), 82 FR 32216 (July 12, 2017); 82 FR 23684 (May 23, 2017) (SR–BatsBZX–2017–035) (notice of filing of Bats BZX proposal).

(b)(1)–(3) of the Rule (*i.e.,* at the open, when there are no valid quotes or when there is a wide quote). In particular, the Exchange has been working with other options exchanges to identify and select a reliable third party vendor (''TP Provider'') that would provide Theoretical Price to the Exchange whenever one or more transactions is under review pursuant to Rule 1092 and the NBBO is unavailable or deemed unreliable pursuant to Rule 1092(b). The Exchange and other options exchanges have selected CBOE Livevol, LLC (''Livevol'') as the TP Provider, as described below. As further described below, proposed Commentary .05 would codify the use of the TP Provider as well as limited exceptions where the Exchange would be able to deviate from the Theoretical Price given by the TP Provider.

Pursuant to proposed Commentary .05, when the Exchange must determine Theoretical Price pursuant to the sub-paragraphs (b)(1)–(3) of the Rule, the Exchange will request Theoretical Price from the third party vendor to which the Exchange and all other options exchanges have subscribed. Thus, as set forth in this proposed language, Theoretical Price would be provided to the Exchange by the TP Provider on request and not through a streaming data feed.[5] This language also makes clear that the Exchange and all other options exchanges will use the same TP Provider.

As noted above, the proposed TP Provider selected by the Exchange and other options exchanges is Livevol. The Exchange proposes to codify this selection in proposed paragraph (d) to Commentary .05. As such, the Exchange would file a rule proposal and would provide notice to the options industry of any proposed change to the TP Provider.

The Exchange and other options exchanges have selected Livevol as the proposed TP Provider after diligence into various alternatives. Livevol has, since 2009, been the options industry leader in providing equity and index options market data and analytics services.[6] The Exchange believes that Livevol has established itself within the options industry as a trusted provider of such services and notes that it and all other options exchanges already subscribe to various Livevol services. In connection with this proposal, Livevol will develop a new tool based on its existing technology and services that will supply Theoretical Price to the Exchange and other options exchanges upon request. The Theoretical Price tool will leverage current market data and surrounding strikes to assist in a relative value pricing approach to generating a Theoretical Price. When relative value methods are incapable of generating a valid Theoretical Price, the Theoretical Price tool will utilize historical trade and quote data to calculate Theoretical Price.

Because the purpose of the proposal is to move away from a subjective determination by Exchange personnel when the NBBO is unavailable or unreliable, the Exchange intends to use the Theoretical Price provided by the TP Provider in all such circumstances. However, the Exchange believes it is necessary to retain the ability to contact the TP Provider if it believes that the Theoretical Price provided is fundamentally incorrect and to determine the Theoretical Price in the limited circumstance of a systems issue experienced by the TP Provider, as described below.

As proposed, to the extent an Official[7] of the Exchange believes that the Theoretical Price provided by the TP Provider is fundamentally incorrect and cannot be used consistent with the maintenance of a fair and orderly market, the Official shall contact the TP Provider to notify the TP Provider of the reason the Official believes such Theoretical Price is inaccurate and to request a review and correction of the calculated Theoretical Price. For example, if an Official received from the TP Provider a Theoretical Price of $80 in a series that the Official might expect to be instead in the range of $8 to $10 because of a recent corporate action in the underlying, the Official would request that the TP Provider review and confirm its calculation and determine whether it had appropriately accounted for the corporate action. In order to ensure that other options exchanges that may potentially be relying on the same Theoretical Price that, in turn, the Official believes to be fundamentally incorrect, the Exchange also proposes to promptly provide notice to other options exchanges that the TP Provider has been contacted to review and correct the calculated Theoretical Price at issue and to include a brief explanation of the reason for the request.[8] Although not directly addressed by the proposed Rule, the Exchange expects that all other options exchanges once in receipt of this notification would await the determination of the TP Provider and would use the corrected price as soon as it is available. The Exchange further notes that it expects the TP Provider to cooperate with, but to be independent of, the Exchange and other options exchanges.[9]

The Exchange believes that the proposed provision to allow an Official to contact the TP Provider if he or she believes the provided Theoretical Price is fundamentally incorrect is necessary, particularly because the Exchange and other options exchanges will be using the new process for the first time. Although the exchanges have conducted thorough diligence with respect to Livevol as the selected TP Provider and would do so with any potential replacement TP Provider, the Exchange is concerned that certain scenarios could arise where the Theoretical Price generated by the TP Provider does not take into account relevant factors and would result in an unfair result for market participants involved in a transaction. The Exchange notes that if such situations do indeed arise, to the extent practicable the Exchange will also work with the TP Provider and other options exchanges to improve the TP Provider's calculation of Theoretical Price in future situations. For instance, if the Exchange determines that a particular type of corporate action is not being appropriately captured by the TP Provider when such provider is generating Theoretical Price, while the Exchange believes that it needs the ability to request a review and correction of the Theoretical Price in connection with a specific review in order to provide a timely decision to market participants, the Exchange would share information regarding the specific situation with the TP Provider and other options exchanges in an effort to improve the Theoretical Price service for future use. The Exchange notes that it does not anticipate needing to rely on this provision frequently, if at all, but

[5] Though the Exchange and other options exchanges considered a streaming feed, it was determined that it would be more feasible to develop and implement an on demand service and that such a service would satisfy the goals of the initiative.

[6] The Exchange notes that in 2015, Livevol was acquired by CBOE Holdings, Inc., the ultimate parent company of the Chicago Board Options Exchange (''CBOE'') and C2 Options Exchange (''C2'').

[7] For purposes of the Rule, an Official is an Exchange staff member or contract employee designated as such by the Chief Regulatory Officer. *See* Rule 1092(a)(3).

[8] *See* proposed paragraph (b) to Commentary .05.

[9] The Exchange expects any TP Provider selected by the Exchange and other options exchanges to act independently in its determination and calculation of Theoretical Price. With respect to Livevol specifically, the Exchange again notes that Livevol is a subsidiary of CBOE Holdings, Inc., which is also the ultimate parent company of multiple options exchanges. The Exchange expects Livevol to calculate Theoretical Price independent of its affiliated exchanges in the same way it will calculate Theoretical Price independent of non-affiliated exchanges.

believes the provision is necessary nonetheless to best prepare for all potential circumstances. Further, the Theoretical Price used by the Exchange in connection with its rulings will always be that received from the TP Provider and the Exchange has not proposed the ability to deviate from such price.[10]

Pursuant to proposed paragraph (c) to Commentary .05, an Official of the Exchange may determine the Theoretical Price if the TP Provider has experienced a systems issue that has rendered its services unavailable to accurately calculate Theoretical Price and such issue cannot be corrected in a timely manner. The Exchange notes that it does not anticipate needing to rely on this provision frequently, if at all, but believes the provision is necessary nonetheless to best prepare for all potential circumstances. Further, consistent with existing text in Rule 1092(e)(4), the Exchange has not proposed a specific time by which the service must be available in order to be considered timely.[11] The Exchange expects that it would await the TP Provider's services becoming available again so long as the Exchange was able to obtain information regarding the issue and the TP Provider had a reasonable expectation of being able to resume normal operations within the next several hours based on communications with the TP Provider. More specifically with respect to Livevol, Livevol has business continuity and disaster recovery procedures that will help to ensure that the Theoretical Price tool remains available or, in the event of an outage, that service is restored in a timely manner.

The Exchange also notes that if a wide-scale event occurred, even if such event did not qualify as a ''Significant Market Event'' pursuant to Rule 1092(e), and the TP Provider was unavailable or otherwise experiencing difficulty, the Exchange believes that it and other options exchanges would seek to coordinate to the extent possible. In particular, the Exchange and other options exchanges now have a process, administered by the Options Clearing Corporation, to invoke a discussion amongst all options exchanges in the event of any widespread or significant market events. The Exchange believes that this process could be used in the event necessary if there were an issue with the TP Provider.

The Exchange also proposes to adopt language in paragraph (d) of Commentary .05 to Rule 1092 to disclaim the liability of the Exchange and the TP Provider in connection with the proposed Rule, the TP Provider's calculation of Theoretical Price, and the Exchange's use of such Theoretical Price. Specifically, the proposed rule would state that neither the Exchange, the TP Provider, nor any affiliate of the TP Provider (the TP Provider and its affiliates are referred to collectively as the ''TP Provider''), makes any warranty, express or implied, as to the results to be obtained by any person or entity from the use of the TP Provider pursuant to Commentary .05. The proposed rule would further state that the TP Provider does not guarantee the accuracy or completeness of the calculated Theoretical Price and that the TP Provider disclaims all warranties of merchantability or fitness for a particular purpose or use with respect to such Theoretical Price. Finally, the proposed Rule would state that neither the Exchange nor the TP Provider shall have any liability for any damages, claims, losses (including any indirect or consequential losses), expenses, or delays, whether direct or indirect, foreseen or unforeseen, suffered by any person arising out of any circumstance or occurrence relating to the use of such Theoretical Price or arising out of any errors or delays in calculating such Theoretical Price. This proposed language is modeled after existing language in Exchange Rules regarding ''reporting authorities'' that calculate indices.[12]

In connection with the proposed change described above, the Exchange proposes to modify Rule 1092 to state that the Exchange will rely on paragraph (b) and Commentary .05 when determining Theoretical Price.

No Valid Quotes—Market Participant Quoting on Multiple Exchanges

As described above, one of the times where the NBB or NBO is deemed to be unreliable for purposes of Theoretical Price is when there are no quotes or no valid quotes for the affected series. In addition to when there are no quotes, the Exchange does not consider the following to be valid quotes: (i) All quotes in the applicable option series published at a time where the last NBB is higher than the last NBO in such series (a ''crossed market''); (ii) quotes published by the Exchange that were submitted by either party to the transaction in question; and (iii) quotes published by another options exchange against which the Exchange has declared self-help. In recognition of today's market structure where certain participants actively provide liquidity on multiple exchanges simultaneously, the Exchange proposes to add an additional category of invalid quotes. Specifically, in order to avoid a situation where a market participant has established the market at an erroneous price on multiple exchanges, the Exchange proposes to consider as invalid the quotes in a series published by another options exchange if either party to the transaction in question submitted the quotes in the series representing such options exchange's best bid or offer. Thus, similar to being able to ignore for purposes of the Rule the quotes published by the Exchange if submitted by either party to the transaction in question, the Exchange would be able to ignore for purposes of the rule quotations on other options exchanges by that same market participant.

In order to continue to apply the Rule in a timely and organized fashion, however, the Exchange proposes to initially limit the scope of this proposed provision in two ways. First, because the process will take considerable coordination with other options exchanges to confirm that the quotations in question on an away options exchange were indeed submitted by a party to a transaction on the Exchange, the Exchange proposes to limit this provision to apply to up to twenty-five (25) total options series (*i.e.,* whether such series all relate to the same underlying security or multiple underlying securities). Second, the Exchange proposes to require the party that believes it established the best bid or offer on one or more other options exchanges to identify to the Exchange the quotes which were submitted by such party and published by other options exchanges. In other words, as proposed, the burden will be on the party seeking that the Exchange disregard their quotations on other options exchanges to identify such quotations. In turn, the Exchange will verify with such other options exchanges that such quotations were indeed submitted by such party.

Below are examples of both the current rule and the rule as proposed to be amended.

[10] To the extent the TP Provider has been contacted by an Official of the Exchange, reviews the Theoretical Price provided but disagrees that there has been any error, then the Exchange would be bound to use the Theoretical Price provided by the TP Provider.

[11] In the context of a Significant Market Event, the Exchange may determine, ''in consultation with other options exchanges . . . that timely adjustment is not feasible due to the extraordinary nature of the situation.'' *See* Rule 1092(e)(4).

[12] *See, e.g.,* Rule 1102A, which relates to index options potentially listed and traded on the Exchange and disclaims liability for a reporting authority and their affiliates.

Example 1—Current Rule, Member Erroneously Quotes on One Exchange

Assumptions

For purposes of this example, assume the following:

- A Member acting as a Market Maker on the Exchange (''Market Maker A'') is quoting in twenty series of options underlying security ABCD on the Exchange (and only the Exchange).
- Market Maker A makes an error in calculating the market for options on ABCD, and publishes quotes in all twenty series to buy options at $1.00 and to sell options at $1.05.
- In fact, options on ABCD in these series are nearly worthless and no other market participant is quoting in such series.
- Therefore, the NBBO in the twenty series at issue is $1.00 × $1.05 (with the Exchange representing the NBBO based on Market Maker A's quotes).
- Assume Member A immediately enters sell orders and executes against Market Maker A's quotes at $1.00.
- Assume Market Maker A submits to the Exchange a timely request for review of the trades with Member A as potentially erroneous transactions to buy.

Result

- Based on the Exchange's current rules, the Exchange would identify Market Maker A as a participant to the trades at issue and would consider Market Maker A's quotations invalid pursuant to Rule 1092(b)(2).
- As there were no other valid quotes to use as a reference price, the Exchange would then determine Theoretical Price.
- Assume the Exchange determines a Theoretical Price of $0.05.
- The execution price of $1.00 exceeds the $0.25 minimum amount set forth in the Exchange's table to determine whether an obvious error has occurred (*i.e.,* $0.05 + $0.25 = $0.30) so any execution at or above this price is an obvious error.
- Accordingly, the executions in all series would be adjusted by the Exchange to executions at $0.20 per contract (Theoretical Price of $0.05 plus $0.15) to the extent the incoming orders submitted by Member A were non-Customer orders.
- The executions in all series would be nullified to the extent the incoming orders submitted by Member A were Customer orders.

Example 2—Current Rule, Member Erroneously Quotes on Multiple Exchanges

Assumptions

For purposes of this example, assume the following:

- A Member acting as a Market Maker on the Exchange (''Market Maker A'') is quoting in twenty series of options underlying security ABCD on the Exchange and on a second exchange (''Away Exchange'').
- Market Maker A makes an error in calculating the market for options on ABCD, and publishes quotes on both the Exchange and the Away Exchange in all twenty series to buy options at $1.00 and to sell options at $1.05.
- In fact, options on ABCD in these series are nearly worthless and no other market participant is quoting in such series.
- Therefore, the NBBO in the twenty series at issue is $1.00 × $1.05 (with the Exchange and the Away Exchange representing the NBBO based on Market Maker A's quotes).
- Assume Member A immediately enters sell orders and executes against Market Maker A's quotes at $1.00.
- Assume Market Maker A submits to the Exchange and to the Away Exchange timely requests for review of the trades with Member A as potentially erroneous transactions to buy.

Result

- Based on the Exchange's current rules, the Exchange would identify Market Maker A as a participant to the trades at issue and would consider Market Maker A's quotations on the Exchange invalid pursuant to Rule 1092(b)(2). The Exchange, however, would view the Away Exchange's quotations as valid, and would thus determine Theoretical Price to be $1.05 (*i.e.,* the NBO in the case of a potentially erroneous buy transaction).
- The execution price of $1.00 does not exceed the $0.25 minimum amount set forth in the Exchange's table to determine whether an obvious error has occurred (*i.e.,* $1.05 + $0.25 = $1.30) so any execution at or above this price is an obvious error.
- The transactions on the Exchange would not be nullified or adjusted.
- As the Exchange and all other options exchanges have identical rules with respect to the process described above, the transactions on the Away Exchange would not be nullified or adjusted.

Example 3—Proposed Rule, Member Erroneously Quotes on Multiple Exchanges [13]

Assumptions

For purposes of this example, assume the following:

- A Member acting as a Market Maker on the Exchange (''Market Maker A'') is quoting in twenty series of options underlying security ABCD on the Exchange and on a second exchange (''Away Exchange'').[14]
- Market Maker A makes an error in calculating the market for options on ABCD, and publishes quotes on both the Exchange and the Away Exchange in all twenty series to buy options at $1.00 and to sell options at $1.05.
- In fact, options on ABCD in these series are nearly worthless and no other market participant is quoting in such series.
- Therefore, the NBBO in the twenty series at issue is $1.00 × $1.05 (with the Exchange and the Away Exchange representing the NBBO based on Market Maker A's quotes).
- Assume Member A immediately enters sell orders and executes against Market Maker A's quotes at $1.00.
- Assume Market Maker A submits to the Exchange and to the Away Exchange timely requests for review of the trades with Member A as potentially erroneous transactions to buy. At the time of submitting the requests for review to the Exchange and the Away Exchange, Market Maker A identifies to the Exchange the quotes on the Away Exchange as quotes also represented by Market Maker A (and to the Away Exchange, the quotes on the Exchange as quotes also represented by Market Maker A).

Result

- Based on the proposed rules, the Exchange would identify Market Maker A as a participant to the trades at issue and would consider Market Maker A's quotations on the Exchange invalid pursuant to Rule 1092(b)(2).
- The Exchange and the Away Exchange would also coordinate to confirm that the quotations identified by Market Maker A on the other exchange were indeed Market Maker A's quotations. Once confirmed, each of the Exchange and the Away Exchange

[13] The Exchange notes that its proposed rule will not impact the proposed handling of a request for review where a market participant is quoting only on the Exchange, thus, the Exchange has not included a separate example for such a fact pattern.

[14] The Exchange notes that the proposed rule would operate the same if Market Maker A was quoting on more than two exchanges. The Exchange has limited the example to two exchanges for simplicity.

would also consider invalid the quotations published on the other exchange.

- As there were no other valid quotes to use as a reference price, the Exchange would then determine Theoretical Price.
- Assume the Exchange determines a Theoretical Price of $0.05.
- The execution price of $1.00 exceeds the $0.25 minimum amount set forth in the Exchange's table to determine whether an obvious error has occurred (*i.e.,* $0.05 + $0.25 = $0.30) so any execution at or above this price is an obvious error.
- Accordingly, the executions in all series would be adjusted by the Exchange to executions at $0.20 per contract (Theoretical Price of $0.05 plus $0.15) to the extent the incoming orders submitted by Member A were non-Customer orders.
- The executions in all series would be nullified to the extent the incoming orders submitted by Member A were Customer orders.
- As the Exchange and all other options exchanges would have identical rules with respect to the process described above, as other options exchanges intend to adopt the same rule if the proposed rule is approved, the transactions on the Away Exchange would also be nullified or adjusted as set forth above.
- If this example was instead modified such that Market Maker A was quoting in 200 series rather than 20, the Exchange notes that Market Maker A could only request that the Exchange consider as invalid their quotations in 25 of those series on other exchanges. As noted above, the Exchange has proposed to limit the proposed rule to 25 series in order to continue to process requests for review in a timely and organized fashion in order to provide certainty to market participants. This is due to the amount of coordination that will be necessary in such a scenario to confirm that the quotations in question on an away options exchange were indeed submitted by a party to a transaction on the Exchange.

Trading Halts—Clarifying Change to Rule 1092, Commentary .03

Commentary .03 to Rule 1092 describes the Exchange's authority to declare trading halts in one or more options traded on the Exchange. The Exchange proposes to modify Commentary .03 to provide that, with respect to equity options, the Exchange shall nullify any transaction that occurs during a regulatory halt as declared by the primary listing market for the underlying security. The Exchange believes this change is necessary to distinguish a declared regulatory halt, where the underlying security should not be actively trading on any venue, from an operational issue on the primary listing exchange where the security continues to safely trade on other trading venues.

Implementation Date

The Exchange proposes to delay the operative date of this proposal to a date within ninety (90) days after the Commission approved the Bats BZX proposal on July 6, 2017. The Exchange will announce the operative date in a Regulatory Alert made available to its Members.

2. Statutory Basis

The Exchange believes that its proposal is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.[15]

Specifically, the proposal is consistent with Section 6(b)(5) of the Act[16] because it would promote just and equitable principles of trade, remove impediments to, and perfect the mechanism of, a free and open market and a national market system, and, in general, protect investors and the public interest.

As described above, the Exchange and other options exchanges are seeking to further modify their harmonized rules related to the adjustment and nullification of erroneous options transactions. The Exchange believes that the proposal to utilize a TP Provider in the event the NBBO is unavailable or unreliable will provide greater transparency and clarity with respect to the adjustment and nullification of erroneous options transactions. Particularly, the proposed changes seek to achieve consistent results for participants across U.S. options exchanges while maintaining a fair and orderly market, protecting investors and protecting the public interest. Thus, the Exchange believes that the proposal is consistent with Section 6(b)(5) of the Act[17] in that the proposed Rule will foster cooperation and coordination with persons engaged in regulating and facilitating transactions.

The Exchange again reiterates that it has retained the standard of the current rule for most reviews of options transactions pursuant to Rule 1092, which is to rely on the NBBO to determine Theoretical Price if such NBBO can reasonably be relied upon. The proposal to use a TP Provider when the NBBO is unavailable or unreliable is consistent with Section 6(b)(5) of the Act[18] in that the proposed Rule will foster cooperation and coordination with persons engaged in regulating and facilitating transactions by further reducing the possibility of disparate results between options exchanges and increasing the objectivity of the application of Rule 1092. Further, the Exchange believes that the proposed Rule is transparent with respect to the limited circumstances under which the Exchange will request a review and correction of Theoretical Price from the TP Provider, and has sought to limit such circumstances as much as possible. The Exchange notes that under the current Rule, Exchange personnel are required to determine Theoretical Price in certain circumstances and yet rarely do so because such circumstances have already been significantly limited under the harmonized rule (for example, because the wide quote provision of the harmonized rule only applies if the quote was narrower and then gapped but does not apply if the quote had been persistently wide). Thus, the Exchange believes it will need to request Theoretical Price from the TP Provider only in very rare circumstances and in turn, the Exchange anticipates that the need to contact the TP Provider for additional review of the Theoretical Price provided by the TP Provider will be even rarer. Similarly, the Exchange believes it is unlikely that an Exchange Official will ever be required to determine Theoretical Price, as such circumstance would only be in the event of a systems issue that has rendered the TP Provider's services unavailable and such issue cannot be corrected in a timely manner.

The Exchange also believes its proposal to adopt language in paragraph (d) of Commentary .05 to Rule 1092 to disclaim the liability of the Exchange and the TP Provider in connection with the proposed Rule, the TP Provider's calculation of Theoretical Price, and the Exchange's use of such Theoretical Price is consistent with the Act. As noted above, this proposed language is modeled after existing language in Exchange Rules regarding ''reporting authorities'' that calculate indices,[19] and is consistent with Section 6(b)(5) of the Act[20] in that the proposed Rule will foster cooperation and coordination

[15] 15 U.S.C. 78f(b).

[16] 15 U.S.C. 78f(b)(5).

[17] *Id.*

[18] *Id.*

[19] *See supra,* note 12.

[20] 15 U.S.C. 78f(b)(5).

with persons engaged in regulating and facilitating transactions.

As described above, the Exchange proposes a modification to the valid quotes provision to also exclude quotes in a series published by another options exchange if either party to the transaction in question submitted the orders or quotes in the series representing such options exchange's best bid or offer. The Exchange believes this proposal is consistent with Section 6(b)(5) of the Act [21] because the application of the rule will foster cooperation and coordination with persons engaged in regulating and facilitating transactions by allowing the Exchange to coordinate with other options exchanges to determine whether a market participant that is party to a potentially erroneous transaction on the Exchange established the market in an option on other options exchanges; to the extent this can be established, the Exchange believes such participant's quotes should be excluded in the same way such quotes are excluded on the Exchange. The Exchange also believes it is reasonable to limit the scope of this provision to twenty-five (25) series and to require the party that believes it established the best bid or offer on one or more other options exchanges to identify to the Exchange the quotes which were submitted by that party and published by other options exchanges. The Exchange believes these limitations are consistent with Section 6(b)(5) of the Act [22] because they will ensure that the Exchange is able to continue to apply the Rule in a timely and organized fashion, thus fostering cooperation and coordination with persons engaged in regulating and facilitating transactions and also removing impediments to and perfecting the mechanism of a free and open market and a national market system.

Finally, with respect to the proposed modification to Commentary .03 to Rule 1092, the Exchange believes that this proposal is consistent with Section 6(b)(5) of the Act [23] because it specifically provides for nullification where a trading halt exists with respect to an underlying security across the industry (*i.e.,* a regulatory halt) as distinguished from a situation where the primary exchange has experienced a technical issue but the underlying security continues to trade on other equities platforms. The Exchange notes that a similar provision already exists in the rules of certain other options exchanges, and thus, has been found to be consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes the entire proposal is consistent with Section 6(b)(8) of the Act [24] in that it does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act as explained below.

Importantly, the Exchange does not believe that the proposal will impose a burden on intermarket competition but rather that it will alleviate any burden on competition because it is the result of a collaborative effort by all options exchanges to further harmonize and improve the process related to the adjustment and nullification o [sic] erroneous options transactions. The Exchange does not believe that the rules applicable to such process is an area where options exchanges should compete, but rather, that all options exchanges should have consistent rules to the extent possible. Particularly where a market participant trades on several different exchanges and an erroneous trade may occur on multiple markets nearly simultaneously, the Exchange believes that a participant should have a consistent experience with respect to the nullification or adjustment of transactions. To that end, the selection and implementation of a TP Provider utilized by all options exchanges will further reduce the possibility that participants with potentially erroneous transactions that span multiple options exchanges are handled differently on such exchanges. Similarly, the proposed ability to consider quotations invalid on another options exchange if ultimately originating from a party to a potentially erroneous transaction on the Exchange represents a proposal intended to further foster cooperation by the options exchanges with respect to market events. The Exchange understands that all other options exchanges either have or they intend to file proposals that are substantially similar to this proposal.

The Exchange does not believe that the proposed rule change imposes a burden on intramarket competition because the proposed provisions apply to all market participants equally.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act [25] and Rule 19b–4(f)(6) [26] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2017–66 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2017–66. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/*

[21] 15 U.S.C. 78f(b)(5).

[22] *Id.*

[23] *Id.*

[24] 15 U.S.C. 78f(b)(8).

[25] 15 U.S.C. 78s(b)(3)(A).

[26] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2017–66, and should be submitted on or before September 5, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[27]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–17067 Filed 8–11–17; 8:45 am]

BILLING CODE 8011–01–P

[27] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81344; File No. SR–NASDAQ–2017–068]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Revise the NASDAQ Options Market LLC Rules Regarding the Options Regulatory Fee

August 8, 2017.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 26, 2017, The NASDAQ Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to revise The NASDAQ Options Market LLC (''NOM'') Rules at Chapter XV, Section 5 to: (i) Make adjustments to the amount of its Options Regulatory Fee (''ORF''); and (ii) more closely reflect the manner in which NOM assesses and collects its ORF.

While the changes proposed herein are effective upon filing, the Exchange has designated the amendments [sic] become operative on August 1, 2017.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaq.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

NOM initially filed to establish its ORF in 2011.[3] The Exchange has amended its ORF several times since the inception of this fee.[4] At this time, the Exchange proposes to: (i) Amend the amount of its ORF; and (ii) revise NOM's Rules at Chapter XV, Section 5 to more closely reflect the manner in which NOM assesses and collects its ORF.

The Exchange supports a common approach for the assessment and collection of ORF among the various options exchanges that assess such a fee. Furthermore, the Exchange supports guidance from the Commission regarding regulatory cost structures to ensure equal knowledge and treatment among options markets assessing ORF.

Proposal 1—Amend the Amount of the ORF

The Exchange assesses an ORF of $0.0021 per contract side. The Exchange proposes to increase the ORF from $0.0021 per contract side to $0.0027 per contract side as of August 1, 2017 to account for a reduction in market volume. The Exchange's proposed change to the ORF should balance the Exchange's regulatory cost [sic] against the anticipated revenue. The Exchange regularly reviews its ORF to ensure that the ORF, in combination with its other regulatory fees and fines, does not exceed regulatory costs. The Exchange believes this adjustment will permit the Exchange to cover a material portion of its regulatory costs, while not exceeding regulatory costs.

The Exchange notified its Participants of this ORF adjustment thirty (30) calendar days prior to the proposed operative date.[5]

Proposal 2—Reflect the Manner in Which NOM Assesses and Collects Its ORF

Currently, NOM assesses its ORF for each Customer option transaction that is either: (1) Executed by a Participant on NOM; or (2) cleared by a NOM Participant at The Options Clearing Corporation (''OCC'') in the Customer range,[6] even if the transaction was executed by a non-member of NOM, regardless of the exchange on which the transaction occurs.[7] If the OCC clearing member is a NOM Participant, ORF is assessed and collected on all cleared Customer contracts (after adjustment for CMTA [8]); and (2) if the OCC clearing member is not a NOM Participant, ORF is collected only on the cleared Customer contracts executed at NOM, taking into account any CMTA instructions which may result in collecting the ORF from a non-member.

By way of example, if Broker A, a NOM Participant, routes a Customer

[3] *See* Securities Exchange Act Release No. 65913 (December 8, 2011), 76 FR 77883 (December 14, 2011) (SR–NASDAQ–2011–163) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to the Options Regulatory Fee).

[4] *See* Securities Exchange Act Release Nos. 76950 (January 21, 2016), 81 FR 4687 January 27, 2016)(SR–NASDAQ–2016–003); and 78360 (July 19, 2016), 81 FR 48475 (July 25, 2016) (SR–NASDAQ–2016–096).

[5] *See* Options Trader Alert #2017–54.

[6] Exchange Rules require each member to record the appropriate account origin code on all orders at the time of entry in order to allow the Exchange to properly prioritize and route orders and assess transaction fees pursuant to the Rules of the Exchange and report resulting transactions to OCC.

[7] The Exchange uses reports from OCC when assessing and collecting the ORF.

[8] CMTA or Clearing Member Trade Assignment is a form of ''give-up'' whereby the position will be assigned to a specific clearing firm at OCC.

order to CBOE and the transaction executes on CBOE and clears in Broker A's OCC Clearing account, ORF will be collected by NOM from Broker A's clearing account at OCC via direct debit. While this transaction was executed on a market other than NOM, it was cleared by a NOM Participant in the Participant's OCC clearing account in the Customer range, therefore there is a regulatory nexus between NOM and the transaction. If Broker A was not a NOM Participant, then no ORF should be assessed and collected because there is no nexus; the transaction did not execute on NOM nor was it cleared by a NOM Participant.

In the case where a Participant both executes a transaction and clears the transaction, the ORF is assessed to and collected from the Participant only once. In the case where a Participant executes a transaction and a different Participant clears the transaction, the ORF is assessed to and collected from the Participant who clears the transaction and not the Participant who executes the transaction. In the case where a non-member executes a transaction at an away market and a Participant clears the transaction, the ORF is assessed to and collected from the Participant who clears the transaction. In the case where a Participant executes a transaction on NOM and a non-member clears the transaction, the ORF is assessed to the Participant that executed the transaction and collected from the non-member who cleared the transaction. In the case where a Participant executes a transaction at an away market and a non-member clears the transaction, the ORF is not assessed to the Participant who executed the transaction or collected from the non-member who cleared the transaction because the Exchange does not have access to the data to make absolutely certain that ORF should apply. Further, the data does not allow the Exchange to identify the Participant executing the trade at an away market.

ORF Revenue and Monitoring of ORF

The Exchange monitors the amount of revenue collected from the ORF to ensure that it, in combination with other regulatory fees and fines, does not exceed regulatory costs. In determining whether an expense is considered a regulatory cost, the Exchange reviews all costs and makes determinations if there is a nexus between the expense and a regulatory function. For example, a cost related to Nasdaq's equity platform, would not be considered an expense that is compared to ORF revenue. An options surveillance employee's cost, however would be an expense that is compared to ORF revenue. The Exchange notes that fines collected by the Exchange in connection with a disciplinary manner offset ORF.

The ORF is designed to recover a material portion of the costs to the Exchange of the supervision and regulation of its Participants, including performing routine surveillances, investigations, examinations, financial monitoring, and policy, rulemaking, interpretive, and enforcement activities.

The Exchange believes that revenue generated from the ORF, when combined with all of the Exchange's other regulatory fees, will cover a material portion, but not all, of the Exchange's regulatory costs. The Exchange will continue to monitor the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory fees and fines, does not exceed regulatory costs. If the Exchange determines regulatory revenues exceed regulatory costs, the Exchange will adjust the ORF by submitting a fee change filing to the Commission.

Finally, the Exchange notes that it is amending its rule text at Chapter XV, Section 5 to remove certain rule text and include new text to make clear the manner in which ORF is assessed and collected on NOM.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act [9] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act [10] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using its facility and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes the proposed clarifications in the Fee Schedule to the ORF further the objectives of Section 6(b)(4) of the Act and are equitable and reasonable since they expressly describe the Exchange's existing practices regarding the manner in which the Exchange assesses and collects its ORF.

Proposal 1—Amend the Amount of the ORF

The Exchange believes that increasing the ORF from $0.0021 per contract side to $0.0027 per contract side as of August 1, 2017 is reasonable because the Exchange's collection of ORF needs to be balanced against the amount of regulatory cost collected [sic] by the Exchange. The Exchange believes that the proposed adjustments noted herein will serve to balance the Exchange's regulatory cost against the anticipated regulatory revenue. The Exchange regularly reviews its ORF to ensure that the ORF, in combination with its other regulatory fees and fines, does not exceed regulatory costs.

The Exchange believes that increasing the ORF from $0.0021 per contract side to $0.0027 per contract side as of August 1, 2017 is equitable and not unfairly discriminatory because this modest increase will serve to balance the Exchange's regulatory revenue against the anticipated regulatory costs. The ORF seeks to recover the costs of supervising and regulating members, including performing routine surveillances, investigations, examinations, financial monitoring, and policy, rulemaking, interpretive, and enforcement activities.

Moreover, the Exchange believes the ORF ensures fairness by assessing fees to those Participants that are directly based on the amount of Customer options business they conduct. Regulating Customer trading activity is much more labor intensive and requires greater expenditure of human and technical resources than regulating non-customer trading activity, which tends to be more automated and less labor-intensive. As a result, the costs associated with administering the Customer component of the Exchange's overall regulatory program are materially higher than the costs associated with administering the non-Customer component (*e.g.* Participant proprietary transactions) of its regulatory program.

The ORF is designed to recover a material portion of the costs of supervising and regulating Participants' Customer options business including performing routine surveillances, investigations, examinations, financial monitoring, and policy, rulemaking, interpretive, and enforcement activities. The Exchange will monitor the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory fees and fines, does not exceed the Exchange's total regulatory costs. The Exchange has designed the ORF to generate revenues that, when combined with all of the Exchange's other regulatory fees, will be less than or equal to the Exchange's regulatory costs, which is consistent with the Commission's view that regulatory fees be used for regulatory purposes and not to support the Exchange's business side. In this regard, the Exchange believes

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(4) and (5).

that the proposed amount of the fee is reasonable.

Proposal 2—Reflect the Manner in Which NOM Assesses and Collects Its ORF

The Exchange believes it is reasonable and appropriate for the Exchange to charge the ORF for options transactions regardless of the exchange on which the transactions occur. The Exchange has a statutory obligation to enforce compliance by Participants and their associated persons under the Act and the rules of the Exchange and to surveil for other manipulative conduct by market participants (including non-members) trading on the Exchange. The Exchange cannot effectively surveil for such conduct without looking at and evaluating activity across all options markets. Many of the Exchange's market surveillance programs require the Exchange to look at and evaluate activity across all options markets, such as surveillance for position limit violations, manipulation, front-running and contrary exercise advice violations/expiring exercise declarations. The Exchange, because it lacks access to information on the identity of the entering firm for executions that occur on away markets, believes it is appropriate to assess the ORF on its Participant's clearing activity, based on information the Exchange receives from OCC, including for away market activity. Among other reasons, doing so better and more accurately captures activity that occurs away from the Exchange over which the Exchange has a degree of regulatory responsibility. In so doing, the Exchange believes that assessing ORF on Participant clearing firms in certain instances equitably distributes the collection of ORF in a fair and reasonable manner. Also, the Exchange and the other options exchanges are required to populate a consolidated options audit trail (''COATS'') [11] system in order to surveil a Participant's activities across markets.[12]

The Exchange believes that assessing the ORF to each Exchange member for options transactions cleared by OCC in the Customer range where the execution occurs on another exchange and is cleared by a NOM member is an equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities. The ORF is collected by OCC on behalf of NOM from Exchange clearing members for all Customer transactions they clear or from non-members for all Customer transactions they clear that were executed on NOM. The Exchange believes that this collection practice is reasonable and appropriate because higher fees are assessed to those members that require more Exchange regulatory services based on the amount of Customer options business they conduct.

Regulating Customer trading activity is more labor intensive and requires greater expenditure of human and technical resources than regulating non-Customer trading activity. Surveillance, regulation and examination of non-Customer trading activity generally tends to be more automated and less labor intensive. As a result, the costs associated with administering the Customer component of the Exchange's overall regulatory program are anticipated to be typically higher than the costs associated with administering the non-Customer component of its regulatory program. The Exchange proposes assessing higher fees to those members that will require more Exchange regulatory services based on the amount of Customer options business they conduct. Additionally, the dues and fees paid by members go into the general funds of the Exchange, a portion of which is used to help pay the costs of regulation. The Exchange has in place a regulatory structure to surveil, conduct examinations and monitor the marketplace for violations of Exchange Rules. The ORF assists the Exchange to fund the cost of this regulation of the marketplace.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The ORF is not intended to have any impact on competition. Rather, it is designed to enable the Exchange to recover a material portion of the Exchange's cost related to its regulatory activities. The Exchange is obligated to ensure that the amount of regulatory revenue collected from the ORF, in combination with its other regulatory fees and fines, does not exceed regulatory costs.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[13]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–NASDAQ–2017–068 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–NASDAQ–2017–068. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use

[11] COATS effectively enhances intermarket options surveillance by enabling the options exchanges to reconstruct the market promptly to effectively surveil certain rules.

[12] In addition to its own surveillance programs, the Exchange works with other SROs and exchanges on intermarket surveillance related issues. Through its participation in the Intermarket Surveillance Group (''ISG''), the Exchange shares information and coordinates inquiries and investigations with other exchanges designed to address potential intermarket manipulation and trading abuses. The Exchange's participation in ISG helps it to satisfy the requirement that it has coordinated surveillance with markets on which security futures are traded and markets on which any security underlying security futures are traded to detect manipulation and insider trading. *See* Section 6(h)(3)(I) of the Act. ISG is an industry organization formed in 1983 to coordinate intermarket surveillance among the SROs by co-operatively sharing regulatory information pursuant to a written agreement between the parties. The goal of the ISG's information sharing is to coordinate regulatory efforts to address potential intermarket trading abuses and manipulations.

[13] 15 U.S.C. 78s(b)(3)(A)(ii).

only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–NASDAQ–2017–068, and should be submitted on or before September 5, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–17049 Filed 8–11–17; 8:45 am]

BILLING CODE 8011–01–P

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81354; File No. SR–GEMX–2017–36]

Self-Regulatory Organizations; Nasdaq GEMX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 720, Nullification and Adjustment of Options Transactions Including Obvious Errors

August 8, 2017.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 3, 2017, Nasdaq GEMX, LLC (''GEMX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 720, Nullification and Adjustment of Options Transactions including Obvious Errors.

While these amendments are effective upon filing, the Exchange has designated the proposed amendments to be operative on a date that is within ninety (90) days after the Commission approved a similar proposal filed by Bats BZX on July 6, 2017.

The text of the proposed rule change is available on the Exchange's Web site at *www.ise.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange and other options exchanges recently adopted a new, harmonized rule related to the adjustment and nullification of erroneous options transactions, including a specific provision related to coordination in connection with large-scale events involving erroneous options transactions.[3] The Exchange believes that the changes the options exchanges implemented with the new, harmonized rule have led to increased transparency and finality with respect to the adjustment and nullification of erroneous options transactions. However, as part of the initial initiative, the Exchange and other options exchanges deferred a few specific matters for further discussion. Specifically, as described in the Initial Filing, the Exchange and all other options exchanges have been working to further improve the review of potentially erroneous transactions as well as their subsequent adjustment by creating an objective and universal way to determine Theoretical Price in the event a reliable NBBO is not available. Because this initiative required additional exchange and industry discussion as well as additional time for development and implementation, the Exchange and the other options exchanges determined to proceed with the Initial Filing and to undergo a secondary initiative to complete any additional improvements to the applicable rule. In this filing, the Exchange proposes to adopt procedures that will lead to a more objective and uniform way to determine Theoretical Price in the event a reliable NBBO is not available. In addition to this change, the Exchange has proposed two additional minor changes to its rules. The Exchange's proposal mirrors that of Bats BZX, which the Exchange [sic] approved on July 6, 2017,[4] and those that the other options exchanges intend to file, except that it omits the section of the proposal that pertains to trading halts due to the fact that the Supplementary Material to Exchange Rule 702 already includes the applicable language.

Calculation of Theoretical Price Using a Third Party Provider

Under the harmonized rule, when reviewing a transaction as potentially erroneous, the Exchange needs to first determine the ''Theoretical Price'' of the option, *i.e.,* the Exchange's estimate of the correct market price for the option. Pursuant to Rule 720, if the applicable option series is traded on at least one other options exchange, then the Theoretical Price of an option series is the last national best bid (''NBB'') just prior to the trade in question with respect to an erroneous sell transaction or the last national best offer (''NBO'') just prior to the trade in question with respect to an erroneous buy transaction unless one of the exceptions described below exists. Thus, whenever the Exchange has a reliable NBB or NBO, as applicable, just prior to the transaction, then the Exchange uses this NBB or NBO as the Theoretical Price.

[3] *See* Securities Exchange Act Release No. 74897 (May 7, 2015); 80 FR 27415 (May 13, 2015) (SR–ISE–Gemini–2015–11) (the ''Initial Filing'').

[4] *See* Securities Exchange Act Release No. 34–81084 (July 6, 2017) (granting approval of Bats BZX proposal), 82 FR 32216 (July 12, 2017); 82 FR 23684 (May 23, 2017) (SR–BatsBZX–2017–035) (notice of filing of Bats BZX proposal).

The Rule also contains various provisions governing specific situations where the NBB or NBO is not available or may not be reliable. Specifically, the Rule specifies situations in which there are no quotes or no valid quotes for comparison purposes, when the national best bid or offer (''NBBO'') is determined to be too wide to be reliable, and at the open of trading on each trading day. In each of these circumstances, in turn, because the NBB or NBO is not available or is deemed to be unreliable, the Exchange determines Theoretical Price. Under the current Rule, when determining Theoretical Price, Exchange personnel generally consult and refer to data such as the prices of related series, especially the closest strikes in the option in question. Exchange personnel may also take into account the price of the underlying security and the volatility characteristics of the option as well as historical pricing of the option and/or similar options. Although the Rule is administered by experienced personnel and the Exchange believes the process is currently appropriate, the Exchange recognizes that it is also subjective and could lead to disparate results for a transaction that spans multiple options exchanges.

The Exchange proposes to adopt Supplementary Material to Rule 720, Item .04 to specify how the Exchange will determine Theoretical Price when required by sub-paragraphs (b)(1)–(3) of the Rule (*i.e.,* at the open, when there are no valid quotes or when there is a wide quote). In particular, the Exchange has been working with other options exchanges to identify and select a reliable third party vendor (''TP Provider'') that would provide Theoretical Price to the Exchange whenever one or more transactions is under review pursuant to Rule 720 and the NBBO is unavailable or deemed unreliable pursuant to Rule 720(b). The Exchange and other options exchanges have selected CBOE Livevol, LLC (''Livevol'') as the TP Provider, as described below. As further described below, proposed Supplementary Material to Rule 720, Item .04 would codify the use of the TP Provider as well as limited exceptions where the Exchange would be able to deviate from the Theoretical Price given by the TP Provider.

Pursuant to proposed Supplementary Material to Rule 720, Item .04, when the Exchange must determine Theoretical Price pursuant to the sub-paragraphs (b)(1)–(3) of the Rule, the Exchange will request Theoretical Price from the third party vendor to which the Exchange and all other options exchanges have subscribed. Thus, as set forth in this proposed language, Theoretical Price would be provided to the Exchange by the TP Provider on request and not through a streaming data feed.[5] This language also makes clear that the Exchange and all other options exchanges will use the same TP Provider.

As noted above, the proposed TP Provider selected by the Exchange and other options exchanges is Livevol. The Exchange proposes to codify this selection in proposed paragraph (d) to Supplementary Material to Rule 720, Item .04. As such, the Exchange would file a rule proposal and would provide notice to the options industry of any proposed change to the TP Provider.

The Exchange and other options exchanges have selected Livevol as the proposed TP Provider after diligence into various alternatives. Livevol has, since 2009, been the options industry leader in providing equity and index options market data and analytics services.[6] The Exchange believes that Livevol has established itself within the options industry as a trusted provider of such services and notes that it and all other options exchanges already subscribe to various Livevol services. In connection with this proposal, Livevol will develop a new tool based on its existing technology and services that will supply Theoretical Price to the Exchange and other options exchanges upon request. The Theoretical Price tool will leverage current market data and surrounding strikes to assist in a relative value pricing approach to generating a Theoretical Price. When relative value methods are incapable of generating a valid Theoretical Price, the Theoretical Price tool will utilize historical trade and quote data to calculate Theoretical Price.

Because the purpose of the proposal is to move away from a subjective determination by Exchange personnel when the NBBO is unavailable or unreliable, the Exchange intends to use the Theoretical Price provided by the TP Provider in all such circumstances. However, the Exchange believes it is necessary to retain the ability to contact the TP Provider if it believes that the Theoretical Price provided is fundamentally incorrect and to determine the Theoretical Price in the limited circumstance of a systems issue experienced by the TP Provider, as described below.

As proposed, to the extent an Official[7] of the Exchange believes that the Theoretical Price provided by the TP Provider is fundamentally incorrect and cannot be used consistent with the maintenance of a fair and orderly market, the Official shall contact the TP Provider to notify the TP Provider of the reason the Official believes such Theoretical Price is inaccurate and to request a review and correction of the calculated Theoretical Price. For example, if an Official received from the TP Provider a Theoretical Price of $80 in a series that the Official might expect to be instead in the range of $8 to $10 because of a recent corporate action in the underlying, the Official would request that the TP Provider review and confirm its calculation and determine whether it had appropriately accounted for the corporate action. In order to ensure that other options exchanges that may potentially be relying on the same Theoretical Price that, in turn, the Official believes to be fundamentally incorrect, the Exchange also proposes to promptly provide notice to other options exchanges that the TP Provider has been contacted to review and correct the calculated Theoretical Price at issue and to include a brief explanation of the reason for the request.[8] Although not directly addressed by the proposed Rule, the Exchange expects that all other options exchanges once in receipt of this notification would await the determination of the TP Provider and would use the corrected price as soon as it is available. The Exchange further notes that it expects the TP Provider to cooperate with, but to be independent of, the Exchange and other options exchanges.[9]

The Exchange believes that the proposed provision to allow an Official to contact the TP Provider if he or she believes the provided Theoretical Price

[5] Though the Exchange and other options exchanges considered a streaming feed, it was determined that it would be more feasible to develop and implement an on demand service and that such a service would satisfy the goals of the initiative.

[6] The Exchange notes that in 2015, Livevol was acquired by CBOE Holdings, Inc., the ultimate parent company of the Chicago Board Options Exchange (''CBOE'') and C2 Options Exchange (''C2'').

[7] For purposes of the Rule, an Official is an Officer of the Exchange or such other employee designee of the Exchange that is trained in the application of this Rule. *See* Rule 720(a)(3).

[8] *See* proposed paragraph (b) to Supplementary Material to Rule 720, Item .04.

[9] The Exchange expects any TP Provider selected by the Exchange and other options exchanges to act independently in its determination and calculation of Theoretical Price. With respect to Livevol specifically, the Exchange again notes that Livevol is a subsidiary of CBOE Holdings, Inc., which is also the ultimate parent company of multiple options exchanges. The Exchange expects Livevol to calculate Theoretical Price independent of its affiliated exchanges in the same way it will calculate Theoretical Price independent of non-affiliated exchanges.

is fundamentally incorrect is necessary, particularly because the Exchange and other options exchanges will be using the new process for the first time. Although the exchanges have conducted thorough diligence with respect to Livevol as the selected TP Provider and would do so with any potential replacement TP Provider, the Exchange is concerned that certain scenarios could arise where the Theoretical Price generated by the TP Provider does not take into account relevant factors and would result in an unfair result for market participants involved in a transaction. The Exchange notes that if such situations do indeed arise, to the extent practicable the Exchange will also work with the TP Provider and other options exchanges to improve the TP Provider's calculation of Theoretical Price in future situations. For instance, if the Exchange determines that a particular type of corporate action is not being appropriately captured by the TP Provider when such provider is generating Theoretical Price, while the Exchange believes that it needs the ability to request a review and correction of the Theoretical Price in connection with a specific review in order to provide a timely decision to market participants, the Exchange would share information regarding the specific situation with the TP Provider and other options exchanges in an effort to improve the Theoretical Price service for future use. The Exchange notes that it does not anticipate needing to rely on this provision frequently, if at all, but believes the provision is necessary nonetheless to best prepare for all potential circumstances. Further, the Theoretical Price used by the Exchange in connection with its rulings will always be that received from the TP Provider and the Exchange has not proposed the ability to deviate from such price.[10]

Pursuant to proposed paragraph (c) to Supplementary Material to Rule 720, Item .04, an Official of the Exchange may determine the Theoretical Price if the TP Provider has experienced a systems issue that has rendered its services unavailable to accurately calculate Theoretical Price and such issue cannot be corrected in a timely manner. The Exchange notes that it does not anticipate needing to rely on this provision frequently, if at all, but believes the provision is necessary nonetheless to best prepare for all potential circumstances. Further, consistent with existing text in Rule 720(e)(4), the Exchange has not proposed a specific time by which the service must be available in order to be considered timely.[11] The Exchange expects that it would await the TP Provider's services becoming available again so long as the Exchange was able to obtain information regarding the issue and the TP Provider had a reasonable expectation of being able to resume normal operations within the next several hours based on communications with the TP Provider. More specifically with respect to Livevol, Livevol has business continuity and disaster recovery procedures that will help to ensure that the Theoretical Price tool remains available or, in the event of an outage, that service is restored in a timely manner.

The Exchange also notes that if a wide-scale event occurred, even if such event did not qualify as a ''Significant Market Event'' pursuant to Rule 720(e), and the TP Provider was unavailable or otherwise experiencing difficulty, the Exchange believes that it and other options exchanges would seek to coordinate to the extent possible. In particular, the Exchange and other options exchanges now have a process, administered by the Options Clearing Corporation, to invoke a discussion amongst all options exchanges in the event of any widespread or significant market events. The Exchange believes that this process could be used in the event necessary if there were an issue with the TP Provider.

The Exchange also proposes to adopt language in paragraph (d) of Supplementary Material to Rule 720, Item .04 to Rule 720 to disclaim the liability of the Exchange and the TP Provider in connection with the proposed Rule, the TP Provider's calculation of Theoretical Price, and the Exchange's use of such Theoretical Price. Specifically, the proposed rule would state that neither the Exchange, the TP Provider, nor any affiliate of the TP Provider (the TP Provider and its affiliates are referred to collectively as the ''TP Provider''), makes any warranty, express or implied, as to the results to be obtained by any person or entity from the use of the TP Provider pursuant to Supplementary Material to Rule 720, Item .04. The proposed rule would further state that the TP Provider does not guarantee the accuracy or completeness of the calculated Theoretical Price and that the TP Provider disclaims all warranties of merchantability or fitness for a particular purpose or use with respect to such Theoretical Price. Finally, the proposed Rule would state that neither the Exchange nor the TP Provider shall have any liability for any damages, claims, losses (including any indirect or consequential losses), expenses, or delays, whether direct or indirect, foreseen or unforeseen, suffered by any person arising out of any circumstance or occurrence relating to the use of such Theoretical Price or arising out of any errors or delays in calculating such Theoretical Price. This proposed language is modeled after existing language in Exchange Rules regarding ''reporting authorities'' that calculate indices.[12]

In connection with the proposed change described above, the Exchange proposes to modify Rule 720 to state that the Exchange will rely on paragraph (b) and Supplementary Material to Rule 720, Item .04 when determining Theoretical Price.

No Valid Quotes—Market Participant Quoting on Multiple Exchanges

As described above, one of the times where the NBB or NBO is deemed to be unreliable for purposes of Theoretical Price is when there are no quotes or no valid quotes for the affected series. In addition to when there are no quotes, the Exchange does not consider the following to be valid quotes: (i) All quotes in the applicable option series published at a time where the last NBB is higher than the last NBO in such series (a ''crossed market''); (ii) quotes published by the Exchange that were submitted by either party to the transaction in question; and (iii) quotes published by another options exchange against which the Exchange has declared self-help. In recognition of today's market structure where certain participants actively provide liquidity on multiple exchanges simultaneously, the Exchange proposes to add an additional category of invalid quotes. Specifically, in order to avoid a situation where a market participant has established the market at an erroneous price on multiple exchanges, the Exchange proposes to consider as invalid the quotes in a series published by another options exchange if either party to the transaction in question submitted the quotes in the series representing such options exchange's

[10] To the extent the TP Provider has been contacted by an Official of the Exchange, reviews the Theoretical Price provided but disagrees that there has been any error, then the Exchange would be bound to use the Theoretical Price provided by the TP Provider.

[11] In the context of a Significant Market Event, the Exchange may determine, ''in consultation with other options exchanges . . . that timely adjustment is not feasible due to the extraordinary nature of the situation.'' *See* Rule 720(e)(4).

[12] *See, e.g.,* ISE Rule 2011, which is incorporated by reference into the GEMX rules and which relates to index options potentially listed and traded on the Exchange and disclaim [sic] liability for a reporting authority and their affiliates.

best bid or offer. Thus, similar to being able to ignore for purposes of the Rule the quotes published by the Exchange if submitted by either party to the transaction in question, the Exchange would be able to ignore for purposes of the rule quotations on other options exchanges by that same market participant.

In order to continue to apply the Rule in a timely and organized fashion, however, the Exchange proposes to initially limit the scope of this proposed provision in two ways. First, because the process will take considerable coordination with other options exchanges to confirm that the quotations in question on an away options exchange were indeed submitted by a party to a transaction on the Exchange, the Exchange proposes to limit this provision to apply to up to twenty-five (25) total options series (*i.e.,* whether such series all relate to the same underlying security or multiple underlying securities). Second, the Exchange proposes to require the party that believes it established the best bid or offer on one or more other options exchanges to identify to the Exchange the quotes which were submitted by such party and published by other options exchanges. In other words, as proposed, the burden will be on the party seeking that the Exchange disregard their quotations on other options exchanges to identify such quotations. In turn, the Exchange will verify with such other options exchanges that such quotations were indeed submitted by such party.

Below are examples of both the current rule and the rule as proposed to be amended.

Example 1—Current Rule, Member Erroneously Quotes on One Exchange

Assumptions

For purposes of this example, assume the following:

- A Member acting as a Market Maker on the Exchange (''Market Maker A'') is quoting in twenty series of options underlying security ABCD on the Exchange (and only the Exchange).
- Market Maker A makes an error in calculating the market for options on ABCD, and publishes quotes in all twenty series to buy options at $1.00 and to sell options at $1.05.
- In fact, options on ABCD in these series are nearly worthless and no other market participant is quoting in such series.
- Therefore, the NBBO in the twenty series at issue is $1.00 × $1.05 (with the Exchange representing the NBBO based on Market Maker A's quotes).
- Assume Member A immediately enters sell orders and executes against Market Maker A's quotes at $1.00.
- Assume Market Maker A submits to the Exchange a timely request for review of the trades with Member A as potentially erroneous transactions to buy.

Result

- Based on the Exchange's current rules, the Exchange would identify Market Maker A as a participant to the trades at issue and would consider Market Maker A's quotations invalid pursuant to Rule 720(b)(2).
- As there were no other valid quotes to use as a reference price, the Exchange would then determine Theoretical Price.
- Assume the Exchange determines a Theoretical Price of $0.05.
- The execution price of $1.00 exceeds the $0.25 minimum amount set forth in the Exchange's table to determine whether an obvious error has occurred (*i.e.,* $0.05 + $0.25 = $0.30) so any execution at or above this price is an obvious error.
- Accordingly, the executions in all series would be adjusted by the Exchange to executions at $0.20 per contract (Theoretical Price of $0.05 plus $0.15) to the extent the incoming orders submitted by Member A were non-Customer orders.
- The executions in all series would be nullified to the extent the incoming orders submitted by Member A were Customer orders.

Example 2—Current Rule, Member Erroneously Quotes on Multiple Exchanges

Assumptions

For purposes of this example, assume the following:

- A Member acting as a Market Maker on the Exchange (''Market Maker A'') is quoting in twenty series of options underlying security ABCD on the Exchange and on a second exchange (''Away Exchange'').
- Market Maker A makes an error in calculating the market for options on ABCD, and publishes quotes on both the Exchange and the Away Exchange in all twenty series to buy options at $1.00 and to sell options at $1.05.
- In fact, options on ABCD in these series are nearly worthless and no other market participant is quoting in such series.
- Therefore, the NBBO in the twenty series at issue is $1.00 × $1.05 (with the Exchange and the Away Exchange representing the NBBO based on Market Maker A's quotes).
- Assume Member A immediately enters sell orders and executes against Market Maker A's quotes at $1.00.
- Assume Market Maker A submits to the Exchange and to the Away Exchange timely requests for review of the trades with Member A as potentially erroneous transactions to buy.

Result

- Based on the Exchange's current rules, the Exchange would identify Market Maker A as a participant to the trades at issue and would consider Market Maker A's quotations on the Exchange invalid pursuant to Rule 720(b)(2). The Exchange, however, would view the Away Exchange's quotations as valid, and would thus determine Theoretical Price to be $1.05 (*i.e.,* the NBO in the case of a potentially erroneous buy transaction).
- The execution price of $1.00 does not exceed the $0.25 minimum amount set forth in the Exchange's table to determine whether an obvious error has occurred (*i.e.,* $1.05 + $0.25 = $1.30) so any execution at or above this price is an obvious error.
- The transactions on the Exchange would not be nullified or adjusted.
- As the Exchange and all other options exchanges have identical rules with respect to the process described above, the transactions on the Away Exchange would not be nullified or adjusted.

Example 3—Proposed Rule, Member Erroneously Quotes on Multiple Exchanges [13]

Assumptions

For purposes of this example, assume the following:

- A Member acting as a Market Maker on the Exchange (''Market Maker A'') is quoting in twenty series of options underlying security ABCD on the Exchange and on a second exchange (''Away Exchange'').[14]
- Market Maker A makes an error in calculating the market for options on ABCD, and publishes quotes on both the Exchange and the Away Exchange in all twenty series to buy options at $1.00 and to sell options at $1.05.
- In fact, options on ABCD in these series are nearly worthless and no other market participant is quoting in such series.

[13] The Exchange notes that its proposed rule will not impact the proposed handling of a request for review where a market participant is quoting only on the Exchange, thus, the Exchange has not included a separate example for such a fact pattern.

[14] The Exchange notes that the proposed rule would operate the same if Market Maker A was quoting on more than two exchanges. The Exchange has limited the example to two exchanges for simplicity.

• Therefore, the NBBO in the twenty series at issue is $1.00 *$1.05 (with the Exchange and the Away Exchange representing the NBBO based on Market Maker A's quotes).

• Assume Member A immediately enters sell orders and executes against Market Maker A's quotes at $1.00.

• Assume Market Maker A submits to the Exchange and to the Away Exchange timely requests for review of the trades with Member A as potentially erroneous transactions to buy. At the time of submitting the requests for review to the Exchange and the Away Exchange, Market Maker A identifies to the Exchange the quotes on the Away Exchange as quotes also represented by Market Maker A (and to the Away Exchange, the quotes on the Exchange as quotes also represented by Market Maker A).

Result

• Based on the proposed rules, the Exchange would identify Market Maker A as a participant to the trades at issue and would consider Market Maker A's quotations on the Exchange invalid pursuant to Rule 720(b)(2).

• The Exchange and the Away Exchange would also coordinate to confirm that the quotations identified by Market Maker A on the other exchange were indeed Market Maker A's quotations. Once confirmed, each of the Exchange and the Away Exchange would also consider invalid the quotations published on the other exchange.

• As there were no other valid quotes to use as a reference price, the Exchange would then determine Theoretical Price.

• Assume the Exchange determines a Theoretical Price of $0.05.

• The execution price of $1.00 exceeds the $0.25 minimum amount set forth in the Exchange's table to determine whether an obvious error has occurred (*i.e.,* $0.05 + $0.25 = $0.30) so any execution at or above this price is an obvious error.

• Accordingly, the executions in all series would be adjusted by the Exchange to executions at $0.20 per contract (Theoretical Price of $0.05 plus $0.15) to the extent the incoming orders submitted by Member A were non-Customer orders.

• The executions in all series would be nullified to the extent the incoming orders submitted by Member A were Customer orders.

• As the Exchange and all other options exchanges would have identical rules with respect to the process described above, as other options exchanges intend to adopt the same rule if the proposed rule is approved, the transactions on the Away Exchange would also be nullified or adjusted as set forth above.

• If this example was instead modified such that Market Maker A was quoting in 200 series rather than 20, the Exchange notes that Market Maker A could only request that the Exchange consider as invalid their quotations in 25 of those series on other exchanges. As noted above, the Exchange has proposed to limit the proposed rule to 25 series in order to continue to process requests for review in a timely and organized fashion in order to provide certainty to market participants. This is due to the amount of coordination that will be necessary in such a scenario to confirm that the quotations in question on an away options exchange were indeed submitted by a party to a transaction on the Exchange.

Implementation Date

The Exchange proposes to delay the operative date of this proposal to a date within ninety (90) days after the Commission approved the Bats BZX proposal on July 6, 2017. The Exchange will announce the operative date in a Regulatory Alert made available to its Members.

2. Statutory Basis

The Exchange believes that its proposal is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.[15] Specifically, the proposal is consistent with Section 6(b)(5) of the Act[16] because it would promote just and equitable principles of trade, remove impediments to, and perfect the mechanism of, a free and open market and a national market system, and, in general, protect investors and the public interest.

As described above, the Exchange and other options exchanges are seeking to further modify their harmonized rules related to the adjustment and nullification of erroneous options transactions. The Exchange believes that the proposal to utilize a TP Provider in the event the NBBO is unavailable or unreliable will provide greater transparency and clarity with respect to the adjustment and nullification of erroneous options transactions. Particularly, the proposed changes seek to achieve consistent results for participants across U.S. options exchanges while maintaining a fair and orderly market, protecting investors and protecting the public interest. Thus, the Exchange believes that the proposal is consistent with Section 6(b)(5) of the Act[17] in that the proposed Rule will foster cooperation and coordination with persons engaged in regulating and facilitating transactions.

The Exchange again reiterates that it has retained the standard of the current rule for most reviews of options transactions pursuant to Rule 720, which is to rely on the NBBO to determine Theoretical Price if such NBBO can reasonably be relied upon. The proposal to use a TP Provider when the NBBO is unavailable or unreliable is consistent with Section 6(b)(5) of the Act[18] in that the proposed Rule will foster cooperation and coordination with persons engaged in regulating and facilitating transactions by further reducing the possibility of disparate results between options exchanges and increasing the objectivity of the application of Rule 720. Further, the Exchange believes that the proposed Rule is transparent with respect to the limited circumstances under which the Exchange will request a review and correction of Theoretical Price from the TP Provider, and has sought to limit such circumstances as much as possible. The Exchange notes that under the current Rule, Exchange personnel are required to determine Theoretical Price in certain circumstances and yet rarely do so because such circumstances have already been significantly limited under the harmonized rule (for example, because the wide quote provision of the harmonized rule only applies if the quote was narrower and then gapped but does not apply if the quote had been persistently wide). Thus, the Exchange believes it will need to request Theoretical Price from the TP Provider only in very rare circumstances and in turn, the Exchange anticipates that the need to contact the TP Provider for additional review of the Theoretical Price provided by the TP Provider will be even rarer. Similarly, the Exchange believes it is unlikely that an Exchange Official will ever be required to determine Theoretical Price, as such circumstance would only be in the event of a systems issue that has rendered the TP Provider's services unavailable and such issue cannot be corrected in a timely manner.

The Exchange also believes its proposal to adopt language in paragraph (d) of Supplementary Material to Rule 720, Item .04 to Rule 720 to disclaim the liability of the Exchange and the TP

[15] 15 U.S.C. 78f(b).

[16] 15 U.S.C. 78f(b)(5).

[17] *Id.*

[18] *Id.*

Provider in connection with the proposed Rule, the TP Provider's calculation of Theoretical Price, and the Exchange's use of such Theoretical Price is consistent with the Act. As noted above, this proposed language is modeled after existing language in Exchange Rules regarding ''reporting authorities'' that calculate indices,[19] and is consistent with Section 6(b)(5) of the Act[20] in that the proposed Rule will foster cooperation and coordination with persons engaged in regulating and facilitating transactions.

As described above, the Exchange proposes a modification to the valid quotes provision to also exclude quotes in a series published by another options exchange if either party to the transaction in question submitted the orders or quotes in the series representing such options exchange's best bid or offer. The Exchange believes this proposal is consistent with Section 6(b)(5) of the Act[21] because the application of the rule will foster cooperation and coordination with persons engaged in regulating and facilitating transactions by allowing the Exchange to coordinate with other options exchanges to determine whether a market participant that is party to a potentially erroneous transaction on the Exchange established the market in an option on other options exchanges; to the extent this can be established, the Exchange believes such participant's quotes should be excluded in the same way such quotes are excluded on the Exchange. The Exchange also believes it is reasonable to limit the scope of this provision to twenty-five (25) series and to require the party that believes it established the best bid or offer on one or more other options exchanges to identify to the Exchange the quotes which were submitted by that party and published by other options exchanges. The Exchange believes these limitations are consistent with Section 6(b)(5) of the Act[22] because they will ensure that the Exchange is able to continue to apply the Rule in a timely and organized fashion, thus fostering cooperation and coordination with persons engaged in regulating and facilitating transactions and also removing impediments to and perfecting the mechanism of a free and open market and a national market system.

[19] *See supra,* note 12.

[20] 15 U.S.C. 78f(b)(5).

[21] 15 U.S.C. 78f(b)(5).

[22] *Id.*

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes the entire proposal is consistent with Section 6(b)(8) of the Act[23] in that it does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act as explained below.

Importantly, the Exchange does not believe that the proposal will impose a burden on intermarket competition but rather that it will alleviate any burden on competition because it is the result of a collaborative effort by all options exchanges to further harmonize and improve the process related to the adjustment and nullification o [sic] erroneous options transactions. The Exchange does not believe that the rules applicable to such process is an area where options exchanges should compete, but rather, that all options exchanges should have consistent rules to the extent possible. Particularly where a market participant trades on several different exchanges and an erroneous trade may occur on multiple markets nearly simultaneously, the Exchange believes that a participant should have a consistent experience with respect to the nullification or adjustment of transactions. To that end, the selection and implementation of a TP Provider utilized by all options exchanges will further reduce the possibility that participants with potentially erroneous transactions that span multiple options exchanges are handled differently on such exchanges. Similarly, the proposed ability to consider quotations invalid on another options exchange if ultimately originating from a party to a potentially erroneous transaction on the Exchange represents a proposal intended to further foster cooperation by the options exchanges with respect to market events. The Exchange understands that all other options exchanges either have or they intend to file proposals that are substantially similar to this proposal.

The Exchange does not believe that the proposed rule change imposes a burden on intramarket competition because the proposed provisions apply to all market participants equally.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

[23] 15 U.S.C. 78f(b)(8).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[24] and subparagraph (f)(6) of Rule 19b–4 thereunder.[25]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–GEMX–2017–36 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–GEMX–2017–36. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's

[24] 15 U.S.C. 78s(b)(3)(A)(iii).

[25] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–GEMX–2017–36, and should be submitted on or before September 5, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–17069 Filed 8–11–17; 8:45 am]

BILLING CODE 8011–01–P

[26] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81343; File No. SR–Phlx–2017–54]

Self-Regulatory Organizations; NASDAQ PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Exchange's Pricing Schedule With Respect to the Options Regulatory Fee

August 8, 2017.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1], and Rule 19b–4 thereunder,[2] notice is hereby given that on July 26, 2017, NASDAQ PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to revise Section IV, Part D of the Pricing Schedule to more closely reflect the manner in which Phlx assesses and collects its Options Regulatory Fee (''ORF'').

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqphlx.cchwallstreet.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

Phlx initially filed to establish its ORF in 2009.[3] The Exchange has amended its ORF several times since the inception of this fee.[4] At this time, the Exchange proposes to revise Section IV, Part D of the Pricing Schedule to more closely reflect the manner in which Phlx assesses and collects its ORF.

The Exchange supports a common approach for the assessment and collection of ORF among the various options exchanges that assess such a fee. Furthermore, the Exchange supports guidance from the Commission regarding regulatory cost structures to ensure equal knowledge and treatment among options markets assessing ORF.

The Exchange assesses an ORF of $0.0045 per contract side. This proposed rule change does not seek to amend the amount of the ORF. Currently, Phlx assesses its ORF for each Customer option transaction that is either: (1) Executed by a member [5] on Phlx; or (2) cleared by a Phlx member at The Options Clearing Corporation (''OCC'') in the Customer range,[6] even if the transaction was executed by a non-member of Phlx, regardless of the exchange on which the transaction occurs.[7] If the OCC clearing member is a Phlx member, ORF is assessed and collected on all cleared Customer contracts (after adjustment for CMTA [8]); and (2) if the OCC clearing member is not a Phlx member, ORF is collected only on the cleared Customer contracts executed at Phlx, taking into account any CMTA instructions which may result in collecting the ORF from a non-member.

By way of example, if Broker A, a Phlx member, routes a Customer order to CBOE and the transaction executes on CBOE and clears in Broker A's OCC Clearing account, ORF will be collected by Phlx from Broker A's clearing account at OCC via direct debit. While this transaction was executed on a market other than Phlx, it was cleared by a Phlx member in the member's OCC clearing account in the Customer range, therefore there is a regulatory nexus between Phlx and the transaction. If Broker A was not a Phlx member, then no ORF should be assessed and collected because there is no nexus; the

[3] *See* Securities Exchange Act Release No. 61133 (December 9, 2009), 74 FR 66715 (December 16, 2009) (SR–Phlx–2009–100) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to an Options Regulatory Fee).

[4] *See* Securities Exchange Act Release Nos. 61529 (February 17, 2010), 75 FR 8421 (February 24, 2010) (SR–Phlx–2010–17); 62619 (July 30, 2010), 75 FR 47874 (August 9, 2010) (SR–Phlx–2010–100); 63436 (December 6, 2010), 75 FR 77021 (December 10, 2010) (SR–Phlx–2010–166); 65897 (December 6, 2011), 76 FR 77277 (December 12, 2011) (SR–Phlx–2011–163); 66664 (March 27, 2012), 77 FR 19743 (April 2, 2012) (SR–Phlx–2012–36); 71569 (February 19, 2014), 79 FR 10593 (February 25, 2014) (SR–Phlx–2014–12); 75749 (August 21, 2015), 80 FR 52073 (August 27, 2017) (SR–Phlx–2015–71); 77032 (February 2, 2016), 81 FR 6560 (February 8, 2016) (SR–Phlx–2016–04); and 79751 (January 6, 2017), 82 FR 3826 (January 12, 2017) (SR–Phlx–2017–02).

[5] For purposes of this filing the term ''member'' shall mean either a ''member'' or a ''member organization.''

[6] Exchange Rules require each member to record the appropriate account origin code on all orders at the time of entry in order to allow the Exchange to properly prioritize and route orders and assess transaction fees pursuant to the Rules of the Exchange and report resulting transactions to OCC. The Exchange represents that it has surveillances in place to verify that members mark orders with the correct account origin code.

[7] The Exchange uses reports from OCC when assessing and collecting the ORF.

[8] CMTA or Clearing Member Trade Assignment is a form of ''give-up'' whereby the position will be assigned to a specific clearing firm at OCC. Phlx Rule 1052 provides that every Clearing Member is responsible for the clearance of the Exchange options transactions of such Clearing Member and of each member who gives up the name of such Clearing Member in an Exchange options transaction, provided the Clearing Member has authorized such member to give up its name with respect to Exchange options transactions.

transaction did not execute on Phlx nor was it cleared by a Phlx member.

In the case where a member both executes a transaction and clears the transaction, the ORF is assessed to and collected from the member only once. In the case where a member executes a transaction and a different member clears the transaction, the ORF is assessed to and collected from the member who clears the transaction and not the member who executes the transaction. In the case where a non-member executes a transaction at an away market and a member clears the transaction, the ORF is assessed to and collected from the member who clears the transaction. In the case where a member executes a transaction on Phlx and a non-member clears the transaction, the ORF is assessed to the member that executed the transaction and collected from the non-member who cleared the transaction. In the case where a member executes a transaction at an away market and a non-member clears the transaction, the ORF is not assessed to the member who executed the transaction or collected from the non-member who cleared the transaction because the Exchange does not have access to the data to make absolutely certain that ORF should apply. Further, the data does not allow the Exchange to identify the member executing the trade at an away market.

ORF Revenue and Monitoring of ORF

The Exchange monitors the amount of revenue collected from the ORF to ensure that it, in combination with other regulatory fees and fines, does not exceed regulatory costs. In determining whether an expense is considered a regulatory cost, the Exchange reviews all costs and makes determinations if there is a nexus between the expense and a regulatory function. For example, a cost related to PSX, the Exchange's equity platform, would not be considered an expense that is compared to ORF revenue. An options surveillance employee's cost, however would be an expense that is compared to ORF revenue. The Exchange notes that fines collected by the Exchange in connection with a disciplinary manner offset ORF.

The ORF is designed to recover a material portion of the costs to the Exchange of the supervision and regulation of its members, including performing routine surveillances, investigations, examinations, financial monitoring, and policy, rulemaking, interpretive, and enforcement activities.

The Exchange believes that revenue generated from the ORF, when combined with all of the Exchange's other regulatory fees, will cover a material portion, but not all, of the Exchange's regulatory costs. The Exchange will continue to monitor the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory fees and fines, does not exceed regulatory costs. If the Exchange determines regulatory revenues exceed regulatory costs, the Exchange will adjust the ORF by submitting a fee change filing to the Commission.

Finally, the Exchange notes that it is amending its rule text at Section IV, Part D to remove outdated rule text and include new rule text to make clear the manner in which ORF is assessed and collected on Phlx.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act [9] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act[10] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using its facility and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes the proposed clarifications in the Fee Schedule to the ORF further the objectives of Section 6(b)(4) of the Act and are equitable and reasonable since they expressly describe the Exchange's existing practices regarding the manner in which the Exchange assesses and collects its ORF.

The Exchange believes it is reasonable and appropriate for the Exchange to charge the ORF for options transactions regardless of the exchange on which the transactions occur. The Exchange has a statutory obligation to enforce compliance by members and their associated persons under the Act and the rules of the Exchange and to surveil for other manipulative conduct by market participants (including non-members) trading on the Exchange. The Exchange cannot effectively surveil for such conduct without looking at and evaluating activity across all options markets. Many of the Exchange's market surveillance programs require the Exchange to look at and evaluate activity across all options markets, such as surveillance for position limit violations, manipulation, front-running and contrary exercise advice violations/expiring exercise declarations. The Exchange, because it lacks access to information on the identity of the entering firm for executions that occur on away markets, believes it is appropriate to assess the ORF on its member's clearing activity, based on information the Exchange receives from OCC, including for away market activity. Among other reasons, doing so better and more accurately captures activity that occurs away from the Exchange over which the Exchange has a degree of regulatory responsibility. In so doing, the Exchange believes that assessing ORF on member clearing firms in certain instances equitably distributes the collection of ORF in a fair and reasonable manner. Also, the Exchange and the other options exchanges are required to populate a consolidated options audit trail (''COATS'') [11] system in order to surveil a member's activities across markets.[12]

The Exchange believes that assessing the ORF to each Exchange member for options transactions cleared by OCC in the Customer range where the execution occurs on another exchange and is cleared by a Phlx member is an equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities. The ORF is collected by OCC on behalf of Phlx from Exchange clearing members for all Customer transactions they clear or from non-members for all Customer transactions they clear that were executed on Phlx. The Exchange believes that this collection practice is reasonable and appropriate because higher fees are assessed to those members that require more Exchange regulatory services based on the amount of Customer options business they conduct.

Regulating Customer trading activity is more labor intensive and requires greater expenditure of human and

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(4) and (5).

[11] COATS effectively enhances intermarket options surveillance by enabling the options exchanges to reconstruct the market promptly to effectively surveil certain rules.

[12] In addition to its own surveillance programs, the Exchange works with other SROs and exchanges on intermarket surveillance related issues. Through its participation in the Intermarket Surveillance Group (''ISG''), the Exchange shares information and coordinates inquiries and investigations with other exchanges designed to address potential intermarket manipulation and trading abuses. The Exchange's participation in ISG helps it to satisfy the requirement that it has coordinated surveillance with markets on which security futures are traded and markets on which any security underlying security futures are traded to detect manipulation and insider trading. *See* Section 6(h)(3)(I) of the Act. ISG is an industry organization formed in 1983 to coordinate intermarket surveillance among the SROs by co-operatively sharing regulatory information pursuant to a written agreement between the parties. The goal of the ISG's information sharing is to coordinate regulatory efforts to address potential intermarket trading abuses and manipulations.

technical resources than regulating non-Customer trading activity, which tends to be more automated and less labor intensive. As a result, the costs associated with administering the Customer component of the Exchange's overall regulatory program are anticipated to be typically higher than the costs associated with administering the non-Customer component of its regulatory program. The Exchange proposes assessing higher fees to those members that will require more Exchange regulatory services based on the amount of Customer options business they conduct. Additionally, the dues and fees paid by members go into the general funds of the Exchange, a portion of which is used to help pay the costs of regulation. The Exchange has in place a regulatory structure to surveil, conduct examinations and monitor the marketplace for violations of Exchange Rules. The ORF assists the Exchange to fund the cost of this regulation of the marketplace.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The ORF is not intended to have any impact on competition. Rather, it is designed to enable the Exchange to recover a material portion of the Exchange's cost related to its regulatory activities. The Exchange is obligated to ensure that the amount of regulatory revenue collected from the ORF, in combination with its other regulatory fees and fines, does not exceed regulatory costs.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[13]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–Phlx–2017–54 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–Phlx–2017–54. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File No. SR–Phlx–2017–54, and should be submitted on or before September 5, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–17048 Filed 8–11–17; 8:45 am]

BILLING CODE 8011–01–P

[13] 15 U.S.C. 78s(b)(3)(A)(ii).

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81350; File No. SR–ISE–2017–77]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Schedule of Fees

August 8, 2017.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 1, 2017, Nasdaq ISE, LLC (''ISE'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Schedule of Fees to (1) eliminate Priority Customer complex order rebates for all net zero complex orders without any associated average daily volume requirement, and (2) reduce the maker fee charged to Market Makers and Non-Nasdaq ISE Market Makers for Regular Orders in Select Symbols when trading against Priority Customer complex orders that leg into the regular order book.

The text of the proposed rule change is available on the Exchange's Web site at *www.ise.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Schedule of Fees to (1) eliminate Priority Customer [3] complex order rebates for all net zero complex orders without any associated average daily volume (''ADV'') requirement, and (2) reduce the maker fee charged to Market Makers [4] and Non-Nasdaq ISE Market Makers [5] for Regular Orders in Select Symbols [6] when trading against Priority Customer complex orders that leg into the regular order book. These changes are designed to eliminate rebate arbitrage where market participants enter valueless complex orders solely for the purpose of earning a rebate, and to reduce disincentives for Market Makers to provide liquidity on the Exchange.

Currently, the Exchange does not provide Priority Customer rebates for complex orders that that leg in to the regular order book and trade at a net price per contract that is at or near $0.00 (*i.e.,* net zero complex orders), provided those orders are entered on behalf of originating market participants that execute an ADV of at least 1,000 contracts in net zero complex orders in a given month. For purposes of determining which complex orders qualify as net zero the Exchange counts all complex orders that leg in to the regular order book and are executed at a net price per contract that is within a range of $0.01 credit and $0.01 debit. The Exchange now proposes to eliminate Priority Customer complex order rebates for all net zero complex orders, regardless of whether the order is entered on behalf of originating market participants that execute a specified ADV of net zero complex orders.

Priority Customer complex orders are typically eligible for tiered rebates that range from $0.26 per contract (*i.e.,* for Tier 1) to $0.49 per contract (*i.e.,* for Tier 8) depending on the member's Priority Customer Complex ADV. Pursuant to the provision described above, however, the Exchange does not provide these rebates for net zero complex orders entered on behalf of originating market participants that execute a significant ADV of these orders in a given month. This provision is designed to prevent members from engaging in rebate arbitrage by entering essentially valueless complex orders solely to recover rebates. While net zero complex orders would generally not find a counterparty in the complex order book, they may leg in to the regular order book where they are typically executed by Market Makers or other market participants on the individual legs who pay a fee to trade with this order flow. Market Makers have continued to express concerns about trading against net zero complex orders that leg into the regular market, as offending firms modify their behavior to stay within the ADV requirements set by the Exchange. These Market Makers have indicated that continued interaction with these economically valueless orders impedes their ability to provide liquidity on the Exchange as they are charged to trade against these net zero complex orders when they leg into the regular market and execute against their quotes.

The Exchange believes that it is in the interest of a fair and orderly market to provide appropriate incentives for Market Makers to maintain quality markets. As a result, the Exchange has instituted several programs that are aimed at incentivizing Market Makers to provide liquidity, including, for example, the Market Maker Plus program, which rewards Market Makers for routinely quoting at the national best bid or offer.[7] Despite the Exchange's efforts to date, market participants have continued to enter valueless net zero complex orders and may earn rebates for those orders if they stay within the ADV threshold described in the rule. In particular, today, market participants can reduce their ADV in net zero complex orders and/or split their net zero order flow across multiple originating market participants to stay within the ADV thresholds set by the Exchange, and thereby qualify for Priority Customer complex order rebates. The Exchange believes that it is appropriate at this time to completely remove incentives for trading net zero complex orders by eliminating the current ADV threshold. With this proposed change, all net zero complex orders will be ineligible for Priority Customer complex order rebates. Eliminating the ADV requirement will discourage market participants from engaging in this economically valueless conduct, which impedes Market Makers' ability to maintain quality markets, as no net zero complex orders will be rebate eligible. Priority Customer complex orders that do not meet the definition of a net zero complex order will continue to receive rebates based on the tier achieved.

In addition, the Exchange proposes to reduce the fee charged to Market Makers and Non-Nasdaq ISE Market Makers for Regular Orders in Select Symbols when trading against Priority Customer complex orders that leg into the regular book. Currently, Market Makers (including Market Makers that qualify for Market Maker Plus) [8] and Non-Nasdaq ISE Market Makers are charged a maker fee of $0.30 per contract for Regular Orders in Select Symbols when trading against Priority Customer complex orders that leg into the regular order book.[9] This higher maker fee was originally adopted because the Exchange pays a rebate to Priority Customer complex orders that leg into the regular order book. With the changes described above, the Exchange believes that it is appropriate to revisit this fee, and now proposes to reduce the fee to $0.10 per contract. This change will reduce disincentives for Market Makers

[3] A ''Priority Customer'' is a person or entity that is not a broker/dealer in securities, and does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s), as defined in Nasdaq ISE Rule 100(a)(37A).

[4] The term ''Market Makers'' refers to ''Competitive Market Makers'' and ''Primary Market Makers'' collectively. See ISE Rule 100(a)(25).

[5] A ''Non-Nasdaq ISE Market Maker'' is a market maker as defined in Section 3(a)(38) of the Securities Exchange Act of 1934, as amended, registered in the same options class on another options exchange.

[6] ''Select Symbols'' are options overlying all symbols listed on the Nasdaq ISE that are in the Penny Pilot Program.

[7] *See* ISE Schedule of Fees, Section I., Regular Order Fees and Rebates.

[8] A Market Maker Plus is a Market Maker who is on the National Best Bid or National Best Offer a specified percentage of the time for series trading between $0.03 and $3.00 (for options whose underlying stock's previous trading day's last sale price was less than or equal to $100) and between $0.10 and $3.00 (for options whose underlying stock's previous trading day's last sale price was greater than $100) in premium in each of the front two expiration months. The specified percentage is at least 80% but lower than 85% of the time for Tier 1, at least 85% but lower than 95% of the time for Tier 2, and at least 95% of the time for Tier 3. A Market Maker's single best and single worst quoting days each month based on the front two expiration months, on a per symbol basis, will be excluded in calculating whether a Market Maker qualifies for this rebate, if doing so will qualify a Market Maker for the rebate.

[9] Market Makers that qualify for Market Maker Plus are not charged a fee or provided a rebate when trading against non-Priority Customer complex orders that leg into the regular order book. Other Market Makers and Non-Nasdaq ISE Market Makers are charged the regular $0.10 per contract fee when trading against non-Priority Customer complex orders that leg into the regular order book.

to provide liquidity to the benefit of all market participants that trade on the Exchange.[10]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[11] in general, and Section 6(b)(4) of the Act,[12] in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among its members and other persons using its facilities.

The Exchange believes that it is reasonable and equitable to remove the ADV threshold from the net zero provision in the Schedule of Fees as this change is designed to remove financial incentives for market participants to engage in rebate arbitrage by entering net zero complex orders on the Exchange that do not have any economic substance. With the current provision, offending firms have repeatedly found ways to continue to submit these economically valueless orders to the detriment of the Exchange and market participants that trade on the Exchange. The continued submission of these net zero complex orders by a handful of market participants has generated complaints from the Market Makers that trade against these orders in the regular order book, as firms recognize these net zero complex orders as essentially non-economic. The Exchange believes that eliminating the ADV threshold will take away the incentives for firms to continue to enter net zero complex orders purely to earn a rebate, thereby reducing the cost of these trades to the Exchange and its members.

Market Makers may be impeded in providing liquidity when doing so may result in trading against these net zero complex orders that leg into the regular market. The Exchange believes that it is important that Market Makers be properly incentivized to maintain quality markets, and is therefore proposing to take steps to eliminate the incentives for market participants to enter net zero complex orders. Priority Customer complex orders, including net zero complex orders that leg in to the regular order book, are currently paid significant rebates by the Exchange, which are funded in part by charging higher fees to the market participants that trade against these orders. The Exchange believes that eliminating the ADV requirement in this provision will discourage market participants from entering valueless net zero complex orders, which are entered for the sole purpose of earning a rebate. As a result, the Exchange believes that Market Makers will be aided in their role of providing liquidity and maintaining quality markets to the benefit of all market participants that trade on the Exchange.

Furthermore, the Exchange believes that the proposed change is not unfairly discriminatory as it is designed to stop market participants from taking advantage of Exchange rebates by entering orders that lack economic substance. The Exchange is proposing to eliminate Priority Customer complex order rebates for all market participants, regardless of their ADV in this activity. Thus, all market participants that enter net zero complex orders will be uniformly denied rebates for those orders. To the extent that those market participants execute non-net zero complex orders, however, they will continue to receive Priority Customer complex order rebates based on their ADV in that activity. The Exchange does not believe that it is unfairly discriminatory to eliminate the ADV threshold for net zero complex orders since the elimination of this threshold means that no market participants will receive rebates for these orders.

The Exchange also believes that it is reasonable and equitable reduce the maker fee charged to Market Makers and Non-Nasdaq ISE Market Makers for Regular Orders in Select Symbols when trading against Priority Customer complex orders that leg into the regular order book. With the changes described above related to net zero complex orders, which will eliminate rebates for certain Priority Customer complex orders that leg in to the regular order book, the Exchange believes that it is appropriate to also reduce the amount charged to Market Makers when trading against such Priority Customer complex orders in the regular order book. Furthermore, the Exchange believes that reducing the fee charged to Market Makers and Non-Nasdaq ISE Makers when trading against Priority Customer complex order that leg into the regular order book will increase incentives for those firms to provide liquidity to the benefit of all market participants that trade on the Exchange. The Exchange does not believe that this change is unfairly discriminatory as the same $0.10 per contract maker fee applies to Market Makers (other than those that qualify for Market Maker Plus) and Non-Nasdaq ISE Market Makers when trading against other orders in these symbols, and is also the same as the maker fees charged to Firm Proprietary,[13] Broker-Dealer,[14] and Professional Customer orders.[15]

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[16] the Exchange does not believe that the proposed rule change will impose any burden on intermarket or intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. By eliminating the ADV requirement applicable to the Exchange's net zero complex order provision in the Schedule of Fees, the proposed rule change is designed to eliminate the ability for certain market participants to engage in rebate arbitrage to the detriment of the Exchange and its members. Rather than impede competition, the Exchange believes that this change will enhance competition by enabling Market Makers to step up and maintain quality markets to the benefit of all market participants that trade on the Exchange. In addition, the reduction of Market Maker and Non-Nasdaq ISE Market Maker fees for trading against Priority Customer complex orders that leg into the regular order book will also further competition as the fees are consistent with those charged to other market participants. The Exchange operates in a highly competitive market in which market participants can readily direct their order flow to competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and rebates to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed fee changes reflect this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

[10] With the proposed fee reduction, Market Makers (other than those that qualify for Market Maker Plus) and Non-Nasdaq ISE Market Makers will be charged a maker fee of $0.10 per contract for Regular Orders in Select Symbols regardless of the order on the other side of the trade. The Exchange therefore proposes to effectuate this change by deleting footnote 11.

[11] 15 U.S.C. 78f.

[12] 15 U.S.C. 78f(b)(4).

[13] A ''Firm Proprietary'' order is an order submitted by a member for its own proprietary account.

[14] A ''Broker-Dealer'' order is an order submitted by a member for a broker-dealer account that is not its own proprietary account.

[15] A ''Professional Customer'' is a person or entity that is not a broker/dealer and is not a Priority Customer.

[16] 15 U.S.C. 78f(b)(8).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[17] and Rule 19b–4(f)(2)[18] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ISE–2017–77 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISE–2017–77. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ISE–2017–77 and should be submitted on or before September 5, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–17065 Filed 8–11–17; 8:45 am]

BILLING CODE 8011–01–P

[17] 15 U.S.C. 78s(b)(3)(A)(ii).

[18] 17 CFR 240.19b–4(f)(2).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81337; File No. SR–NYSEAMER–2017–02]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Change in Connection With Its Recent Name Change From NYSE MKT LLC to NYSE American LLC and the Related Rebranding of NYSE Amex Options to NYSE American Options

DATES: August 8, 2017.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on July 27, 2017, NYSE American LLC (the ''Exchange'' or ''NYSE American'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes in connection with its recent name change from NYSE MKT LLC (''NYSE MKT'') to NYSE American and the related rebranding of NYSE Amex Options to NYSE American Options, to make technical and conforming changes to the rules of the Exchange (''Rules'') and the NYSE American Options Fee Schedule (''Fee Schedule''). The proposed change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes, in connection with its name change from NYSE MKT to NYSE American and the related rebranding of NYSE Amex Options to NYSE American Options, to make technical and conforming changes the Rules and Fee Schedule.[4]

Background

On March 16, 2017, the Exchange filed rule changes with the Commission in connection with its name change to NYSE American.[5] In addition, on May 19, 2017, the Exchange filed rule changes with the Commission associated with the rebranding of NYSE Amex Options, the Exchange's facility for trading options, to NYSE American Options.[6] In those filings, the Exchange committed to submitting subsequent rule filings as necessary to make any technical and conforming changes to proposed rule changes that were pending as of the time of those filings or that occurred after such filings but before the operative date of the name

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Exchange originally filed the proposed changes on July 21, 2017 (SR–NYSEMKT–2017–47) and withdrew such filing on July 27, 2017.

[5] *See* Securities Exchange Act Release No.80283 (March 21, 2017), 82 FR 15244 (March 27, 2017) (SR–NYSEMKT–2017–14).

[6] *See* Securities Exchange Act Release No. 80748 (May 23, 2017), 82 FR 24764 (May 30, 2017) (SR–NYSEMKT 2017–20).

change.[7] The Exchange's name change became operative on July 24, 2017. Accordingly, the Exchange now proposes to make technical and conforming changes to its Rules and Fee Schedule to reflect the name change to NYSE American and rebrand from NYSE Amex Options to NYSE American Options, as detailed below.

Proposed Changes

- In Rule 36—Equities, Supplementary Materials .21, .23, and .70 (Communications Between Exchange and Members' Offices), the Exchange proposes to change references to ''NYSE Amex Options Trading Floor'' to ''NYSE American Options Trading Floor.''
- In the Fee Schedule, under Section I. Options Transaction Fees and Credits, subpart M.BOLD Mechanism Fees & Credits, the Exchange proposes to change the reference to ''NYSE Amex Options Market Makers'' to ''NYSE American Options Market Makers''.

None of the foregoing changes are substantive.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Exchange Act [8] in general, and with Section 6(b)(1) [9] in particular, in that it enables the Exchange to be so organized as to have the capacity to be able to carry out the purposes of the Exchange Act and to comply, and to enforce compliance by its exchange members and persons associated with its exchange members, with the provisions of the Exchange Act, the rules and regulations thereunder, and the rules of the Exchange.

The proposed rule change is a non-substantive change and does not impact the governance or ownership of the Exchange. The Exchange believes that the proposed rule change would enable the Exchange to continue to be so organized as to have the capacity to carry out the purposes of the Exchange Act and comply and enforce compliance with the provisions of the Exchange Act by its members and persons associated with its members, because ensuring that the Rules and Fee Schedule accurately reflect the name of the Exchange and its facility for trading options would contribute to the orderly operation of the Exchange by adding clarity and transparency to such documents and rules.

For similar reasons, the Exchange also believes that the proposed rule change is consistent with Section 6(b)(5) of the Act,[10] in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change would remove impediments to and perfect the mechanism of a free and open market and a national market system by ensuring that market participants can more easily navigate, understand and comply with the Rules and Fee Schedule. The Exchange believes that, by ensuring that the Rules and Fee Schedule accurately reflect the name of the Exchange and its options market the proposed rule change would reduce potential investor or market participant confusion.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended to address competitive issues but rather is concerned solely with updating the Rules and Fee Schedule to reflect its name change from NYSE MKT to NYSE American and the related rebranding of NYSE Amex Options to NYSE American Options.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [11] and Rule 19b–4(f)(3) [12] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [13] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEAMER–2017–02 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEAMER–2017–02. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make

[7] *See supra* note 5 at 15246 and note 6 at 24765.

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(1).

[10] 15 U.S.C. 78f(b)(5).

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(3).

[13] 15 U.S.C. 78s(b)(2)(B).

available publicly. All submissions should refer to File Number SR–NYSEAMER–2017–02 and should be submitted on or before September 5, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–17042 Filed 8–11–17; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81342; File No. SR–GEMX–2017–31]

Self-Regulatory Organizations; Nasdaq GEMX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend GEMX's Schedule of Fees With Respect to the Options Regulatory Fee

August 8, 2017.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 26, 2017, Nasdaq GEMX, LLC (''GEMX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to revise GEMX's Schedule of Fees to: (i) More closely reflect the manner in which GEMX assesses and collects its ORF; and (ii) remove rule text related to the timing when the Exchange may increase or decrease the amount of the ORF.

The text of the proposed rule change is available on the Exchange's Web site at *www.ise.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

GEMX initially filed to establish its ORF in 2013.[3] At this time, the Exchange proposes to: (i) More closely reflect the manner in which GEMX assesses and collects its ORF; and (ii) remove rule text related to the timing when the Exchange may increase or decrease the amount of its ORF.

The Exchange supports a common approach for the assessment and collection of ORF among the various options exchanges that assess such a fee. Furthermore, the Exchange supports guidance from the Commission regarding regulatory cost structures to ensure equal knowledge and treatment among options markets assessing ORF.

Proposal 1—Reflect the Manner in Which GEMX Assesses and Collects Its ORF

Currently, GEMX assesses an ORF of $0.0010 per contract side. This proposed rule change does not seek to amend the amount of the ORF. Currently, GEMX assesses its ORF for each customer option transaction that is either: (1) Executed by a member on GEMX; or (2) cleared by a GEMX member at The Options Clearing Corporation (''OCC'') in the customer range,[4] even if the transaction was executed by a non-member of GEMX, regardless of the exchange on which the transaction occurs.[5] If the OCC clearing member is a GEMX member, ORF is assessed and collected on all cleared customer contracts (after adjustment for CMTA[6]); and (2) if the OCC clearing member is not a GEMX member, ORF is collected only on the cleared customer contracts executed at GEMX, taking into account any CMTA instructions which may result in collecting the ORF from a non-member.

By way of example, if Broker A, a GEMX member, routes a customer order to CBOE and the transaction executes on CBOE and clears in Broker A's OCC Clearing account, ORF will be collected by GEMX from Broker A's clearing account at OCC via direct debit. While this transaction was executed on a market other than GEMX, it was cleared by a GEMX member in the member's OCC clearing account in the customer range, therefore there is a regulatory nexus between GEMX and the transaction. If Broker A was not a GEMX member, then no ORF should be assessed and collected because there is no nexus; the transaction did not execute on GEMX nor was it cleared by a GEMX member.

In the case where a member both executes a transaction and clears the transaction, the ORF is assessed to and collected from the member only. In the case where a member executes a transaction and a different member clears the transaction, the ORF is assessed to and collected from the member who clears the transaction and not the member who executes the transaction. In the case where a non-member executes a transaction at an away market and a member clears the transaction, the ORF is assessed to and collected from the member who clears the transaction. In the case where a member executes a transaction on GEMX and a non-member clears the transaction, the ORF is assessed to the member that executed the transaction and collected from the non-member who cleared the transaction. In the case where a member executes a transaction at an away market and a non-member clears the transaction, the ORF is not assessed to the member who executed the transaction or collected from the non-member who cleared the transaction because the Exchange does not have access to the data to make absolutely certain that ORF should apply. Further, the data does not allow the Exchange to identify the member executing the trade at an away market.

ORF Revenue and Monitoring of ORF

The Exchange monitors the amount of revenue collected from the ORF to ensure that it, in combination with other regulatory fees and fines, does not exceed regulatory costs. In determining whether an expense is considered a regulatory cost, the Exchange reviews all costs and makes determinations if there is a nexus between the expense

[14] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release Nos. 70200 (August 14, 2013), 74 FR 51242 (August 20, 2013) (SR-Topaz-2013–01) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Establish the Schedule of Fees).

[4] Members must record the appropriate account origin code on all orders at the time of entry in order. The Exchange represents that it has surveillances in place to verify that members mark orders with the correct account origin code.

[5] The Exchange uses reports from OCC when assessing and collecting the ORF.

[6] CMTA or Clearing Member Trade Assignment is a form of ''give-up'' whereby the position will be assigned to a specific clearing firm at OCC.

and a regulatory function. The Exchange notes that fines collected by the Exchange in connection with a disciplinary manner offset ORF.

The ORF is designed to recover a material portion of the costs to the Exchange of the supervision and regulation of its members, including performing routine surveillances, investigations, examinations, financial monitoring, and policy, rulemaking, interpretive, and enforcement activities.

The Exchange believes that revenue generated from the ORF, when combined with all of the Exchange's other regulatory fees, will cover a material portion, but not all, of the Exchange's regulatory costs. The Exchange will continue to monitor the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory fees and fines, does not exceed regulatory costs. If the Exchange determines regulatory revenues exceed regulatory costs, the Exchange will adjust the ORF by submitting a fee change filing to the Commission.

Finally, the Exchange notes that it is amending GEMX's Schedule of Fees to remove certain rule text and include new rule text to make clear the manner in which ORF is assessed and collected on GEMX.

Proposal 2—Semi-Annual Changes to ORF

The Exchange's current ORF rule text provides that, ''The Exchange may only increase or decrease the Options Regulatory Fee semi-annually, and any such fee change will be effective on the first business day of February or August.'' The Exchange is proposing to eliminate the requirement that its ORF may be only increased or decreased semi-annually because the Exchange believes it requires the flexibility to amend its ORF as needed to meet its regulatory requirements and adjust its ORF to account for the regulatory revenue that it receives and the costs that it incurs. While the Exchange is eliminating the requirement to adjust only semi-annually, it will continue to submit a rule proposal with the Commission for each modification to the ORF and notify participants via an Options Trader Alert of any proposed change in the amount of the fee at least thirty (30) calendar days prior to the effective date. The Exchange believes that the prior notification to market participants will provide guidance on the timing of any changes to the ORF and ensure market participants are prepared to configure their systems to properly account for the ORF.

The Exchange also notes it now issues Options Trader Alerts instead of circulars to provide notification to members. The Exchange is amending the rule text to reflect this change.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act [7] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act [8] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using its facility and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes the proposed clarifications in the Fee Schedule to the ORF further the objectives of Section 6(b)(4) of the Act and are equitable and reasonable since they expressly describe the Exchange's existing practices regarding the manner in which the Exchange assesses and collects its ORF.

Proposal 1—Reflect the Manner in Which GEMX Assesses and Collects Its ORF

The Exchange believes it is reasonable and appropriate for the Exchange to charge the ORF for options transactions regardless of the exchange on which the transactions occur. The Exchange has a statutory obligation to enforce compliance by members and their associated persons under the Act and the rules of the Exchange and to surveil for other manipulative conduct by market participants (including non-members) trading on the Exchange. The Exchange cannot effectively surveil for such conduct without looking at and evaluating activity across all options markets. Many of the Exchange's market surveillance programs require the Exchange to look at and evaluate activity across all options markets, such as surveillance for position limit violations, manipulation, front-running and contrary exercise advice violations/expiring exercise declarations. The Exchange, because it lacks access to information on the identity of the entering firm for executions that occur on away markets, believes it is appropriate to assess the ORF on its member's clearing activity, based on information the Exchange receives from OCC, including for away market activity. Among other reasons, doing so better and more accurately captures activity that occurs away from the Exchange over which the Exchange has a degree of regulatory responsibility. In so doing, the Exchange believes that assessing ORF on member clearing firms in certain instances equitably distributes the collection of ORF in a fair and reasonable manner. Also, the Exchange and the other options exchanges are required to populate a consolidated options audit trail (''COATS'') [9] system in order to surveil a member's activities across markets.[10]

The Exchange believes that assessing the ORF to each Exchange member for options transactions cleared by OCC in the customer range where the execution occurs on another exchange and is cleared by a GEMX member is an equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities. The ORF is collected by OCC on behalf of GEMX from Exchange clearing members for all customer transactions they clear or from non-members for all customer transactions they clear that were executed on GEMX. The Exchange believes that this collection practice is reasonable and appropriate because higher fees are assessed to those members that require more Exchange regulatory services based on the amount of customer options business they conduct.

Regulating customer trading activity is more labor intensive and requires greater expenditure of human and technical resources than regulating non-customer trading activity, which tends to be more automated and less labor intensive. As a result, the costs associated with administering the customer component of the Exchange's overall regulatory program are anticipated to be typically higher than the costs associated with administering the non-customer component of its

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(4) and (5).

[9] COATS effectively enhances intermarket options surveillance by enabling the options exchanges to reconstruct the market promptly to effectively surveil certain rules.

[10] In addition to its own surveillance programs, the Exchange works with other SROs and exchanges on intermarket surveillance related issues. Through its participation in the Intermarket Surveillance Group (''ISG''), the Exchange shares information and coordinates inquiries and investigations with other exchanges designed to address potential intermarket manipulation and trading abuses. The Exchange's participation in ISG helps it to satisfy the requirement that it has coordinated surveillance with markets on which security futures are traded and markets on which any security underlying security futures are traded to detect manipulation and insider trading. *See* Section 6(h)(3)(I) of the Act. ISG is an industry organization formed in 1983 to coordinate intermarket surveillance among the SROs by co-operatively sharing regulatory information pursuant to a written agreement between the parties. The goal of the ISG's information sharing is to coordinate regulatory efforts to address potential intermarket trading abuses and manipulations.

regulatory program. The Exchange proposes assessing higher fees to those members that will require more Exchange regulatory services based on the amount of customer options business they conduct. Additionally, the dues and fees paid by members go into the general funds of the Exchange, a portion of which is used to help pay the costs of regulation. The Exchange has in place a regulatory structure to surveil, conduct examinations and monitor the marketplace for violations of Exchange Rules. The ORF assists the Exchange to fund the cost of this regulation of the marketplace.

Proposal 2—Semi-Annual Changes to ORF

The Exchange believes that the proposed rule change to remove the limit to amend the ORF only semi-annually, with advance notice, is reasonable because the Exchange will continue to provide market participants with thirty (30) days advance notice of amending the amount of the ORF. Also, the Exchange is required to monitor the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory fees and fines, do not exceed regulatory costs. Therefore, the Exchange believes it is reasonable to remove the semi-annual limit to amend its ORF in order to permit the Exchange to make amendments to its ORF as necessary to comply with the Exchange's obligations. This proposed change would conform this rule with that of NASDAQ PHLX LLC (''Phlx''), The NASDAQ Options Market LLC (''NOM'') and NASDAQ BX, Inc. (''BX'').[11]

The Exchange believes that the proposed rule change to remove the limit to amend the ORF only semi-annually, with advance notice, is equitable and not unfairly discriminatory because it will apply in the same manner to all members that are subject to the ORF. The Exchange has in place a regulatory structure to surveil for, conduct examinations and monitor the marketplace for violations of Exchange Rules. The ORF assists the Exchange to fund the cost of this regulation of the marketplace.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The ORF is not intended to have any impact on competition. Rather, it is designed to enable the Exchange to recover a material portion of the Exchange's cost related to its regulatory activities. The Exchange is obligated to ensure that the amount of regulatory revenue collected from the ORF, in combination with its other regulatory fees and fines, does not exceed regulatory costs.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[12] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–GEMX–2017–31 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–GEMX–2017–31. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–GEMX–2017–31, and should be submitted on or before September 5, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–17047 Filed 8–11–17; 8:45 am]

BILLING CODE 8011–01–P

[11] *See* Phlx's Pricing Schedule and NOM and BX Rules at Chapter XV, Sections 5.

[12] 15 U.S.C. 78s(b)(3)(A)(ii).

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81346; File No. SR–IEX–2017–25]

Self-Regulatory Organizations; Investors Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Make a Correction to the Exchange Fee Schedule Related to Fees for Executions That Involve Taking Resting Interest With Non-Displayed Priority With a Displayable Order

August 8, 2017.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on August 7, 2017, the Investors Exchange LLC (''IEX'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Pursuant to the provisions of Section 19(b)(1) under the Securities Exchange Act of 1934 (''Act''),[4] and Rule 19b–4 thereunder,[5] Investors Exchange LLC (''IEX'' or ''Exchange'') is filing with the Commission a proposed rule change to make a correction to the Exchange Fee Schedule related to fees for executions that involve taking resting interest with non-displayed priority with a displayable order. The Exchange proposes to implement the change beginning on September 1, 2017.

The text of the proposed rule change is available at the Exchange's Web site at *www.iextrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statement [sic] may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fee Schedule, pursuant to IEX Rule 15.110(a) and (c), to make a correction related to the fees for executions that involve taking non-displayed resting interest with a displayable order. Subject to certain exceptions, the Exchange charges $0.0009 per share (or 0.30% of the total dollar value of the transaction for securities priced below $1.00) to Members for executions on IEX that include resting non-displayed interest[6] for both the liquidity providing and liquidity removing order (the ''Non-Displayed Match Fee'').[7] One exception relates to certain displayable orders that remove non-displayed liquidity upon entry. The Exchange Fee Schedule provides that the Non-Displayed Match Fee is not charged for displayable orders[8] that remove non-displayed liquidity upon entry if, on a monthly basis, at least 90% of the liquidity removing Member's aggregate executed shares of displayable orders added liquidity during the month in question.[9]

The Fee Schedule describes the calculation to determine if the Non-Displayed Match Fee is charged with reference to ''TMVD'' which means ''total monthly volume displayable calculated as the sum of executions from the Member's displayable orders during the calendar month.''[10] However, the reference to a ''Member's'' displayable orders was inadvertent, and should instead have referred to each of a Member's market participant identifiers, or MPIDs, which is how the Exchange in practice has been calculating TMVD and thus determines whether the Non-Displayed Match Fee is applicable to particular executions.

Accordingly, the Exchange proposes to correct the IEX Fee Schedule to provide that TMVD means ''total monthly volume displayable calculated as the sum of executions from each of the Member's MPIDs (on a per MPID basis) displayable orders during the calendar month.'' In addition, the Exchange proposes a clarifying amendment to the single asterisked footnote related to the Non-Displayed Match Fee to specify that the 90% calculation will be performed on a per MPID basis. Thus, the phrase ''on a per MPID basis'' would be added after the phrase ''at least 90% of TMVD'' in the footnote. Finally, the Exchange proposes to add a definition of MPID to the Fee Schedule.

With respect to the calculation of the Non-Displayed Match Fee and the applicable 90% threshold exception for executions of displayable orders that remove resting non-displayed liquidity upon entry, IEX reviewed Member invoices since its launch as an exchange in August 2016 through June 30, 2017 to assess whether any Members were charged fees that differed from those described in the Fee Schedule. In other words, IEX recalculated the Non-Displayed Match Fee and the 90% threshold exception on a ''per Member'' basis (which is how the Fee Schedule currently reads) instead of on a ''per MPID'' basis (which is how IEX in practice had been calculating that fee). This assessment identified that nine Members were charged such differential fees in particular months, in some cases more than the fees described in the Fee Schedule and in some cases less than the fees described in the Fee Schedule. In total, seven Members were charged and paid $18,948.54 in excess fees[11] and eight Members were not charged $44,175.28 in fees that should have been charged.[12] Five Members were overcharged and undercharged in different months.

In order to address the discrepancies, IEX will charge or credit each impacted member for the net amount overpaid or underpaid and will be included in the August 2017 monthly invoices to be sent in September 2017 pursuant to IEX Rule 15.120 notwithstanding that fees included thereof are for trading activity that occurred over prior months.[13]

The Exchange proposes to implement the revised fee on a going forward basis as of September 1, 2017, after which IEX will assess this fee on a MPID basis. Members will be charged for July and August based on the current Fee Schedule whereby the 90% calculation will be performed on a per Member basis, aggregating all of the Member's MPIDs.

2. Statutory Basis

IEX believes that the proposed rule change is consistent with the provisions of Section 6(b)[14] of the Act in general, and furthers the objectives of Sections 6(b)(4)[15] of the Act, in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities. In addition, the Exchange believes that it is consistent with the Act to correct the Fee Schedule so that the Fee Schedule is accurate, avoiding

[4] 15 U.S.C. 78s(b)(1).

[5] 17 CFR 240.19b–4.

[6] Non-displayed priority refers to an order or portion of a reserve order that is booked and ranked with non-display priority on the Order Book. *See* Rules 11.190(b)(3) and 11.190(b)(2).

[7] This pricing is referred to by the Exchange as the ''Non-Displayed Match Fee'' on the Fee Schedule with a Fee Code of 'I' which is provided by the Exchange on execution reports.

[8] *See* Rule 11.190(b)(3).

[9] However, in such transactions, the non-displayed liquidity adding interest will be subject to the Non-Displayed Match Fee. The Exchange also does not charge a fee where the adding and removing order originated from the same Exchange Member.

[10] *See* IEX Fee Schedule.

[11] The range is from $0.09 to 7811.66.

[12] The range is from $1.51 to $29,482.12.

[13] In the event that a Member owed a credit declines the credit, IEX will make a charitable donation in the amount of such credit.

[14] 15 U.S.C. 78f.

[15] 15 U.S.C. 78f(b)(4).

any potential confusion among Members. The Exchange further believes that the correction to the Fee Schedule is reasonable, equitable, and not unfairly discriminatory because all similar situated Members will be subject to the same fee structure.

The Exchange also believes that it is consistent with the Act and an equitable allocation of reasonable dues, fees and other charges among its members and other persons using its facilities to measure whether the 90% threshold for adding liquidity with displayable orders is reached on an MPID basis. As explained in IEX's rule change adopting the exception to the Non-Displayed Match Fee, the flexibility is designed to address limited inadvertent liquidity removal by Members who are largely adding displayed liquidity and generally intend to add displayed liquidity on IEX, to further encourage aggressively priced displayed orders.[16] The Exchange believes that Members that utilize multiple MPIDs generally use different MPIDs for different trading strategies or customers. Therefore, the Exchange believes that measuring by MPIDs is a more precise manner of assessing whether a Member's trading strategy (or that of a customer) is largely adding displayed liquidity and generally intends to add displayed liquidity with displayable orders.

B. Self-Regulatory Organization's Statement on Burden on Competition

IEX does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is designed to correct an inadvertent error rather than a competitive issue. The Exchange does not believe the proposed rule change will result on a burden on intramarket competition because all Members will be subject to the Non-Displayed Match Fee in the same manner on a fair and consistent basis. While different fees will be assessed in some circumstances, these different fees are not based on the type of Member entering the order and all Members can submit any type of order. Further, assessing whether the Non-Displayed Match Fee is applicable on a per MPID basis is intended to encourage market participants to enter aggressively priced displayed orders on the Exchange, which enhances price discovery and deepens the Exchange's liquidity pool to the benefit of all market participants. Further, the Exchange operates in a highly competitive environment in which market participants can readily favor competing venues if fee schedules at other venues are viewed as more favorable.

The Exchange also does not believe that the proposed rule change will result in any burden on intermarket competition because other venues are free to adopt comparable pricing.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii)[17] of the Act. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[18] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–IEX–2017–25 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–IEX–2017–25. This file number should be included in the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–IEX–2017–25 and should be submitted on or before September 5, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–17051 Filed 8–11–17; 8:45 am]

BILLING CODE 8011–01–P

[16] *See* Securities Exchange Act Release No. 78550 (August 11, 2016), 81 FR 54873 (August 17, 2016) (SR–IEX–2016–09).

[17] 15 U.S.C. 78s(b)(3)(A)(ii).

[18] 15 U.S.C. 78s(b)(2)(B).

[19] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Delegation of Authority: 245–2]

Delegation From the Secretary to the Deputy Secretary of Authorities of the Secretary of State

By virtue of the authority vested in the Secretary of State by the laws of the United States, including 22 U.S.C. 2651a, I hereby delegate to the Deputy Secretary, to the extent authorized by law, all authorities and functions vested in the Secretary of State or the head of agency by any act, order, determination, delegation of authority, regulation, or executive order, now or hereafter issued.

This Delegation includes all authorities and functions that have been or may be delegated or re-delegated to

other Department officials but does not repeal delegations to such officials.

Notwithstanding this delegation of authority, the Secretary of State may exercise any function or authority delegated by this delegation.

This Delegation of Authority supersedes Delegation of Authority 245–1, dated February 13, 2009.

This memorandum shall be published in the **Federal Register.**

Dated: July 31, 2017.

Rex W. Tillerson,

Secretary of State.

[FR Doc. 2017–17134 Filed 8–11–17; 8:45 am]

BILLING CODE 4710–08–P

DEPARTMENT OF STATE

[Public Notice 10086]

Notice of Public Meeting

The Department of State will conduct an open meeting at 9:30 a.m. on Wednesday, August 30, 2017, in room 7P15–01 of the Douglas A. Munro Coast Guard Headquarters Building at St. Elizabeth's, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593. The primary purpose of the meeting is to prepare for the fourth session of the International Maritime Organization's (IMO) Sub-Committee on Carriage of Cargoes and Containers to be held at the IMO Headquarters, United Kingdom, September 11–15, 2017.

The agenda items to be considered include:

—Adoption of the agenda
—Decisions of other IMO bodies
—Amendments to the IGF Code and development of guidelines for low-flashpoint fuels
—Suitability of high manganese austenitic steel for cryogenic service and development of any necessary amendments to the IGC Code and IGF Code
—Amendments to the IMSBC Code and supplements
—Amendments to the IMDG Code and supplements
—Unified interpretations of provisions of IMO safety, security and environment-related conventions
—Consideration of reports of incidents involving dangerous goods or marine pollutants in packaged form on board ships or in port areas
—Biennial status report and provisional agenda for CCC 5
—Election of Chair and Vice-Chair for 2018
—Any other business
—Report to the Committees

Members of the public may attend this meeting up to the seating capacity of the room. Upon request to the meeting coordinator, members of the public may also participate via teleconference, up to the capacity of the teleconference phone line. To access the teleconference line, participants should call (202) 475–4000 and use Participant Code: 887 809 72. To facilitate the building security process, and to request reasonable accommodation, those who plan to attend should contact the meeting coordinator, Dr. Amy Parker, by email at *Amy.M.Parker@uscg.mil,* by phone at (202) 372–1423, or in writing at 2703 Martin Luther King Jr. Ave. SE., Stop 7509, Washington DC 20593–7509 not later than August 24, 2017, five working days prior to the meeting. Requests made after August 24, 2017 might not be able to be accommodated. Please note that due to security considerations, two valid, government-issued photo identifications must be presented to gain entrance to the Coast Guard Headquarters building. USCG Headquarters is accessible by taxi, public transportation, and privately owned conveyance (upon request).

Joel C. Coito,

Coast Guard Liaison Officer, Office of Ocean and Polar Affairs, Department of State.

[FR Doc. 2017–17111 Filed 8–11–17; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2017–67]

Petition for Exemption; Summary of Petition Received; Rolls-Royce plc

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before August 24, 2017.

ADDRESSES: Send comments identified by docket number FAA–2017–0791 using any of the following methods:

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

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

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

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

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

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

FOR FURTHER INFORMATION CONTACT: Brent Hart (202) 267–4034, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591. This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on August 7, 2017.

Lirio Liu,

Director, Office of Rulemaking.

PETITION FOR EXEMPTION

Docket No.: FAA–2017–0791.

Petitioner: Rolls-Royce plc.

Section(s) of 14 CFR Affected: 34.21(e)(2) and 87.23(c)(1).

Description of Relief Sought: Rolls-Royce plc seeks a time limited exemption to allow production of the Trent 1000–TEN engine models identified its petition, while Rolls-Royce plc develops and implements modifications to ensure compliance with 14 CFR 34.21(e)(2) and 40 CFR 87.23(c)(1).

[FR Doc. 2017–17035 Filed 8–11–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Twelfth RTCA SC–229 406 MHz ELT Joint Plenary With EUROCAE WG–98

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

ACTION: Twelfth RTCA SC–229 406 MHz ELT Joint Plenary with EUROCAE WG–98.

SUMMARY: The FAA is issuing this notice to advise the public of the Twelfth RTCA SC–229 406 MHz ELT Plenary held jointly with EUROCAE WG–98. SC–229 is a subcommittee to RTCA.

DATES: The meeting will be held September 5–8, 2017 from 9:00 a.m.–5:00 p.m.

ADDRESSES: The meeting will be held at: EUROCAE Facilities, Triangle, 9–23 rue Paul Lafargue, 93200 Saint-Denis, France.

FOR FURTHER INFORMATION CONTACT: Rebecca Morrison at *rmorrison@rtca.org* or 202–330–0654, or The RTCA Secretariat, 1150 18th Street NW., Suite 910, Washington, DC 20036, or by telephone at (202) 833–9339, fax at (202) 833–9434, or Web site at *http://www.rtca.org.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a meeting of the Twelfth RTCA SC–229 406 MHz ELT Joint Plenary with EUROCAE WG–98. The agenda will include the following:

Tuesday September 5, 2017, 9:00 a.m.–5:00 p.m

1. Welcome/Introductions/Administrative Remarks
2. Agenda Overview and Approval
3. Minutes Washington D.C. Meeting Review and Approval
4. Review Action Items From Washington D.C. Meeting
5. Industry Coordination and Presentations
6. Week's Plan
7. Working Group of the Whole Meeting (Rest of the Day)

Wednesday September 6, 2017, 9:00 a.m.–5:00 p.m.

1. Working Group of the Whole Meeting

Thursday September 7, 2017, 9:00 a.m.–5:00 p.m.

1. Working Group of the Whole Meeting

Friday September 8, 2017, 9:00 a.m.–4:00 p.m.

1. Working Group of the Whole Meeting
2. Industry Coordination and Presentations (if any)
3. Work Plan
4. Discuss a Motion To Begin Open Consultation/Final Review and Comment on the ED–62A/DO–204A Document To Become Revision B
5. Other Business
6. Adjourn

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC on August 8, 2017.

Mohannad Dawoud,

Management & Program Analyst, Partnership Contracts Branch, ANG–A17, NextGen, Procurement Services Division, Federal Aviation Administration.

[FR Doc. 2017–17056 Filed 8–11–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Thirtieth RTCA SC–217 Aeronautical Databases Joint Plenary With WG–44

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

ACTION: Thirtieth RTCA SC–217 Aeronautical Databases Joint Plenary with WG–44.

SUMMARY: The FAA is issuing this notice to advise the public of the Thirtieth RTCA SC–217 Aeronautical Databases Plenary held jointly with WG–44.

DATES: The meeting will be held September 13–15, 2017 from 9:00 a.m.–5:00 p.m.

ADDRESSES: The meeting will be held at: EUROCAE Facilities, Triangle, 9–23 Rue Paul Lafargue, 93200 Saint-Denis, France.

FOR FURTHER INFORMATION CONTACT: Rebecca Morrison at *rmorrison@rtca.org* or 202–330–0654, or The RTCA Secretariat, 1150 18th Street NW., Suite 910, Washington, DC 20036, or by telephone at (202) 833–9339, fax at (202) 833–9434, or Web site at *http://www.rtca.org.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a meeting of the Thirtieth RTCA SC–217 Aeronautical Databases Joint Plenary with WG–44. The agenda will include the following:

Wednesday September 13, 2017, 9:00 a.m.–5:00 p.m.

1. Co-Chairmen's Remarks and Introductions
2. Housekeeping & Meeting Logistics
3. DFO Statement and RTCA/EUROCAE IP and Membership Policies
4. Approve Minutes From SC217 29th/WG 44 25th Meeting
5. Review and Approve Meeting Agenda for SC217 30th/WG44 26th Meeting
6. Action Item List Review
7. Presentations (TBD)
8. Break Into Working Groups

Thursday September 14, 2017, 9:00 a.m.–5:00 p.m.

1. Working Group Sessions

Friday September 15, 2017, 9:00 a.m.–5:00 p.m.

1. Working Group Sessions in the Morning
2. Meeting Wrap-Up: Main Conclusions and Way Forward
3. Review of Action Items
4. Review of Document Update Status
5. Next Meetings
6. Any Other Business
7. Adjourn

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC on August 8, 2017.

Mohannad Dawoud,

Management & Program Analyst, Partnership Contracts Branch, ANG–A17, NextGen, Procurement Services Division, Federal Aviation Administration.

[FR Doc. 2017–17055 Filed 8–11–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2017–0002–N–22]

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of information collection; request for comment.

SUMMARY: Under the Paperwork Reduction Act of 1995 (PRA), this notice announces that FRA is forwarding the Information Collection Request (ICR) abstracted below to the Office of Management and Budget (OMB) for review and comment. The ICR describes the information collection and its expected burden. On May 22, 2017, FRA published a notice providing a 60-day period for public comment on the ICR.

DATES: Comments must be submitted on or before September 13, 2017.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Brogan, Information Collection Clearance Officer, Office of Railroad Safety, Regulatory Analysis Division, RRS–21, Federal Railroad Administration, 1200 New Jersey Avenue SE., Mail Stop 25, Washington, DC 20590 (Telephone: (202) 493–6292); or Ms. Kim Toone, Information Collection Clearance Officer, Office of Administration, Office of Information Technology, RAD–20, Federal Railroad Administration, 1200 New Jersey Avenue SE., Mail Stop 35, Washington, DC 20590 (Telephone: (202) 493–6132).

SUPPLEMENTARY INFORMATION: The PRA, 44 U.S.C. 3501–3520, and its implementing regulations, 5 CFR part 1320, require Federal agencies to issue two notices seeking public comment on information collection activities before OMB may approve paperwork packages. 44 U.S.C. 3506, 3507; 5 CFR 1320.5, 1320.8(d)(1), and 1320.10. On May 22, 2017, FRA published a 60-day notice in the **Federal Register** soliciting comment on the ICR for which it is now seeking OMB approval. *See* 82 FR 17498. FRA received no comments in response to that notice.

Before OMB decides whether to approve these proposed collections of information, it must provide 30 days for public comment. 44 U.S.C. 3507(b); 5 CFR 1320.10. Federal law requires OMB to approve or disapprove paperwork packages between 30 and 60 days after the 30-day notice is published. 44 U.S.C. 3507(b)–(c); 5 CFR 1320.10; *see also* 60 FR 44978, 44983, Aug. 29, 1995. OMB believes the 30-day notice gives the regulated community to the opportunity to file relevant comments and affords the agency adequate time to digest public comments before it renders a decision. *Id.* Therefore, respondents should submit their respective comments to OMB within 30 days of publication to best ensure having their full effect.

The summary below describes the ICR and its expected burden. FRA is submitting this renewal request for clearance by OMB as the PRA requires.

Title: Survey of Plant and Insular Tourist Railroads Subject to FRA Bridge Safety Standards (49 CFR part 237).

OMB Control Number: 2130–0617.

Abstract: FRA's *Bridge Safety Standards* (49 CFR part 237) apply to all owners of railroad track with a gage of 2 feet or more supported by a bridge. This includes track owners with bridges located within an installation which is not part of the general railroad system of transportation (general system), but over which a general system railroad operates (*i.e.,* bridges within an insular tourist railroad, and bridges within an industrial installation (plant) that is not part of the general system, but over which a general system railroad operates). Currently, FRA relies on the railroad accident/incident reports (49 CFR part 225) to identify track owners subject to the requirements of part 237. However, plant and insular tourist railroads are exempt from 49 CFR part 225 (Railroad Accidents/Incidents: Reports, Classification, and Investigations). FRA wants to identify plant and insular tourist railroads that may be subject to part 237 requirements, but are exempt from part 225 reporting requirements. FRA will use this information to help evaluate risks related to railroad safety and to plan oversight activities.

FRA is requesting any railroad serving a plant and moving railroad equipment over bridges within the plant, or the plant itself, to advise FRA by email if there are railroad bridges within the plant potentially subject to FRA Bridge Safety Standards. FRA is also requesting insular tourist railroads whose tracks are supported by one or more bridges to advise FRA of the existence of their bridges by email. Email notifications should be sent to *FRAPlantTouristSurvey@dot.gov* and should include the name of the plant, installation, or insular tourist railroad, and that entity's address (including city and State, contact name, telephone number, and email address). Notification may also be made by telephone to Yujiang Zhang at (202) 493–6460. This survey is ongoing with approval requested for 3 years.

Type of Request: Extension without change of a previously approved information collection.

Affected Public: Freight railroads, industrial installations (plants), insular tourist railroads.

Form(s): N/A.

Total Estimated Annual Responses: 210.

Total Estimated Annual Burden: 53 hours.

Addressee: Send comments regarding these information collections to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503, Attention: FRA Desk Officer. Comments may also be sent via email to OMB at the following address: *oira_submissions@omb.eop.gov.*

FRA requests comment on all aspects of this ICR, but commenters should focus on the following: Whether the proposed collection of information is necessary for DOT to properly perform its functions, including whether the information will have practical utility; the accuracy of DOT's estimates of the burden of the proposed information collections; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collections of information on respondents, including the use of automated collection techniques or other forms of information technology.

A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this notice in the **Federal Register**.

Authority: 44 U.S.C. 3501–3520.

Sarah L. Inderbitzin,

Deputy Chief Counsel.

[FR Doc. 2017–17115 Filed 8–11–17; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Sanctions Actions Pursuant to the Foreign Narcotics Kingpin Designation Act

AGENCY: Office of Foreign Assets Control, Department of the Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of persons whose property and interests in property are blocked pursuant to the Foreign Narcotics Kingpin Designation Act (Kingpin Act).

DATES: OFAC's actions described in this notice were effective on August 9, 2017.

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480, Assistant Director for Regulatory Affairs, tel.: 202–622–4855, Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; or the Department of the Treasury's Office of the General Counsel: Office of the Chief

Counsel (Foreign Assets Control), tel.: 202–622–2410 (not toll free numbers).

SUPPLEMENTARY INFORMATION:

Electronic Availability

The list of Specially Designated Nationals and Blocked Persons (SDN List) and additional information concerning OFAC sanctions programs are available on OFAC's Web site at *http://www.treasury.gov/ofac.*

Notice of OFAC Actions

On August 9, 2017, OFAC's Acting Director determined that the property and interests in property of the following persons are blocked pursuant to the Kingpin Act and placed them on the SDN List.

Individuals

1. ALVAREZ MONTELONGO, Julio Cesar (a.k.a. ALVAREZ, Julion), Paseo de la Hacienda 443, Fracc. Los Mangos, Mazatlan, Sinaloa, Mexico; Ontario 1102, Col. Providencia, Guadalajara, Jalisco 44630, Mexico; Coras 3644, Col. Monraz, Guadalajara, Jalisco 44670, Mexico; Av. Manuel Acuna 3497, Col. Rinconada Santa Rita, Guadalajara, Jalisco 44690, Mexico; DOB 11 Apr 1983; POB La Concordia, Chiapas, Mexico; citizen Mexico; Web site *www.julionalvarez.net;* Gender Male; R.F.C. AAMJ8304112F0 (Mexico); C.U.R.P. AAMJ830411HCSLNL05 (Mexico) (individual) [SDNTK] (Linked To: JCAM EDITORA MUSICAL, S.A. DE C.V.; Linked To: NORYBAN PRODUCTIONS, S.A. DE C.V.; Linked To: TICKET BOLETO, S.A. DE C.V.; Linked To: FLORES DRUG TRAFFICKING ORGANIZATION). Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION.

2. ALVAREZ PERALTA, Fernando Gustavo, Guadalajara, Jalisco, Mexico; DOB 23 Jan 1961; citizen Bolivia; Gender Male; R.F.C. AAPF610123BJ0 (Mexico); NIT # 2970301015 (Bolivia); C.U.R.P. AAPF610123HNELRR02 (Mexico); Residency Number 0434529 (Mexico) (individual) [SDNTK] (Linked To: FLORES DRUG TRAFFICKING ORGANIZATION). Designated pursuant to section 805(b)(2) of the Kingpin Act, 21 U.S.C. 1904(b)(2), for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION; and designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION.

3. AYALA ROMERO, Diego, Mexico; DOB 27 Nov 1974; POB Acatic, Jalisco, Mexico; citizen Mexico; Gender Male; R.F.C. AARD7411274XA (Mexico); C.U.R.P. AARD741127HJCYMG09 (Mexico) (individual) [SDNTK] (Linked To: FLORES DRUG TRAFFICKING ORGANIZATION). Designated pursuant to section 805(b)(2) of the Kingpin Act, 21 U.S.C. 1904(b)(2), for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION; and designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION.

4. CAMPOS TIRADO, Linda Elizabeth, Mexico; DOB 20 Sep 1980; POB Ahome, Sinaloa, Mexico; citizen Mexico; Gender Female; R.F.C. CATL800920L32 (Mexico); C.U.R.P. CATL800920MSLMRN02 (Mexico) (individual) [SDNTK] (Linked To: FLORES DRUG TRAFFICKING ORGANIZATION). Designated pursuant to section 805(b)(2) of the Kingpin Act, 21 U.S.C. 1904(b)(2), for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION; and designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION.

5. CARO URIAS, Efrain, Av. de las Americas 2000–607, Col. Vista del Country, Guadalajara, Jalisco, Mexico; Av. Americas 2000–7, Col. Vistas del Country, Guadalajara, Jalisco, Mexico; Jose Maria Vigil 2830, Col. Providencia, Guadalajara, Jalisco, Mexico; Av. Americas 1417–A, Col. Providencia, Guadalajara, Jalisco 44630, Mexico; Av. Americas 1417–B, Col. Providencia, Guadalajara, Jalisco 44630, Mexico; Giovanni Papini 364–B, Col. Jardines de la Patria, Zapopan, Jalisco 45110, Mexico; Calle San Gonzalo 1970–43, Col. Santa Isabel, Zapopan, Jalisco, Mexico; Los Cerezos 86, Coto 3, Col. Jardin Real, Zapopan, Jalisco, Mexico; Paseo Puesta del Sol 4282–6, Col. Lomas Altas, Zapopan, Jalisco 45110, Mexico; DOB 11 Apr 1974; POB Guadalajara, Jalisco, Mexico; citizen Mexico; Gender Male; R.F.C. CAUE740411RG0 (Mexico); C.U.R.P. CAUE740411HJCRRF07 (Mexico) (individual) [SDNTK] (Linked To: FLORES DRUG TRAFFICKING ORGANIZATION; Linked To: LOLA LOLITA 1110, S. DE R.L. DE C.V.; Linked To: MARIMBA ENTERTAINMENT, S.R.L. DE C.V.; Linked To: NOCTURNUM INC, S. DE R.L. DE C.V.). Designated pursuant to section 805(b)(2) of the Kingpin Act, 21 U.S.C. 1904(b)(2), for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION; and designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION.

6. CARO URIAS, Omar, Calle San Gonzalo 1970–43, Col. Santa Isabel, Zapopan, Jalisco, Mexico; Av. Ramon Corona 4750 Int. L–2, Col. Jardin Real, Zapopan, Jalisco, Mexico; Av. Ramon Corona 4750 Int. L–3, Col. Jardin Real, Zapopan, Jalisco, Mexico; Av. Ramon Corona 4750 Int. L–6, Col. Jardin Real, Zapopan, Jalisco, Mexico; Av. Ramon Corona 4750 Int. L–7, Col. Jardin Real, Zapopan, Jalisco, Mexico; Av. Ramon Corona 4750 Int. L–8, Col. Jardin Real, Zapopan, Jalisco, Mexico; DOB 19 Jun 1977; POB Jalisco, Mexico; citizen Mexico; Gender Male; R.F.C. CAUO770619C87 (Mexico); C.U.R.P. CAUO770619HJCRRM08 (Mexico) (individual) [SDNTK] (Linked To: FLORES DRUG TRAFFICKING ORGANIZATION; Linked To: LOLA LOLITA 1110, S. DE R.L. DE C.V.; Linked To: NOCTURNUM INC, S. DE R.L. DE C.V.). Designated pursuant to section 805(b)(2) of the Kingpin Act, 21 U.S.C. 1904(b)(2), for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION; and designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION.

7. CARRANZA ZEPEDA, Victor Manuel, Av. Rio Nilo 69, Col.

Camichines, Tonala, Jalisco, Mexico; Calle Franz Schubert 5373, Fracc. La Estancia, Zapopan, Jalisco, Mexico; Calle Lazaro Cardenas 3050–A, Fracc. Residencial Loma Bonita, Guadalajara, Jalisco 44570, Mexico; Av. Lazaro Cardenas 3050, Col. El Retiro, Guadalajara, Jalisco 44280, Mexico; Cholula 2514, Col. Hidalgo, Ciudad Juarez, Chihuahua 32300, Mexico; DOB 15 Mar 1978; POB Tijuana, Baja California, Mexico; citizen Mexico; Gender Male; R.F.C. CAZV7803151P4 (Mexico); C.U.R.P. CAZV780315HBCRPC03 (Mexico) (individual) [SDNTK] (Linked To: FLORES DRUG TRAFFICKING ORGANIZATION). Designated pursuant to section 805(b)(2) of the Kingpin Act, 21 U.S.C. 1904(b)(2), for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION; and designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION.

8. CARRANZA ZEPEDA, Hugo Ivan, Av. Rio Nilo 69, Col. Camichines, Tonala, Jalisco, Mexico; Franz Schubert 5373, Col. La Estancia, Zapopan, Jalisco 45030, Mexico; Franz Schubert 7373, Col. La Estancia, Zapopan, Jalisco, Mexico; Economos 6617–35, Col. Rinconada del Parque, Zapopan, Jalisco, Mexico; Mixcoatl 1371, Col. Ciudad del Sol, Zapopan, Jalisco 45050, Mexico; DOB 03 Mar 1982; POB Zapopan, Jalisco, Mexico; citizen Mexico; Gender Male; R.F.C. CAZH820303JF9 (Mexico); C.U.R.P. CAZH820303HJCRPG02 (Mexico); alt. C.U.R.P. CAZH820303HJCRPG10 (Mexico) (individual) [SDNTK] (Linked To: FLORES DRUG TRAFFICKING ORGANIZATION; Linked To: CAMELIAS BAR, S.A. DE C.V.; Linked To: EVENTOS LA MORA, S.A. DE C.V.; Linked To: COMERCIALIZADORA CHAPALA AJIJIC, S.A. DE C.V.; Linked To: CONSORCIO LUNALO, S.A. DE C.V.; Linked To: CONSORCIO NUJOMA, SOCIEDAD CIVIL; Linked To: CONSORCIO RIRFUS, S.A. DE C.V.; Linked To: CORPORATIVO ARZACA, S.C.; Linked To: CORPORATIVO FEARFI, S.A. DE C.V.; Linked To: CORPORATIVO SOSVAL, S.A. DE C.V.; Linked To: GRUPO EGMONT, S.A. DE C.V.; Linked To: GRUPO PRODUCSIL, S.P.R. DE R.L. DE C.V.; Linked To: RESTAURANT FOLKLOR Y CANTINA, S.A. DE C.V.; Linked To: RODRIGUEZ LOPEZ, S.A. DE C.V.; Linked To: SERVICIOS EMPRESARIALES SODA, S.A. DE C.V.). Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION and EVENTOS LA MORA, S.A. DE C.V. and CAMELIAS BAR, S.A. DE C.V.

9. CHAVEZ MARTINEZ, Maria Icela (a.k.a. CHAVEZ MARTINEZ, Ma Isela; a.k.a. CHAVEZ MARTINEZ, Maria Isela), Tchaikovsky 474, Col. Arcos de Guadalupe, Zapopan, Jalisco, Mexico; Piotr Tchaikovski 474, Col. Arcos de Guadalupe, Zapopan, Jalisco 45030, Mexico; Av. Sebastian Bach 5115, Col. Residencial La Estancia, Zapopan, Jalisco, Mexico; Av. Chapalita 50, Col. Jardines Plaza del Sol, Guadalajara, Jalisco, Mexico; Cam 1, Col. San Patricio o Melaque, San Patricio o Melaque, Jalisco 48980, Mexico; DOB 07 Nov 1967; POB Guadalajara, Jalisco, Mexico; citizen Mexico; Gender Female; R.F.C. CAMI671107GZA (Mexico); alt. R.F.C. CAMI671107MY5 (Mexico); C.U.R.P. CAMI671107MJCHRC07 (Mexico); alt. C.U.R.P. CAMI671107MJCHRS06 (Mexico) (individual) [SDNTK] (Linked To: FLORES DRUG TRAFFICKING ORGANIZATION; Linked To: A & S CARRIER INTERNACIONAL, S.A. DE C.V.; Linked To: BOUNGALOWS VILLA AZUL, S.A. DE C.V.; Linked To: CLUB DEPORTIVO MORUMBI, ASOCIACION CIVIL). Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION.

10. CORDERO CARDENAS, Jose Antonio, C Eca Do Queiros 5522, Col. Vallarta Universidad, Zapopan, Jalisco 45110, Mexico; Privada Juan de la Barrera 1727, Col. Ninos Heroes, Guadalajara, Jalisco, Mexico; DOB 01 Dec 1957; POB Guadalajara, Jalisco, Mexico; citizen Mexico; Gender Male; R.F.C. COCA571201JV2 (Mexico); Credencial electoral CRCRAN57120114H000 (Mexico); C.U.R.P. COCA571201HJCRRN19 (Mexico); alt. C.U.R.P. COCA571201HJCRRN01 (Mexico); I.F.E. 3087029297960 (Mexico) (individual) [SDNTK] (Linked To: FLORES DRUG TRAFFICKING ORGANIZATION; Linked To: CIRCULO REPRESENTACIONES INTERNACIONALES, S. DE R.L. DE C.V.; Linked To: CORPORATIVO INMOBILIARIO UNIVERSAL, S.A. DE C.V.; Linked To: FC GRUPO EMPRESARIAL, S.A. DE C.V.; Linked To: GRUPO GASOLINERO COJIM, S.A. DE C.V.; Linked To: INMOBILIARIA FLORES CASTRO, S. DE R.L. DE C.V.; Linked To: RODRIGUEZ LOPEZ, S.A. DE C.V.). Designated pursuant to section 805(b)(2) of the Kingpin Act, 21 U.S.C. 1904(b)(2), for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION; and designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION.

11. DAMIAN RAMIREZ, Irma Lizet, Dominico Scarlatti 260, Col. Vallarta La Patria, Zapopan, Jalisco, Mexico; Montevideo 2590, Col. Providencia, Guadalajara, Jalisco, Mexico; Av. Universidad 1151 Int. 3–H, Col. Puerta Aqua, Zapopan, Jalisco, Mexico; DOB 04 Apr 1981; POB Tecuala, Nayarit, Mexico; citizen Mexico; Gender Female; R.F.C. DARI810404P98 (Mexico); C.U.R.P. DARI810404MJCMMR00 (Mexico); alt. C.U.R.P. DARI810404MNTMMR04 (Mexico) (individual) [SDNTK] (Linked To: FLORES DRUG TRAFFICKING ORGANIZATION; Linked To: CONSORCIO VINICOLA DE OCCIDENTE, S.A. DE C.V.). Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION.

12. FERNANDEZ SANTANA, Mario Alberto, Av. Moctezuma 4297, Col. Jardines del Sol, Zapopan, Jalisco, Mexico; DOB 09 May 1977; POB Guadalajara, Jalisco, Mexico; citizen Mexico; Gender Male; R.F.C. FESM770509RQ7 (Mexico); C.U.R.P. FESM770509HJCRNR06 (Mexico) (individual) [SDNTK] (Linked To: FLORES DRUG TRAFFICKING ORGANIZATION; Linked To: EVENTOS LA MORA, S.A. DE C.V.; Linked To: MONTALVA INMOBILIARIA, S.A. DE C.V.). Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION and EVENTOS LA MORA, S.A. DE C.V.

13. FLORES TINAJERO, Saul, Mexico; DOB 23 Aug 1975; POB Guadalajara, Jalisco, Mexico; citizen Mexico; Gender

Male; R.F.C. FOTS7508237W0 (Mexico); C.U.R.P. FOTS750823HJCLNL01 (Mexico) (individual) [SDNTK] (Linked To: FLORES DRUG TRAFFICKING ORGANIZATION). Designated pursuant to section 805(b)(2) of the Kingpin Act, 21 U.S.C. 1904(b)(2), for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION; and designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION.

14. FLORES HERNANDEZ, Raul (a.k.a. CASAS LINARES, Miguel), Distrito Federal, Mexico; Guadalajara, Jalisco, Mexico; Calle Piotr Tchaikovski 474, Col. Arcos de Guadalupe, Zapopan, Jalisco 45030, Mexico; Av. Sebastian Bach 5115, Col. Residencial La Estancia, Zapopan, Jalisco, Mexico; Av. Chapalita 50, Col. Jardines Plaza del Sol, Guadalajara, Jalisco, Mexico; Calle 72, Panfilo Perez, 750 Sector Libertad, Col. Blanco y Cuellar, Guadalajara, Jalisco 44730, Mexico; Calle Llamarada 193, Fracc. Residencial Sumiya, Jiutepec, Morelos 62560, Mexico; Zaragoza Sur 201, Col. Centro, San Martin Texmelucan, Puebla 74000, Mexico; DOB 03 Oct 1952; alt. DOB 05 Mar 1951; POB Autlan de Navarro, Jalisco, Mexico; alt. POB San Martin Texmelucan, Puebla, Mexico; citizen Mexico; Gender Male; R.F.C. FOHR521003SF7 (Mexico); alt. R.F.C. FOHR510305SF7 (Mexico); C.U.R.P. FOHR521003HJCLRL07 (Mexico); alt. C.U.R.P. FOHR510305HPLLRL08 (Mexico) (individual) [SDNTK] (Linked To: FLORES DRUG TRAFFICKING ORGANIZATION). Designated pursuant to section 805(b)(1) of the Kingpin Act, 21 U.S.C. 1904(b)(1), for playing a significant role in international narcotics trafficking.

15. FLORES CHAVEZ, Kevin Sebastian, Calle Tchaikovsky 474, Col. Arcos de Guadalupe, Zapopan, Jalisco, Mexico; DOB 01 Mar 1995; POB Jalisco, Mexico; citizen Mexico; Gender Male; R.F.C. FOCK950301E94 (Mexico); C.U.R.P. FOCK950301HJCLHV00 (Mexico) (individual) [SDNTK] (Linked To: FLORES DRUG TRAFFICKING ORGANIZATION; Linked To: BOUNGALOWS VILLA AZUL, S.A. DE C.V.). Designated pursuant to section 805(b)(2) of the Kingpin Act, 21 U.S.C. 1904(b)(2), for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION; and designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION.

16. FLORES GOMEZ, Felipe, Mariano Abasolo 87, Autlan de Navarro Centro, Autlan de Navarro, Jalisco 48900, Mexico; Av. Fray Junipero Serra 843, Col. Alcalde Barranquitas, Guadalajara, Jalisco 44270, Mexico; Paulino Navarro 42, Col. Centro, Casimiro Castillo, Jalisco 48930, Mexico; DOB 20 Sep 1953; POB Villa Purificacion, Jalisco, Mexico; citizen Mexico; Gender Male; R.F.C. FOGF530920KX7 (Mexico); C.U.R.P. FOGF530920HJCLML09 (Mexico) (individual) [SDNTK] (Linked To: FLORES DRUG TRAFFICKING ORGANIZATION; Linked To: BOUNGALOWS VILLA AZUL, S.A. DE C.V.; Linked To: CLUB DEPORTIVO MORUMBI, ASOCIACION CIVIL). Designated pursuant to section 805(b)(2) of the Kingpin Act, 21 U.S.C. 1904(b)(2), for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION; and designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION.

17. FLORES CASTRO, Sendy (a.k.a. FLORES CASTRO, Sandy), Av. Ramon Corona 4750, Loc. 15, Col. Exhacienda de la Mora, Zapopan, Jalisco 45138, Mexico; Av. Ramon Corona 4750, Loc. 5, Zapopan, Jalisco 45138, Mexico; Av. Ramon Corona 4750, Zapopan, Jalisco 45019, Mexico; Tchaikovsky 474, Zapopan, Jalisco, Mexico; Piotr Tchaikovski 474, Col. Arcos de Guadalupe, Zapopan, Jalisco 45030, Mexico; Av. Sebastian Bach 5115, Col. Residencial La Estancia, Zapopan, Jalisco, Mexico; Av. Chapalita 50, Col. Jardines Plaza del Sol, Guadalajara, Jalisco, Mexico; Abraham Gonzalez 1375, Col. Sector Libertad, Zapopan, Jalisco, Mexico; DOB 10 Mar 1981; POB Guadalajara, Jalisco, Mexico; citizen Mexico; Gender Female; R.F.C. FOCS810310836 (Mexico); C.U.R.P. FOCS810310MJCLSN09 (Mexico); alt. C.U.R.P. FOCS810301MJCLSN00 (Mexico) (individual) [SDNTK] (Linked To: FLORES DRUG TRAFFICKING ORGANIZATION; Linked To: A & S CARRIER INTERNACIONAL, S.A. DE C.V.; Linked To: BOUNGALOWS VILLA AZUL, S.A. DE C.V.). Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION.

18. FLORES ESPARZA, Moises, C Playa Santiago 6041, Dep. 3, Rdcial Moctezuma PTE, Zapopan, Jalisco 45050, Mexico; DOB 14 Dec 1977; POB Tepic, Nayarit, Mexico; citizen Mexico; Gender Male; R.F.C. FOEM7712145E7 (Mexico); Credencial electoral FLESMS77121418H100 (Mexico); C.U.R.P. FOEM771214HNTLSS07 (Mexico) (individual) [SDNTK] (Linked To: FLORES DRUG TRAFFICKING ORGANIZATION). Designated pursuant to section 805(b)(2) of the Kingpin Act, 21 U.S.C. 1904(b)(2), for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION; and designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION.

19. FREGOSO GONZALEZ, Marco Antonio, Av. Patria 2085, Mezzanine, Col. Puerta de Hierro, Guadalajara, Jalisco 45116, Mexico; Francisco Javier Gamboa 388–201, Col. Americana, Guadalajara, Jalisco 44110, Mexico; DOB 23 Sep 1978; POB Zapopan, Jalisco, Mexico; citizen Mexico; Gender Male; Passport G01106795 (Mexico); R.F.C. FEGM780923PH4 (Mexico); C.U.R.P. FEGM780923HJCRNR01 (Mexico); alt. C.U.R.P. FEGM780923HJCRNR19 (Mexico) (individual) [SDNTK] (Linked To: GRUPO NUTRICIONAL ALHOMA, S.A. DE C.V.). Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Rafael MARQUEZ ALVAREZ.

20. HEREDIA HORNER, Mauricio, Calle Ceja de la Barranca 500–4, Fracc. Loma Real, Zapopan, Jalisco 45110, Mexico; Blvd. Puerta de Hierro 5210–6, Col. Puerta de Hierro, Zapopan, Jalisco 45116, Mexico; J.J. Martinez Aguirre 4248, Ciudad de los Ninos, Zapopan, Jalisco 45040, Mexico; Toltecas 3134, Fracc. Monraz, Guadalajara, Jalisco 44670, Mexico; Eulogio Parra 3200, Piso 2, Local 21, Fracc. Monraz, Guadalajara, Jalisco 44670, Mexico; Popocatepetl

2907–1, Col. Ciudad del Sol, Zapopan, Jalisco, Mexico; DOB 29 Jul 1978; POB Guadalajara, Jalisco, Mexico; citizen Mexico; Gender Male; R.F.C. HEHM780729FZ5 (Mexico); alt. R.F.C. HEHM780729HJC (Mexico); C.U.R.P. HEHM780729HJCRRR07 (Mexico) (individual) [SDNTK] (Linked To: ESCUELA DE FUTBOL RAFAEL MARQUEZ, ASOCIACION CIVIL; Linked To: FUTBOL Y CORAZON, ASOCIACION CIVIL; Linked To: GRUPO DEPORTIVO ALVANER, S.A. DE C.V.; Linked To: GRUPO DEPORTIVO MARQUEZ PARDO, S. DE R.L. DE C.V.; Linked To: GRUPO NUTRICIONAL ALHOMA, S.A. DE C.V.; Linked To: GRUPO TERAPEUTICO HORMARAL, S.A. DE C.V.; Linked To: GRUPO TERAPEUTICO PUERTO VALLARTA, S.A. DE C.V.; Linked To: PROSPORT & HEALTH IMAGEN, S.A. DE C.V.; Linked To: SERVICIOS EDUCATIVOS Y DE NEGOCIOS, S. DE R.L. DE C.V.). Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Rafael MARQUEZ ALVAREZ.

21. JIMENEZ HERNANDEZ, Oscar Armando, Calle Ramon Castellanos 1037–A, Col. San Isidro, Guadalajara, Jalisco, Mexico; C Emilio Rabaza 2027, Col. Blanco y Cuellar, Guadalajara, Jalisco 44730, Mexico; DOB 30 Jun 1978; POB Guadalajara, Jalisco, Mexico; citizen Mexico; Gender Male; R.F.C. JIHO780630A70 (Mexico); Credencial electoral JMHROS78063014H200 (Mexico); alt. Credencial electoral JIHO78063014H200 (Mexico); C.U.R.P. JIHO780630HJCMRS07 (Mexico); alt. C.U.R.P. JIHO780730HJCMRS06 (Mexico); I.F.E. 069582506439 (Mexico) (individual) [SDNTK] (Linked To: FLORES DRUG TRAFFICKING ORGANIZATION; Linked To: CORPORATIVO INMOBILIARIO UNIVERSAL, S.A. DE C.V.; Linked To: SERVICIOS EMPRESARIALES FICIE, S.A. DE C.V.). Designated pursuant to section 805(b)(2) of the Kingpin Act, 21 U.S.C. 1904(b)(2), for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION; and designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION.

22. MARQUEZ ALVAREZ, Rafael (a.k.a. MARQUEZ, Rafa), Calle Popocatepetl 2907–1, Col. Ciudad del Sol, Zapopan, Jalisco, Mexico; Toltecas 3134, Fracc. Monraz, Guadalajara, Jalisco 44670, Mexico; Av. Patria 2085, Mezzanine, Col. Puerta de Hierro, Zapopan, Jalisco 45116, Mexico; Moliere 330–303, Col. Polanco, Mexico, Distrito Federal 11560, Mexico; J.J. Martinez Aguirre 4248, Ciudad de los Ninos, Zapopan, Jalisco 45040, Mexico; Blvd. Adolfo Lopez Mateos 1810, Col. La Martinica, Leon, Guanajuato, Mexico; DOB 13 Feb 1979; POB Zamora, Michoacan de Ocampo, Mexico; citizen Mexico; Gender Male; R.F.C. MAAR7902132V4 (Mexico); C.U.R.P. MAAR790213HMNRLF03 (Mexico) (individual) [SDNTK] (Linked To: ESCUELA DE FUTBOL RAFAEL MARQUEZ, ASOCIACION CIVIL; Linked To: FUTBOL Y CORAZON, ASOCIACION CIVIL; Linked To: GRUPO DEPORTIVO ALVANER, S.A. DE C.V.; Linked To: FLORES DRUG TRAFFICKING ORGANIZATION; Linked To: GRUPO DEPORTIVO MARQUEZ PARDO, S. DE R.L. DE C.V.; Linked To: GRUPO NUTRICIONAL ALHOMA, S.A. DE C.V.; Linked To: GRUPO TERAPEUTICO HORMARAL, S.A. DE C.V.; Linked To: GRUPO TERAPEUTICO PUERTO VALLARTA, S.A. DE C.V.; Linked To: PROSPORT & HEALTH IMAGEN, S.A. DE C.V.). Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION.

Entities

1. A & S CARRIER INTERNACIONAL, S.A. DE C.V. (a.k.a. A Y S CARRIER INTERNACIONAL, S.A. DE C.V.), Zapopan, Jalisco, Mexico; Folio Mercantil No. 22839 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Maria Icela CHAVEZ MARTINEZ and Sendy FLORES CASTRO.

2. BOUNGALOWS VILLA AZUL, S.A. DE C.V., Guadalajara, Jalisco, Mexico; Folio Mercantil No. 18740 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION and Maria Icela CHAVEZ MARTINEZ and Sendy FLORES CASTRO and Kevin Sebastian FLORES CHAVEZ.

3. CAMELIAS BAR, S.A. DE C.V. (a.k.a. CAMELIAS BAR; a.k.a. LA CAMELIA RESTAURANTE & CANTINA; a.k.a. RESTAURANTE BAR LA CAMELIA; a.k.a. ''LA CAMELIA''), Guadalajara, Jalisco, Mexico; Av. Chapalita 50, Guadalajara, Jalisco, Mexico; Lazaro Cardenas 2729 y Arboledas, Guadalajara, Jalisco, Mexico; Mariano Otero 1499, Col. Verde Valle, Guadalajara, Jalisco, Mexico; Folio Mercantil No. 26075 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(2) of the Kingpin Act, 21 U.S.C. 1904(b)(2), for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION; and designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION.

4. CIRCULO REPRESENTACIONES INTERNACIONALES, S. DE R.L. DE C.V., Zapopan, Jalisco, Mexico; Folio Mercantil No. 42993 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION and Jose Antonio CORDERO CARDENAS and EVENTOS LA MORA, S.A. DE C.V. and FC GRUPO EMPRESARIAL, S.A. DE C.V.

5. CLUB DEPORTIVO MORUMBI, ASOCIACION CIVIL (a.k.a. CLUB DEPORTIVO AUTLAN; a.k.a. CLUB DEPORTIVO MORUMBI; a.k.a. CLUB DEPORTIVO MORUMBI, A.C.; a.k.a. GUERREROS DE AUTLAN; a.k.a. PROMOTORA CULTURAL Y DEPORTIVA MORUMBI; a.k.a. ''MORUMBI''), Zapopan, Jalisco, Mexico; Av. Del Bajio S/N, Col. El Bajio, Zapopan, Jalisco, Mexico; Folio Mercantil No. 4123 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION and Maria Icela CHAVEZ MARTINEZ and Felipe FLORES GOMEZ.

6. COMERCIALIZADORA CHAPALA AJIJIC, S.A. DE C.V., Guadalajara, Jalisco, Mexico; Folio Mercantil No. 58593 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed

by, or acting for or on behalf of, Hugo Ivan CARRANZA ZEPEDA.

7. COMERCIALIZADORA E IMPORTADORA YESSI, S.A. DE C.V., Guadalajara, Jalisco, Mexico; Folio Mercantil No. 43753 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION.

8. CONSORCIO LUNALO, S.A. DE C.V., Guadalajara, Jalisco, Mexico; Av. Adolfo Lopez Mateos 525–C, Int. 9, Col. Ladron de Guevara, Guadalajara, Jalisco 44600, Mexico; R.F.C. CLU140217RX4 (Mexico); Folio Mercantil No. 79775 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Hugo Ivan CARRANZA ZEPEDA.

9. CONSORCIO NUJOMA, SOCIEDAD CIVIL (a.k.a. CONSORCIO NUJOMA, S.C.), Torreon, Coahuila, Mexico; Guadalajara, Jalisco, Mexico; Juan Salvador Agraz 1179–13, Col. Moderna, Guadalajara, Jalisco 44190, Mexico; R.F.C. CNU130416UJ3 (Mexico); Folio Mercantil No. 28153 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Hugo Ivan CARRANZA ZEPEDA.

10. CONSORCIO RIRFUS, S.A. DE C.V., Guadalajara, Jalisco, Mexico; Vidrio 2335–138, Col. Americana, Guadalajara, Jalisco 44160, Mexico; R.F.C. CRI130109KL8 (Mexico); Folio Mercantil No. 72346 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Hugo Ivan CARRANZA ZEPEDA.

11. CONSORCIO VINICOLA DE OCCIDENTE, S.A. DE C.V., Zapopan, Jalisco, Mexico; Folio Mercantil No. 10740 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Irma Lizet DAMIAN RAMIREZ.

12. CORPORATIVO ARZACA, S.C. (a.k.a. CORPORATIVO ARZACA, SOCIEDAD CIVIL), Av. Adolfo Lopez Mateos 525–C, Int. 4, Col. Circunvalacion Guevara, Guadalajara, Jalisco 44680, Mexico; R.F.C. CAR130927UU3 (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Hugo Ivan CARRANZA ZEPEDA.

13. CORPORATIVO FEARFI, S.A. DE C.V., Guadalajara, Jalisco, Mexico; Folio Mercantil No. 88504 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Hugo Ivan CARRANZA ZEPEDA.

14. CORPORATIVO INMOBILIARIO UNIVERSAL, S.A. DE C.V., Zapopan, Jalisco, Mexico; Cuitlahuac 435, Depto. 4, Zapopan, Jalisco 45050, Mexico; Juan Sebastian Bach 5187, Col. Residencial La Estancia, Zapopan, Jalisco, Mexico; Folio Mercantil No. 19451 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Jose Antonio CORDERO CARDENAS and Oscar Armando JIMENEZ HERNANDEZ.

15. CORPORATIVO SOSVAL, S.A. DE C.V., Guadalajara, Jalisco, Mexico; Nebulosa 2781, Col. Jardines del Bosque, Guadalajara, Jalisco 44520, Mexico; Nebulosa. 2781–14, Col. Jardines del Bosque, Guadalajara, Jalisco 44520, Mexico; R.F.C. CSO130410P32 (Mexico); Folio Mercantil No. 73550 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Hugo Ivan CARRANZA ZEPEDA.

16. ESCUELA DE FUTBOL RAFAEL MARQUEZ, ASOCIACION CIVIL (a.k.a. ESC DE FUTBOL RAFAEL MARQUEZ; a.k.a. ESCUELA DE FUTBOL RAFAEL MARQUEZ), Guadalajara, Jalisco, Mexico; Av. del Bajio 1134, Col. El Bajio, Guadalajara, Jalisco, Mexico; Del Bajio 1134, San Juan de Ocotan, Guadalajara, Jalisco, Mexico; Folio Mercantil No. 23461 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Rafael MARQUEZ ALVAREZ and Mauricio HEREDIA HORNER.

17. EVENTOS LA MORA, S.A. DE C.V. (a.k.a. EVENTOS LA MORA), Zapopan, Jalisco, Mexico; Lopez Mateos Sur 4527, Col. La Calma, Zapopan, Jalisco 45070, Mexico; Lopez Mateos Sur 4527, Col. Residencial Loma Bonita, Zapopan, Jalisco 45086, Mexico; Lopez Mateos Sur 4527, Tlaquepaque, Jalisco 45070, Mexico; Folio Mercantil No. 29070 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION.

18. FC GRUPO EMPRESARIAL, S.A. DE C.V., Guadalajara, Jalisco, Mexico; Folio Mercantil No. 42946 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION and Jose Antonio CORDERO CARDENAS.

19. FLORES DRUG TRAFFICKING ORGANIZATION (a.k.a. FLORES DTO), Mexico City, Distrito Federal, Mexico; Mexico; Guadalajara, Jalisco, Mexico [SDNTK]. Designated pursuant to section 805(b)(1) of the Kingpin Act, 21 U.S.C. 1904(b)(1), for playing a significant role in international narcotics trafficking.

20. FUTBOL Y CORAZON, ASOCIACION CIVIL (a.k.a. CENTRO INFANTIL RM; a.k.a. FUNDACION FUTBOL Y CORAZON, A.C.; a.k.a. FUNDACION RAFA MARQUEZ; a.k.a. FUNDACION RAFA MARQUEZ FUTBOL Y CORAZON, A.C.; a.k.a. FUTBOL Y CORAZON, A.C.; a.k.a. RAFA MARQUEZ FOUNDATION), Guadalajara, Jalisco, Mexico; Av. Xochitl 4262–6, Prados del Tepeyac, Zapopan, Jalisco 45050, Mexico; Popocatepetl 2907, Col. Ciudad del Sol, Zapopan, Jalisco 45050, Mexico; Santa Isabel 62, Col. Santa Isabel, Tonala, Jalisco, Mexico; Lic. Alfonso Garcia Robles 74, Col. Adolfo Lopez Mateos, Zamora, Michoacan, Mexico; Privada Primitivo Torres 52, Col. El Terrero, El Quince, El Salto, Jalisco 45680, Mexico; alt. Web site *www.fundacionrafa marquez.org;* R.F.C. FCO0505306V0 (Mexico); Folio Mercantil No. 10328 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Rafael MARQUEZ ALVAREZ and Mauricio HEREDIA HORNER.

21. GRAND CASINO (a.k.a. GRAND CASINO ZAPOPAN), Av. Adolfo Lopez Mateos Sur 4527, Col. La Calma, Zapopan, Jalisco 45070, Mexico [SDNTK]. Designated pursuant to section 805(b)(2) of the Kingpin Act, 21 U.S.C. 1904(b)(2), for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION; and designated pursuant to section 805(b)(3) of the

Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION.

22. GRUPO DEPORTIVO ALVANER, S.A. DE C.V., Guadalajara, Jalisco, Mexico; Folio Mercantil No. 72016 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Rafael MARQUEZ ALVAREZ and Mauricio HEREDIA HORNER.

23. GRUPO DEPORTIVO MARQUEZ PARDO, S. DE R.L. DE C.V., Guadalajara, Jalisco, Mexico; Popocatepetl 2907–1, Col. Ciudad del Sol, Zapopan, Jalisco 45050, Mexico; R.F.C. GDM090907NE0 (Mexico); Folio Mercantil No. 51360 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Rafael MARQUEZ ALVAREZ and Mauricio HEREDIA HORNER.

24. GRUPO EGMONT, S.A. DE C.V., Guadalajara, Jalisco, Mexico; Fernando de Alba 765–3, Col. Chapalita, Guadalajara, Jalisco 44500, Mexico; R.F.C. GEG130219MY1 (Mexico); Folio Mercantil No. 72549 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Hugo Ivan CARRANZA ZEPEDA.

25. GRUPO GASOLINERO COJIM, S.A. DE C.V. (a.k.a. GRUPO COJIM, S.A. DE C.V.), Guadalajara, Jalisco, Mexico; KM 39 700 Carretera Jalostotitlan, San Julian, San Miguel El Alto, Jalisco, Mexico; Carretera Jalostotitlan San Julian KM 39.70, San Miguel El Alto, Jalisco, Mexico; KM 1.5 Carretera San Julian a San Miguel El Alto, San Julian, Jalisco 47140, Mexico; Folio Mercantil No. 79563 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Jose Antonio CORDERO CARDENAS.

26. GRUPO NUTRICIONAL ALHOMA, S.A. DE C.V., Guadalajara, Jalisco, Mexico; Av. Lopez Mateos Sur 1710–4, Fracc. El Palomar, Tlajomulco de Zuniga, Jalisco 45643, Mexico; R.F.C. GNA120828LL8 (Mexico); Folio Mercantil No. 69366 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Rafael MARQUEZ ALVAREZ and Mauricio HEREDIA HORNER and Marco Antonio FREGOSO GONZALEZ.

27. GRUPO PRODUCSIL, S.P.R. DE R.L. DE C.V. (a.k.a. GRUPO PRODUCSIL, S. DE P.R. DE R.L. DE C.V.), Guadalajara, Jalisco, Mexico; Paseo de la Arboleda 768–10, Col. Jardines del Bosque, Guadalajara, Jalisco 44520, Mexico; R.F.C. GPR140605GC0 (Mexico); Folio Mercantil No. 83061 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Hugo Ivan CARRANZA ZEPEDA.

28. GRUPO TERAPEUTICO HORMARAL, S.A. DE C.V. (a.k.a. GRUPO TERAPEUTICO HERMORAL, S.A. DE C.V.; a.k.a. PRO SPORT & HEALTH; a.k.a. PROSPORT & HEALTH; a.k.a. PROSPORT&HEALTH), Guadalajara, Jalisco, Mexico; Av. General Eulogio Parra 3200–21, Fracc. Terrazas Monraz, Guadalajara, Jalisco 44670, Mexico; Calle Lisboa 175, Col. Versalles, Puerto Vallarta, Jalisco, Mexico; Web site *www.prosport.mx;* R.F.C. GTH1206069J8 (Mexico); Folio Mercantil No. 68188 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Rafael MARQUEZ ALVAREZ and Mauricio HEREDIA HORNER.

29. GRUPO TERAPEUTICO PUERTO VALLARTA, S.A. DE C.V. (a.k.a. GRUPO TERAPEUTICO DE VALLARTA, S.A. DE C.V.; a.k.a. PROSPORT & HEALTH), Puerto Vallarta, Jalisco, Mexico; Lisboa 175, Col. Versalles, Puerto Vallarta, Jalisco 48320, Mexico; Folio Mercantil No. 16405 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Rafael MARQUEZ ALVAREZ and Mauricio HEREDIA HORNER.

30. INMOBILIARIA FLORES CASTRO, S. DE R.L. DE C.V. (a.k.a. INMOVILIARIA FLORES CASTRO, S. DE R.L. DE C.V.), Zapopan, Jalisco, Mexico; Folio Mercantil No. 42969 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION and Jose Antonio CORDERO CARDENAS and FC GRUPO EMPRESARIAL, S.A. DE C.V.

31. JCAM EDITORA MUSICAL, S.A. DE C.V., Mazatlan, Sinaloa, Mexico; Av. Manuel Acuna 3497, Terrazas Monraz, Guadalajara, Jalisco 44670, Mexico; Folio Mercantil No. 19365 (Sinaloa) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Julio Cesar ALVAREZ MONTELONGO.

32. LOLA LOLITA 1110, S. DE R.L. DE C.V. (a.k.a. LOLALOLITA 1110, S. DE R.L. DE C.V.), Av. Vallarta 1110, Col. Americana, Guadalajara, Jalisco 44160, Mexico; Guadalajara, Jalisco, Mexico; Web site *www.lolalolita.com;* Folio Mercantil No. 60645 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Efrain CARO URIAS and Omar CARO URIAS.

33. MARIMBA ENTERTAINMENT, S.R.L. DE C.V., Guadalajara, Jalisco, Mexico; Folio Mercantil No. 52828 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Efrain CARO URIAS.

34. MONTALVA INMOBILIARIA, S.A. DE C.V., Guadalajara, Jalisco, Mexico; Folio Mercantil No. 77704 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Mario Alberto FERNANDEZ SANTANA.

35. NOCTURNUM INC, S. DE R.L. DE C.V. (a.k.a. CORTEZ COCINA AUTENTICA; a.k.a. NOCTURN INC, S. DE R.L. DE C.V.; a.k.a. ''CORTEZ''; a.k.a. ''EL CORTEZ''; a.k.a. ''RESTAURANT CORTEZ''; a.k.a. ''RESTAURANTE CORTEZ''), Guadalajara, Jalisco, Mexico; Diagonal San Jorge 100, Guadalajara, Jalisco, Mexico; Av. Americas 1417–B, Col. Providencia 2A Seccion, Guadalajara, Jalisco 44630, Mexico; Web site *www.cortez.com.mx;* RFC NIN130327JBO (Mexico); Folio Mercantil No. 74711 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Raul FLORES HERNANDEZ and the FLORES DRUG TRAFFICKING ORGANIZATION and Efrain CARO URIAS and Omar CARO URIAS.

36. NORYBAN PRODUCTIONS, S.A. DE C.V., Mazatlan, Sinaloa, Mexico; Av. Gutierrez Najera 104 Altos, Centro, Mazatlan, Sinaloa 82000, Mexico; Coras

3644, Guadalajara, Jalisco 44670, Mexico; Calle Manuel Acuna 3497, Col. Santa Rita, Guadalajara, Jalisco 44690, Mexico; Ontario 1102, Col. Providencia, Guadalajara, Jalisco 44630, Mexico; R.F.C. NPR0903058I3 (Mexico); Folio Mercantil No. 18949 (Sinaloa) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Julio Cesar ALVAREZ MONTELONGO.

37. PROSPORT & HEALTH IMAGEN, S.A. DE C.V. (a.k.a. PROSPORT & HEALTH, S.A. DE C.V.; a.k.a. PROSPORT Y HEALTH IMAGEN, S.A. DE C.V.), Guadalajara, Jalisco, Mexico; Calle Golfo de Cortes 4114, Local 4 y 5, Col. Monraz, Guadalajara, Jalisco 44670, Mexico; Web site *www.pshimagen.mx;* R.F.C. PAH130925LG0 (Mexico); alt. R.F.C. PAH130925IG0 (Mexico); Folio Mercantil No. 77129 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Rafael MARQUEZ ALVAREZ and Mauricio HEREDIA HORNER.

38. RESTAURANT FOLKLOR Y CANTINA, S.A. DE C.V. (a.k.a. RESTAURANTE FOLKLOR Y CANTINA), Guadalajara, Jalisco, Mexico; Av. Manuel J. Clouthier 1614, Col. Jardines de Guadalupe, Zapopan, Jalisco, Mexico; Folio Mercantil No. 60417 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Hugo Ivan CARRANZA ZEPEDA.

39. RODRIGUEZ LOPEZ, S.A. DE C.V., Guadalajara, Jalisco, Mexico; Carr. San Julian KM 1.5, San Miguel El Alto, San Julian, Jalisco 47170, Mexico; R.F.C. RLO960524C18 (Mexico); Folio Mercantil No. 12651 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Hugo Ivan CARRANZA ZEPEDA and Jose Antonio CORDERO CARDENAS.

40. SERVICIOS EDUCATIVOS Y DE NEGOCIOS, S. DE R.L. DE C.V., Zapopan, Jalisco, Mexico; Folio Mercantil No. 51560 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Mauricio HEREDIA HORNER.

41. SERVICIOS EMPRESARIALES FICIE, S.A. DE C.V., Guadalajara, Jalisco, Mexico; Folio Mercantil No. 84399 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Oscar Armando JIMENEZ HERNANDEZ.

42. SERVICIOS EMPRESARIALES SODA, S.A. DE C.V., Guadalajara, Jalisco, Mexico; Folio Mercantil No. 82219 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Hugo Ivan CARRANZA ZEPEDA.

43. TICKET BOLETO, S.A. DE C.V., Guadalajara, Jalisco, Mexico; Folio Mercantil No. 88198 (Jalisco) (Mexico) [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Julio Cesar ALVAREZ MONTELONGO.

Dated: August 9, 2017.

Andrea Gacki,

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2017–17083 Filed 8–11–17; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Department of the Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for applicable date.

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global Targeting, tel.: (202) 622–2420; Assistant Director for Licensing, tel.: (202) 622–2480; Assistant Director for Regulatory Affairs, tel.: (202) 622–4855; Assistant Director for Sanctions Compliance & Evaluation, tel.: (202) 622–2490; or the Department of the Treasury's Office of the General Counsel: Office of the Chief Counsel (Foreign Assets Control), tel.: (202) 622–2410.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The list of Specially Designated Nationals and Blocked Persons (SDN List) and additional information concerning OFAC sanctions programs are available on OFAC's Web site (*http://www.treasury.gov/ofac*).

Notice of OFAC Actions

On August 9, 2017, OFAC determined that the property and interests in property of the following persons are blocked under the relevant sanctions authority listed below.

1. AMELIACH ORTA, Francisco Jose (Latin: AMELIACH ORTA, Francisco José), Carabobo, Venezuela; DOB 14 Jun 1963; POB Valencia, Carabobo, Venezuela; citizen Venezuela; Gender Male; Cedula No. 7062172 (Venezuela); Constituent of Venezuela's Constituent Assembly for Valencia Municipality in Carabobo State; Member of Venezuela's Presidential Commission for the Constituent Assembly (individual) [VENEZUELA]. Designated pursuant to section 1(a)(ii)(C) of Executive Order 13692 of March 8, 2015, ''Blocking Property and Suspending Entry of Certain Persons Contributing to the Situation in Venezuela'' (E.O. 12692) for being a current or former official of the Government of Venezuela.

2. CHAVEZ FRIAS, Adan Coromoto (Latin: CHÁVEZ FRÍAS, Adán Coromoto), Barinas, Venezuela; DOB 11 Apr 1953; citizen Venezuela; Gender Male; Cedula No. 3915103 (Venezuela); Constituent of Venezuela's Constituent Assembly for Barinas Municipality in Barinas State; Secretary of Venezuela's Presidential Commission for the Constituent Assembly (individual) [VENEZUELA]. Designated pursuant to section 1(a)(ii)(C) of E.O. 13692 for being a current or former official of the Government of Venezuela.

3. D'AMELIO CARDIET, Tania, Vargas, Venezuela; DOB 05 Dec 1971; Gender Female; Cedula No. 11691429 (Venezuela); Rector of Venezuela's National Electoral Council (individual) [VENEZUELA]. Designated pursuant to section 1(a)(ii)(C) of E.O. 13692 for being a current or former official of the Government of Venezuela.

4. ESCARRA MALAVE, Hermann Eduardo, Miranda, Venezuela; DOB 08 Apr 1952; citizen Venezuela; Gender Male; Cedula No. 3820195 (Venezuela); Constituent of Venezuela's Constituent Assembly for Zamora Municipality in Miranda State; Member of Venezuela's Presidential Commission for the Constituent Assembly (individual)

[VENEZUELA]. Designated pursuant to section 1(a)(ii)(A)(1) of E.O. 13692 for being responsible for or complicit in, or responsible for ordering, controlling, or otherwise directing, or to have participated in, directly or indirectly, actions or policies that undermine democratic processes or institutions in or in relation to Venezuela.

5. FARIAS PENA, Erika del Valle (Latin: FARÍAS PEÑA, Erika del Valle), Cojedes, Venezuela; DOB 31 Oct 1972; citizen Venezuela; Gender Female; Cedula No. 9493443 (Venezuela); Constituent of Venezuela's Constituent Assembly for Ezequiel Zamora Municipality in Cojedes State (individual) [VENEZUELA]. Designated pursuant to section 1(a)(ii)(C) of E.O. 13692 for being a current or former official of the Government of Venezuela.

6. LUGO ARMAS, Bladimir Humberto (a.k.a. LUGO ARMAS, Vladimir Humberto), Caracas, Capital District, Venezuela; DOB 18 Nov 1968; Gender Male; Cedula No. 8760081 (Venezuela); Commander of the Special Unit to the Federal Legislative Palace of Venezuela's Bolivarian National Guard (individual) [VENEZUELA]. Designated pursuant to section 1(a)(ii)(C) of E.O. 13692 for being a current or former official of the Government of Venezuela.

7. MELENDEZ RIVAS, Carmen Teresa (Latin: MELÉNDEZ RIVAS, Carmen Teresa), Lara, Venezuela; DOB 03 Nov 1961; POB Barinas, Venezuela; citizen Venezuela; Gender Female; Cedula No. 8146803 (Venezuela); Constituent of Venezuela's Constituent Assembly for Iribarren Municipality in Lara State (individual) [VENEZUELA]. Designated pursuant to section 1(a)(ii)(C) of E.O. 13692 for being a current or former official of the Government of Venezuela.

8. VIVAS VELASCO, Ramon Dario, Vargas, Venezuela; DOB 12 Jun 1950; citizen Venezuela; Gender Male; Cedula No. 3569721 (Venezuela); Constituent of Venezuela's Constituent Assembly for Vargas Municipality in Vargas State (individual) [VENEZUELA]. Designated pursuant to section 1(a)(ii)(C) of E.O. 13692 for being a current or former official of the Government of Venezuela.

Dated: August 9, 2017.

Andrea M. Gacki,

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2017–17127 Filed 8–11–17; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Extension of Information Collection Request Submitted for Public Comment; Election To Expense Certain Refineries

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently, the IRS is soliciting comments concerning the election to expense certain refineries.

DATES: Written comments should be received on or before October 13, 2017 to be assured of consideration.

ADDRESSES: Direct all written comments to Tuawana Pinkston, Internal Revenue Service, Room 6141, 1111 Constitution Avenue NW., Washington, DC 20224. Requests for additional information or copies of the regulations should be directed to R. Joseph Durbala, at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet, at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Election To Expense Certain Refineries.

OMB Number: 1545–2103.

Regulation Project Number: TD 9547.

Abstract: This document contains regulations relating to the election to expense qualified refinery property under section 179C of the Internal Revenue Code, and affects taxpayers who own refineries located in the United States. These regulations reflect the Energy Policy Act of 2005.

Section 179C of the Internal Revenue Code provides that a taxpayer can elect to treat 50% of the cost of ''qualified refinery property'' as a deductible expense not chargeable to capital account. The taxpayer makes an election under section 179C by entering the amount of the deduction at the appropriate place on the taxpayer's timely filed original federal income tax return for the taxable year in which the qualified refinery property is placed in service and by attaching a report specifying (a) the name and address of the refinery and (b) the production capacity requirement under which the refinery qualifies.

If the taxpayer making the expensing election described above is a cooperative described in section 1381, and one or more persons directly holding an ownership interest in the taxpayer are organizations described in section 1381, the taxpayer can elect to allocate all or a portion of the deduction allowable under section 179C to those persons. The allocation must be equal to the person's ratable share of the total amount allocated, determined on the basis of the person's ownership interest in the taxpayer/cooperative.

Current Actions: There is no change to the burden previously approved.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 12.

Estimated Time per Respondent: 10 Hours.

Estimated Total Annual Burden Hours: 120.

The following paragraph applies to all of the collections of information covered by this notice:

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

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Desired Focus of Comments: The Internal Revenue Service (IRS) is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology,

e.g., by permitting electronic submissions of responses.

Comments submitted in response to this notice will be summarized and/or included in the ICR for OMB approval of the extension of the information collection; they will also become a matter of public record.

Approved: August 8, 2017.

R. Joseph Durbala,

IRS Tax Analyst.

[FR Doc. 2017–17139 Filed 8–11–17; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning suspension or reduction of safe harbor nonelective contributions.

DATES: Written comments should be received on or before October 13, 2017 to be assured of consideration.

ADDRESSES: Direct all written comments to L. Brimmer, Internal Revenue Service, room 6529, 1111 Constitution Avenue NW., Washington, DC 20224. Requests for additional information or copies of the regulations should be directed to Kerry Dennis, Internal Revenue Service, Room 6529, 1111 Constitution Avenue NW., Washington DC 20224, or through the internet, at *Kerry.Dennis@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Suspension or Reduction of Safe Harbor Nonelective Contributions.

OMB Number: 1545–2191.

Regulation Project Number: T.D. 9641.

Abstract: The final regulation allows a 401(k) plan using the safe harbor provisions of section 401(k)(12) to suspend or reduce nonelective safe harbor contributions if the employer is operating at an economic loss described in section 412(2)(A). The final regulations permit an employer to reduce or suspend safe harbor nonelective contributions without regard to the financial condition of the employer if notice is provided to participants before the beginning of the plan year which discloses the possibility that the contributions might be reduced or suspended midyear. The final regulations also permit matching contributions to be reduced or suspended under a mid-year amendment if the notice provided to participants before the beginning of the plan year discloses that the contributions might be reduced or suspended mid-year. These notices must also provide that a supplemental notice will be provided to plan participants if a reduction or suspension does occur and that the reduction or suspension will not apply until at least 30 days after the supplemental notice is provided.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals and Households, Businesses and other for-profit organizations.

Estimated Number of Respondents: 5,000.

Estimated Time per Respondent: 2 hours.

Estimated Total Annual Burden Hours: 10,000.

The following paragraph applies to all of the collections of information covered by this notice.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: August 7, 2017.

L. Brimmer,

Senior Tax Analyst.

[FR Doc. 2017–17136 Filed 8–11–17; 8:45 am]

BILLING CODE P

FEDERAL REGISTER

Vol. 82 Monday,

No. 155 August 14, 2017

Book 2 of 2 Books

Pages 37989–38590

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 412, 413, *et al.*

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2018 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Program Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Provider-Based Status of Indian Health Service and Tribal Facilities and Organizations; Costs Reporting and Provider Requirements; Agreement Termination Notices; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 412, 413, 414, 416, 486, 488, 489, and 495

[CMS–1677–F]

RIN 0938–AS98

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2018 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Program Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Provider-Based Status of Indian Health Service and Tribal Facilities and Organizations; Costs Reporting and Provider Requirements; Agreement Termination Notices

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

ACTION: Final rule.

SUMMARY: We are revising the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from our continuing experience with these systems for FY 2018. Some of these changes implement certain statutory provisions contained in the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013, the Improving Medicare Post-Acute Care Transformation Act of 2014, the Medicare Access and CHIP Reauthorization Act of 2015, the 21st Century Cures Act, and other legislation. We also are making changes relating to the provider-based status of Indian Health Service (IHS) and Tribal facilities and organizations and to the low-volume hospital payment adjustment for hospitals operated by the IHS or a Tribe. In addition, we are providing the market basket update that will apply to the rate-of-increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost basis subject to these limits for FY 2018. We are updating the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) for FY 2018.

In addition, we are establishing new requirements or revising existing requirements for quality reporting by specific Medicare providers (acute care hospitals, PPS-exempt cancer hospitals, LTCHs, and inpatient psychiatric facilities). We also are establishing new requirements or revising existing requirements for eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) participating in the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs. We are updating policies relating to the Hospital Value-Based Purchasing (VBP) Program, the Hospital Readmissions Reduction Program, and the Hospital-Acquired Condition (HAC) Reduction Program.

We also are making changes relating to transparency of accrediting organization survey reports and plans of correction of providers and suppliers; electronic signature and electronic submission of the Certification and Settlement Summary page of the Medicare cost reports; and clarification of provider disposal of assets.

DATES: This final rule is effective on October 1, 2017.

FOR FURTHER INFORMATION CONTACT:

Donald Thompson, (410) 786–4487, and Michele Hudson, (410) 786–4487, Operating Prospective Payment, MS–DRGs, Wage Index, New Medical Service and Technology Add-On Payments, Hospital Geographic Reclassifications, Graduate Medical Education, Capital Prospective Payment, Excluded Hospitals, Sole Community Hospitals, Medicare Disproportionate Share Hospital (DSH) Payment Adjustment, Medicare-Dependent Small Rural Hospital (MDH) Program, and Low-Volume Hospital Payment Adjustment Issues.

Michele Hudson, (410) 786–4487, Mark Luxton, (410) 786–4530, and Emily Lipkin, (410) 786–3633, Long-Term Care Hospital Prospective Payment System and MS–LTC–DRG Relative Weights Issues.

Mollie Knight, (410) 786–7948, and Bridget Dickensheets, (410) 786–8670, Rebasing and Revising the Hospital Market Basket Issues.

Siddhartha Mazumdar, (410) 786–6673, Rural Community Hospital Demonstration Program Issues.

Jeris Smith, (410) 786–0110, Frontier Community Health Integration Project Demonstration Issues.

Lein Han, (617) 879–0129, Hospital Readmissions Reduction Program—Readmission Measures for Hospitals Issues.

James Poyer, (410) 786–2261, Hospital Readmissions Reduction Program—Administration Issues.

Elizabeth Bainger, (410) 786–0529, Hospital-Acquired Condition Reduction Program Issues.

Joseph Clift, (410) 786–4165, Hospital-Acquired Condition Reduction Program—Measures Issues.

Grace Im, (410) 786–0700, and James Poyer, (410) 786–2261, Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing—Program Administration, Validation, and Reconsideration Issues.

Reena Duseja, (410) 786–1999, and Cindy Tourison, (410) 786–1093, Hospital Inpatient Quality Reporting—Measures Issues Except Hospital Consumer Assessment of Healthcare Providers and Systems Issues; and Readmission Measures for Hospitals Issues.

Kim Spaulding Bush, (410) 786–3232, Hospital Value-Based Purchasing Efficiency Measures Issues.

Elizabeth Goldstein, (410) 786–6665, Hospital Inpatient Quality Reporting—Hospital Consumer Assessment of Healthcare Providers and Systems Measures Issues.

James Poyer, (410) 786–2261, PPS-Exempt Cancer Hospital Quality Reporting Issues.

Mary Pratt, (410) 786–6867, Long-Term Care Hospital Quality Data Reporting Issues.

Jeffrey Buck, (410) 786–0407, and Cindy, Tourison (410) 786–1093, Inpatient Psychiatric Facilities Quality Data Reporting Issues.

Lisa Marie Gomez, (410) 786–1175, EHR Incentive Program Clinical Quality Measure Related Issues.

Kathleen Johnson, (410) 786–3295, and Steven Johnson (410) 786–3332, EHR Incentive Program Nonclinical Quality Measure Related Issues.

Caecilia Blondiaux, (410), 786–2190, and Ariadne Saklas, (410) 786–3322, Changes in Notice of Termination of Medicare Providers and Suppliers Issues.

Monda Shaver, (410) 786–3410, and Patricia Chmielewski, (410) 786–6899, Accrediting Organizations Survey Reporting Transparency Issues.

Kellie Shannon, (410) 786–0416, Medicare Cost Reporting and Valuation of Assets Issues.

SUPPLEMENTARY INFORMATION:

Electronic Access

This **Federal Register** document is available from the **Federal Register** online database through Federal Digital System (FDsys), a service of the U.S. Government Printing Office. This database can be accessed via the Internet at: *http://www.gpo.gov/fdsys.*

Tables Available Only Through the Internet on the CMS Web Site

In the past, a majority of the tables referred to throughout this preamble and in the Addendum to the proposed rule and the final rule were published in the **Federal Register** as part of the annual proposed and final rules. However, beginning in FY 2012, some of the IPPS tables and LTCH PPS tables are no longer published in the **Federal Register**. Instead, these tables generally will be available only through the Internet. The IPPS tables for this final rule are available through the Internet on the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Click on the link on the left side of the screen titled, ''FY 2018 IPPS Final Rule Home Page'' or ''Acute Inpatient—Files for Download''. The LTCH PPS tables for this FY 2018 final rule are available through the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1677–F. For further details on the contents of the tables referenced in this final rule, we refer readers to section VI. of the Addendum to this final rule.

Readers who experience any problems accessing any of the tables that are posted on the CMS Web sites identified above should contact Michael Treitel at (410) 786–4552.

Acronyms

3M 3M Health Information System
AAMC Association of American Medical Colleges
ACGME Accreditation Council for Graduate Medical Education
ACoS American College of Surgeons
AHA American Hospital Association
AHIC American Health Information Community
AHIMA American Health Information Management Association
AHRQ Agency for Healthcare Research and Quality
AJCC American Joint Committee on Cancer
ALOS Average length of stay
ALTHA Acute Long-Term Hospital Association
AMA American Medical Association
AMGA American Medical Group Association
AMI Acute myocardial infarction
AO Accrediting Organizations
AOA American Osteopathic Association
APR DRG All Patient Refined Diagnosis Related Group System
APRN Advanced practice registered nurse
ARRA American Recovery and Reinvestment Act of 2009, Public Law 111–5
ASCA Administrative Simplification Compliance Act of 2002, Public Law 107–105
ASITN American Society of Interventional and Therapeutic Neuroradiology
ASPE Assistant Secretary for Planning and Evaluation (DHHS)
ATRA American Taxpayer Relief Act of 2012, Public Law 112–240
BBA Balanced Budget Act of 1997, Public Law 105–33
BBRA Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999, Public Law 106–113
BIPA Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Benefits Improvement and Protection Act of 2000, Public Law 106–554
BLS Bureau of Labor Statistics
CABG Coronary artery bypass graft [surgery]
CAH Critical access hospital
CARE [Medicare] Continuity Assessment Record & Evaluation [Instrument]
CART CMS Abstraction & Reporting Tool
CAUTI Catheter-associated urinary tract infection
CBSAs Core-based statistical areas
CC Complication or comorbidity
CCN CMS Certification Number
CCR Cost-to-charge ratio
CDAC [Medicare] Clinical Data Abstraction Center
CDAD *Clostridium difficile*-associated disease
CDC Centers for Disease Control and Prevention
CEHRT Certified electronic health record technology
CERT Comprehensive error rate testing
CDI *Clostridium difficile* [C. difficile] infection
CFR Code of Federal Regulations
CLABSI Central line-associated bloodstream infection
CIPI Capital input price index
CMI Case-mix index
CMS Centers for Medicare & Medicaid Services
CMSA Consolidated Metropolitan Statistical Area
COBRA Consolidated Omnibus Reconciliation Act of 1985, Public Law 99–272
COLA Cost-of-living adjustment
CoP [Hospital] condition of participation
COPD Chronic obstructive pulmonary disease
CPI Consumer price index
CQL Clinical quality language
CQM Clinical quality measure
CY Calendar year
DACA Data Accuracy and Completeness Acknowledgement
DPP Disproportionate patient percentage
DRA Deficit Reduction Act of 2005, Public Law 109–171
DRG Diagnosis-related group
DSH Disproportionate share hospital
EBRT External beam radiotherapy
ECE Extraordinary circumstances exemption
ECI Employment cost index
eCQM Electronic clinical quality measure
EDB [Medicare] Enrollment Database
EHR Electronic health record
EMR Electronic medical record
EMTALA Emergency Medical Treatment and Labor Act of 1986, Public Law 99–272
EP Eligible professional
FAH Federation of American Hospitals
FDA Food and Drug Administration
FFY Federal fiscal year
FPL Federal poverty line
FQHC Federally qualified health center
FR Federal Register
FTE Full-time equivalent
FY Fiscal year
GAF Geographic Adjustment Factor
GME Graduate medical education
HAC Hospital-acquired condition
HAI Healthcare-associated infection
HCAHPS Hospital Consumer Assessment of Healthcare Providers and Systems
HCFA Health Care Financing Administration
HCO High-cost outlier
HCP Healthcare personnel
HCRIS Hospital Cost Report Information System
HF Heart failure
HHA Home health agency
HHS Department of Health and Human Services
HICAN Health Insurance Claims Account Number
HIPAA Health Insurance Portability and Accountability Act of 1996, Public Law 104–191
HIPC Health Information Policy Council
HIS Health information system
HIT Health information technology
HMO Health maintenance organization
HPMP Hospital Payment Monitoring Program
HSA Health savings account
HSCRC [Maryland] Health Services Cost Review Commission
HSRV Hospital-specific relative value
HSRVcc Hospital-specific relative value cost center
HQA Hospital Quality Alliance
HQI Hospital Quality Initiative
HwH Hospital-within-hospital
HWR Hospital-wide readmission
ICD–9–CM International Classification of Diseases, Ninth Revision, Clinical Modification
ICD–10–CM International Classification of Diseases, Tenth Revision, Clinical Modification
ICD–10–PCS International Classification of Diseases, Tenth Revision, Procedure Coding System
ICR Information collection requirement
ICU Intensive care unit
IGI IHS Global, Inc.
IHS Indian Health Service
IME Indirect medical education
IMPACT Act Improving Medicare Post-Acute Care Transformation Act of 2014, Public Law 113–185
I–O Input-Output
IOM Institute of Medicine
IPF Inpatient psychiatric facility
IPFQR Inpatient Psychiatric Facility Quality Reporting [Program]
IPPS [Acute care hospital] inpatient prospective payment system
IRF Inpatient rehabilitation facility
IQR [Hospital] Inpatient Quality Reporting
LAMCs Large area metropolitan counties
LDS Limited Data Set
LOS Length of stay
LTC–DRG Long-term care diagnosis-related group

LTCH Long-term care hospital
LTCH QRP Long-Term Care Hospital Quality Reporting Program
MA Medicare Advantage
MAC Medicare Administrative Contractor
MACRA Medicare Access and CHIP Reauthorization Act of 2015, Public Law 114–10
MAP Measure Application Partnership
MCC Major complication or comorbidity
MCE Medicare Code Editor
MCO Managed care organization
MDC Major diagnostic category
MDH Medicare-dependent, small rural hospital
MedPAC Medicare Payment Advisory Commission
MedPAR Medicare Provider Analysis and Review File
MEI Medicare Economic Index
MGCRB Medicare Geographic Classification Review Board
MIEA–TRHCA Medicare Improvements and Extension Act, Division B of the Tax Relief and Health Care Act of 2006, Public Law 109–432
MIPPA Medicare Improvements for Patients and Providers Act of 2008, Public Law 110–275
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173
MMEA Medicare and Medicaid Extenders Act of 2010, Public Law 111–309
MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007, Public Law 110–173
MOON Medicare Outpatient Observation Notice
MRHFP Medicare Rural Hospital Flexibility Program
MRSA Methicillin-resistant *Staphylococcus aureus*
MSA Metropolitan Statistical Area
MS–DRG Medicare severity diagnosis-related group
MS–LTC–DRG Medicare severity long-term care diagnosis-related group
MU Meaningful Use [EHR Incentive Program]
MUC Measure under consideration
NAICS North American Industrial Classification System
NALTH National Association of Long Term Hospitals
NCD National coverage determination
NCHS National Center for Health Statistics
NCQA National Committee for Quality Assurance
NCVHS National Committee on Vital and Health Statistics
NECMA New England County Metropolitan Areas
NHSN National Healthcare Safety Network
NOP Notice of Participation
NOTICE Act Notice of Observation Treatment and Implication for Care Eligibility Act, Public Law 114–42
NQF National Quality Forum
NQS National Quality Strategy
NTIS National Technical Information Service
NTTAA National Technology Transfer and Advancement Act of 1991, Public Law 104–113
NUBC National Uniform Billing Code
NVHRI National Voluntary Hospital Reporting Initiative
OACT [CMS'] Office of the Actuary
OBRA 86 Omnibus Budget Reconciliation Act of 1986, Public Law 99–509
OES Occupational employment statistics
OIG Office of the Inspector General
OMB [Executive] Office of Management and Budget
ONC Office of the National Coordinator for Health Information Technology
OPM [U.S.] Office of Personnel Management
OQR [Hospital] Outpatient Quality Reporting
O.R. Operating room
OSCAR Online Survey Certification and Reporting [System]
PAC Post-acute care
PAMA Protecting Access to Medicare Act of 2014, Public Law 113–93
PCH PPS-exempt cancer hospital
PCHQR PPS-exempt cancer hospital quality reporting
PMSAs Primary metropolitan statistical areas
POA Present on admission
PPI Producer price index
PPR Potentially Preventable Readmissions
PPS Prospective payment system
PRA Paperwork Reduction Act
PRM Provider Reimbursement Manual
ProPAC Prospective Payment Assessment Commission
PRRB Provider Reimbursement Review Board
PRTFs Psychiatric residential treatment facilities
PSF Provider-Specific File
PSI Patient safety indicator
PS&R Provider Statistical and Reimbursement [System]
PQRS Physician Quality Reporting System
PUF Public use file
QDM Quality data model
QIES ASAP Quality Improvement Evaluation System Assessment Submission and Processing
QIG Quality Improvement Group [CMS]
QIO Quality Improvement Organization
QM Quality measure
QPP Quality Payment Program
QRDA Quality Reporting Document Architecture
RFA Regulatory Flexibility Act, Public Law 96–354
RHC Rural health clinic
RHQDAPU Reporting hospital quality data for annual payment update
RIM Reference information model
RNHCI Religious nonmedical health care institution
RPL Rehabilitation psychiatric long-term care (hospital)
RRC Rural referral center
RSMR Risk-standard mortality rate
RSP Risk-standardized payment
RSSR Risk-standard readmission rate
RTI Research Triangle Institute, International
RUCAs Rural-urban commuting area codes
RY Rate year
SAF Standard Analytic File
SCH Sole community hospital
SCHIP State Child Health Insurance Program
SCIP Surgical Care Improvement Project
SFY State fiscal year
SGR Sustainable Growth Rate
SIC Standard Industrial Classification
SIR Standardized infection ratio
SNF Skilled nursing facility
SNF QRP Skilled Nursing Facility Quality Reporting Program
SNF VBP Skilled Nursing Facility Value-Based Purchasing
SOCs Standard occupational classifications
SOM State Operations Manual
SRR Standardized risk ratio
SSI Surgical site infection
SSI Supplemental Security Income
SSO Short-stay outlier
SUD Substance use disorder
TEFRA Tax Equity and Fiscal Responsibility Act of 1982, Public Law 97–248
TEP Technical expert panel
THA/TKA Total hip arthroplasty/total knee arthroplasty
TMA TMA [Transitional Medical Assistance], Abstinence Education, and QI [Qualifying Individuals] Programs Extension Act of 2007, Public Law 110–90
TPS Total Performance Score
UHDDS Uniform hospital discharge data set
UR Utilization review
VBP [Hospital] Value Based Purchasing [Program]
VTE Venous thromboembolism

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A. Executive Summary

1. Purpose and Legal Authority

This final rule makes payment and policy changes under the Medicare inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals as well as for certain hospitals and hospital units excluded from the IPPS. We also are making changes relating to the provider-based status of Indian Health Service (IHS) and Tribal facilities and organizations and to the IPPS low-volume hospital payment adjustment for hospitals operated by the IHS or a Tribe. In addition, it makes payment and policy changes for inpatient hospital services provided by long-term care hospitals (LTCHs) under the long-term care hospital prospective payment system (LTCH PPS). It also makes policy changes to programs associated with Medicare IPPS hospitals, IPPS-excluded hospitals, and LTCHs.

We are establishing new requirements or revising requirements for quality reporting by specific providers (acute care hospitals, PPS-exempt hospitals, LTCHs, and inpatient psychiatric facilities) that are participating in Medicare. We also are establishing new requirements or revising existing requirements for eligible professionals (EPs), eligible hospitals, and CAHs participating in the Medicare and Medicaid EHR Incentive Programs. We are updating policies relating to the Hospital Value-Based Purchasing (VBP) Program, the Hospital Readmissions Reduction Program, and the Hospital-Acquired Condition (HAC) Reduction Program. We also are making changes related to the transparency of accrediting organization survey reports and plans of correction; to allow electronic signature and electronic submission of the Certification and Settlement Summary page of the Medicare cost reports; and to clarify provider reimbursement regulations relative to the sale or scrapping of depreciable assets on or after December 1, 1997.

Under various statutory authorities, we are making changes to the Medicare IPPS, to the LTCH PPS, and to other related payment methodologies and programs for FY 2018 and subsequent fiscal years. These statutory authorities include, but are not limited to, the following:

- Section 1886(d) of the Social Security Act (the Act), which sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires that, instead of paying for capital-related costs of inpatient hospital services on a reasonable cost basis, the Secretary use a prospective payment system (PPS).
- Section 1886(d)(1)(B) of the Act, which specifies that certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: Rehabilitation hospitals and units; LTCHs; psychiatric hospitals and units; children's hospitals; cancer hospitals; extended neoplastic disease care hospitals (previously referred to as ''long-term care neoplastic disease hospitals'' and renamed in this final rule), and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS.
- Sections 123(a) and (c) of the BBRA (Pub. L. 106–113) and section 307(b)(1) of the BIPA (Pub. L. 106–554) (as codified under section 1886(m)(1) of the Act), which provide for the development and implementation of a prospective payment system for payment for inpatient hospital services of LTCHs described in section 1886(d)(1)(B)(iv) of the Act.
- Sections 1814(l), 1820, and 1834(g) of the Act, which specify that payments are made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services and that these payments are generally based on 101 percent of reasonable cost.

• Section 1866(k) of the Act, as added by section 3005 of the Affordable Care Act, which establishes a quality reporting program for hospitals described in section 1886(d)(1)(B)(v) of the Act, referred to as ''PPS-exempt cancer hospitals.''

• Section 1886(a)(4) of the Act, which specifies that costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act.

• Section 1886(b)(3)(B)(viii) of the Act, which requires the Secretary to reduce the applicable percentage increase that would otherwise apply to the standardized amount applicable to a subsection (d) hospital for discharges occurring in a fiscal year if the hospital does not submit data on measures in a form and manner, and at a time, specified by the Secretary.

• Section 1886(o) of the Act, which requires the Secretary to establish a Hospital Value-Based Purchasing (VBP) Program under which value-based incentive payments are made in a fiscal year to hospitals meeting performance standards established for a performance period for such fiscal year.

• Section 1886(p) of the Act, as added by section 3008 of the Affordable Care Act, which establishes a Hospital-Acquired Condition (HAC) Reduction Program, under which payments to applicable hospitals are adjusted to provide an incentive to reduce hospital-acquired conditions.

• Section 1886(q) of the Act, as added by section 3025 of the Affordable Care Act and amended by section 10309 of the Affordable Care Act and section 15002 of the 21st Century Cures Act, which establishes the ''Hospital Readmissions Reduction Program.'' Under the program, payments for discharges from an ''applicable hospital'' under section 1886(d) of the Act will be reduced to account for certain excess readmissions. Section 15002 of the 21st Century Cures Act requires the Secretary to compare cohorts of hospitals to each other in determining the extent of excess readmissions.

• Section 1886(r) of the Act, as added by section 3133 of the Affordable Care Act, which provides for a reduction to disproportionate share hospital (DSH) payments under section 1886(d)(5)(F) of the Act and for a new uncompensated care payment to eligible hospitals. Specifically, section 1886(r) of the Act requires that, for fiscal year 2014 and each subsequent fiscal year, subsection (d) hospitals that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act will receive two separate payments: (1) 25 percent of the amount they previously would have received under section 1886(d)(5)(F) of the Act for DSH (''the empirically justified amount''), and (2) an additional payment for the DSH hospital's proportion of uncompensated care, determined as the product of three factors. These three factors are: (1) 75 percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act; (2) 1 minus the percent change in the percent of individuals who are uninsured (minus 0.2 percentage point for FY 2018 through FY 2019); and (3) a hospital's uncompensated care amount relative to the uncompensated care amount of all DSH hospitals expressed as a percentage.

• Section 1886(m)(6) of the Act, as added by section 1206(c) of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67), which provided for the establishment of site neutral payment rate criteria under the LTCH PPS with implementation beginning in FY 2016.

• Section 1886(m)(6) of the Act, as amended by section 15009 of the 21st Century Cures Act (Pub. L. 114–255), which provides for a temporary exception to the application of the site neutral payment rate under the LTCH PPS for certain spinal cord specialty hospitals for discharges in cost reporting periods beginning during FYs 2018 and 2019.

• Section 1886(m)(6) of the Act, as amended by section 15010 of the 21st Century Cures Act (Pub. L. 114–255), which provides for a temporary exception to the application of the site neutral payment rate under the LTCH PPS for certain LTCHs with certain discharges with severe wounds occurring in cost reporting periods beginning during FY 2018.

• Section 1886(m)(5)(D)(iv) of the Act, as added by section 1206(c) of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67), which provides for the establishment of a functional status quality measure under the LTCH QRP for change in mobility among inpatients requiring ventilator support.

• Section 1899B of the Act, as added by section 2(a) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act, Pub. L. 113–185), which provides for the establishment of data reporting for certain post-acute care providers, including LTCHs.

2. Summary of the Major Provisions

a. MS–DRG Documentation and Coding Adjustment

Section 631 of the American Taxpayer Relief Act of 2012 (ATRA, Pub. L. 112–240) amended section 7(b)(1)(B) of Public Law 110–90 to require the Secretary to make a recoupment adjustment to the standardized amount of Medicare payments to acute care hospitals to account for changes in MS–DRG documentation and coding that do not reflect real changes in case-mix, totaling $11 billion over a 4-year period of FYs 2014, 2015, 2016, and 2017. The FY 2014 through FY 2017 adjustments represented the amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013. Prior to the ATRA, this amount could not have been recovered under Public Law 110–90. Section 414 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10) replaced the single positive adjustment we intended to make in FY 2018 with a 0.5 percent positive adjustment to the standardized amount of Medicare payments to acute care hospitals for FYs 2018 through 2023. The FY 2018 adjustment was subsequently adjusted to 0.4588 percent by section 15005 of the 21st Century Cures Act.

For FY 2018, we are making the 0.4588 percent positive adjustment to the standardized amount as required by section 414 of Public Law 114–10, as amended by section 15005 of the 21st Century Cures Act.

b. Adjustment to IPPS Rates Resulting From 2-Midnight Policy

In FY 2017, we made a permanent adjustment to the standardized amount, the hospital-specific payment rates, and the national capital Federal rate to prospectively remove the 0.2 percent reduction to the rates put in place in FY 2014 to offset the estimated increase in IPPS expenditures as a result of the 2-midnight policy. In addition, we made a temporary one-time prospective increase to the FY 2017 standardized amount, the hospital-specific payment rates, and the national capital Federal rate of 0.6 percent by including a temporary one-time factor of 1.006 in the calculation of the standardized amount, the hospital-specific payment rates, and the national capital Federal rate to address the effects of the 0.2 percent reduction to the rate for the 2-midnight policy in effect for FYs 2014, 2015, and 2016.

For FY 2018, we are including a factor of (1/1.006) in the calculation of the FY

2018 standardized amount, the hospital-specific payment rates, and the national capital Federal rate to remove the temporary one-time factor of 1.006, as established in the FY 2017 IPPS/LTCH PPS final rule.

c. Reduction of Hospital Payments for Excess Readmissions

We are making changes to policies for the Hospital Readmissions Reduction Program, which is established under section 1886(q) of the Act, as added by section 3025 of the Affordable Care Act, as amended by section 10309 of the Affordable Care Act. The Hospital Readmissions Reduction Program requires a reduction to a hospital's base operating DRG payment to account for excess readmissions of selected applicable conditions. For FY 2018 and subsequent years, the reduction is based on a hospital's risk-adjusted readmission rate during a 3-year period for acute myocardial infarction (AMI), heart failure (HF), pneumonia, chronic obstructive pulmonary disease (COPD), total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG). In this final rule, we are establishing the following policies: (1) Specify applicable time period for FY 2018; (2) specifying the calculation of aggregate payments for excess readmissions for FY 2018; (3) making changes to the payment adjustment factor in accordance with the 21st Century Cures Act for FY 2019; and (4) updating the Extraordinary Circumstances Exceptions policy.

d. Hospital Value-Based Purchasing (VBP) Program

Section 1886(o) of the Act requires the Secretary to establish a Hospital VBP Program under which value-based incentive payments are made in a fiscal year to hospitals based on their performance on measures established for a performance period for such fiscal year. In this final rule, we are removing one previously adopted measure, the PSI 90: Patient Safety for Selected Indicators measure, from the Hospital VBP Program beginning with the FY 2019 program year. We also are adopting one new measure, Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode of Care for Pneumonia, beginning with the FY 2022 program year, and adopting a modified version of a previously adopted measure, Patient Safety and Adverse Events Composite (NQF #0531), beginning with the FY 2023 program year. In addition, we are making two modifications to our domain scoring policies beginning with the FY 2019 program year, and further establishing a new weighting methodology for the measures within the Efficiency and Cost Reduction domain. We also are addressing public comment submitted in response to our comment solicitation on whether and how to account for social risk factors in the Hospital VBP Program.

e. Hospital-Acquired Condition (HAC) Reduction Program

Section 1886(p) of the Act, as added under section 3008(a) of the Affordable Care Act, establishes an incentive to hospitals to reduce the incidence of hospital-acquired conditions by requiring the Secretary to make an adjustment to payments to applicable hospitals effective for discharges beginning on October 1, 2014. This 1-percent payment reduction applies to a hospital whose ranking is in the top quartile (25 percent) of all applicable hospitals, relative to the national average, of conditions acquired during the applicable period and on all of the hospital's discharges for the specified fiscal year. In this final rule, we are establishing the following policies: (1) Specifying the data collection time periods for the FY 2020 HAC Reduction Program; and (2) updating the Extraordinary Circumstances Exception policy for the HAC Reduction Program. In this final rule, we also are responding to comments received regarding: (1) Additional measures and potential future adoption; (2) accounting for social risk factors; and (3) the inclusion of disability and medical complexity for the CDC NHSN measures.

f. DSH Payment Adjustment and Additional Payment for Uncompensated Care

Section 3133 of the Affordable Care Act modified the Medicare disproportionate share hospital (DSH) payment methodology beginning in FY 2014. Under section 1886(r) of the Act, which was added by section 3133 of the Affordable Care Act, starting in FY 2014, DSHs receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments in section 1886(d)(5)(F) of the Act. The remaining amount, equal to 75 percent of the amount that otherwise would have been paid as Medicare DSH payments, is paid as additional payments after the amount is reduced for changes in the percentage of individuals that are uninsured. Each Medicare DSH will receive an additional payment based on its share of the total amount of uncompensated care for all Medicare DSHs for a given time period.

In this final rule, we are updating our estimates of the three factors used to determine uncompensated care payments for FY 2018. The statute permits the use of a data source other than the CBO estimates to determine the percent change in the rate of uninsurance as part of the calculation of Factor 2 beginning in FY 2018. We are using uninsured estimates produced by CMS' Office of the Actuary (OACT) as part of the development of the National Health Expenditure Accounts (NHEA) in the calculation of Factor 2. We also are beginning to incorporate data from Worksheet S–10 in the calculation of hospitals' share of uncompensated care by combining data on uncompensated care costs from the Worksheet S–10 for FY 2014 with proxy data regarding a hospital's share of low-income insured days for FYs 2012 and 2013 to determine Factor 3 for FY 2018. We will continue to use data from three cost reporting periods to calculate Factor 3, which will gradually incorporate uncompensated care data from Worksheet S–10 into the calculation of Factor 3. As part of this policy, we are including a definition of uncompensated care costs consisting of the sum of charity care and bad debt and a trim methodology to address aberrant cost-to-charge ratios (CCRs) as well as potentially aberrant uncompensated care costs that exceed a threshold of 50 percent of total operating costs. We also are providing that, for Puerto Rico hospitals, Indian Health Service and Tribal hospitals, and all-inclusive rate providers, we will substitute data regarding low-income insured days for FY 2013 for the Worksheet S–10 data from FY 2014 cost reports.

We are continuing the policies that were finalized in FY 2015 to address several specific issues concerning the process and data to be employed in determining hospitals' share of uncompensated care in the case of hospital mergers. We also are continuing the policies finalized in FY 2017 concerning the methodology for calculating each hospital's relative share of uncompensated care, such as combining data from multiple cost reports beginning in the same fiscal year and averaging the sum of three individual Factor 3s by the number of cost reporting periods with data. In addition, we are annualizing hospital cost reports that do not span 12 months. We also are applying a scaling factor to each hospital's uncompensated care amount so that total uncompensated care payments will be consistent with the estimated amount available to make

uncompensated care payments for FY 2018.

g. Changes to the LTCH PPS

In this final rule, we set forth changes to the LTCH PPS Federal payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2018; changes to the payment methodology under the short-stay outlier (SSO) policy; implementation of several provisions of the 21st Century Cures Act; and the adoption of a 1-year regulatory delay on the full implementation of the 25-percent threshold policy for discharges occurring in FY 2018 (that is, for the fiscal year after expiration of the current statutory moratoria under the 21st Century Cures Act, which is set to expire September 30, 2017).

h. Hospital Inpatient Quality Reporting (IQR) Program

Under section 1886(b)(3)(B)(viii) of the Act, subsection (d) hospitals are required to report data on measures selected by the Secretary for a fiscal year in order to receive the full annual percentage increase that would otherwise apply to the standardized amount applicable to discharges occurring in that fiscal year. In past years, we have established measures on which hospitals must report data and the process for submittal and validation of the data.

In this final rule, we are finalizing several changes. First, we are refining two previously adopted measures. Specifically, we are finalizing an update to the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey measure by replacing the three existing questions about Pain Management with three new questions that address Communication About Pain During the Hospital Stay, beginning with the FY 2020 payment determination with modification that public reporting would be delayed. In addition, we are finalizing an update to the stroke mortality measure to include the use of NIH Stroke Scale claims data for risk adjustment, beginning with the FY 2023 payment determination. We also are adopting the Hospital-Wide All-Cause Unplanned Readmission Hybrid Measure as a voluntary measure for the CY 2018 reporting period.

In addition, we are finalizing a modified, reduced policy for eCQM reporting as compared to our proposals. For both the CY 2017 reporting period/FY 2019 payment determination and CY 2018 reporting period/FY 2020 payment determination, we are finalizing that hospitals will be required to select and submit four of the available eCQMs included in the Hospital IQR Program measure set and provide one self-selected, calendar year quarter of data. We are also modifying our eCQM certification requirements such that for the CY 2018 reporting period hospitals will be able to use: (1) The 2014 Edition of CERHT, (2) the 2015 Edition of CEHRT, or (3) a combination of both the 2014 and 2015 Editions of CEHRT. In addition, we are finalizing the following policies: (1) For the CY 2017 reporting period/FY 2019 payment determination and the CY 2018 reporting period/FY 2020 payment determination, a hospital using EHR technology certified to the 2014 or 2015 Edition, but for which such EHR technology is not certified to all 15 available eCQMs available to report, will be required to have its EHR technology certified to all 15 eCQMs that are available to report in the Hospital IQR Program; (2) for the CY 2017 reporting period/FY 2019 payment determination, hospitals will be required to use the most recent version of the eCQM electronic specifications (namely, the Spring 2016 version of the eCQM specifications and any applicable addenda); (3) for the CY 2018 reporting period/FY 2020 payment determination, hospitals will be required to use the most recent version of the eCQM electronic specifications (namely, the Spring 2017 version of the eCQM specifications and any applicable addenda); and (5) hospitals' EHR technology certified to all 15 eCQMs would not need to be recertified each time it is updated to a more recent version of the eCQMs. These policies are being made in alignment with the CQM electronic reporting policies for the Medicare and Medicaid EHR Incentive Programs, and will decrease the required number of eCQMs and quarters of reporting as compared with the previously finalized requirements in the FY 2017 IPPS/LTCH PPS final rule.

Furthermore, we are finalizing our policies for the eCQM data validation process, whereby we will select eight cases per quarter (the number of quarters required will vary by specific FY payment determination) to complete eCQM validation for the FY 2020 payment determination and subsequent years. In addition, for the FY 2020 payment determination and subsequent years, we are establishing policies related to the exclusion criteria for hospital and case selection, and the data submission requirements for participating hospitals. For the FY 2021 payment determination and subsequent years, we are finalizing our proposal to extend our previously finalized medical record submission policy for eCQM validation requiring submission of at least 75 percent of sampled eCQM measure medical records in a timely and complete manner. Also, we are: (1) Formalizing our educational review process for chart-abstracted measures for the FY 2020 payment determination and subsequent years, and (2) finalizing that we will use this process to correct quarterly scores for any of the first 3 quarters of validation in order to compute the final confidence interval.

Moreover, we are establishing policies related to our Hospital IQR Program Extraordinary Circumstances Extension or Exemptions policy, including a change to the name of the policy to Extraordinary Circumstances Exceptions (ECE) policy and updates to 42 CFR 412.140(c)(2) to reflect our ECE policy. Finally, we responded to our solicitation of public comment on accounting for social risk factors in the Hospital IQR Program, the confidential and potential future public reporting of clinical quality measure data stratified by patients' dual-eligible status, and the following clinical quality measures that we are considering for future inclusion in the Hospital IQR Program: (1) Quality of Informed Consent Documents for Hospital-Performed, Elective Procedures measure; (2) four End-of-Life process and outcome measures for cancer patients; (3) two nurse staffing measures; and (4) 11 newly specified electronic clinical quality measures (eCQMs).

i. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

Section 1886(m)(5) of the Act requires LTCHs to report certain quality data to CMS in order to receive their full annual update under the LTCH PPS. In this final rule, we are adopting one new outcome measure related to pressure ulcers and two new measures (one process and one outcome) related to ventilator weaning. We also are defining the certain standardized patient assessment data that LTCHs must report to comply with section 1886(m)(5)(F)(ii) of the Act, as well as the requirements for the reporting of these data. Finally, we will publicly report data on four assessment-based measures and three claims-based measures.

j. Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program

For the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program, we are making several policy changes. First, beginning with the FY 2019 payment determination (that is, for extraordinary circumstances occurring during CY 2018), we are updating the IPFQR Program's extraordinary circumstances

exceptions (ECE) policy by: (1) Allowing designated personnel to provide their contact information and sign the ECE request in lieu of the requesting IPF's Chief Executive Officer (CEO); (2) allowing up to 90 days after the extraordinary circumstance to submit the request; and (3) stating that we will strive to respond to ECE requests within 90 days of receiving them. Second, we are changing the annual data submission period from a specific date range to a 45-day period that begins at least 30 days following the end of the collection period. Third, we are aligning our deadlines for submission of a Notice of Participation (NOP) or program withdrawal with this data submission timeframe. Finally, we are establishing factors by which we will evaluate measures for removal from or retention under the IPFQR Program. These factors align with those in use in other quality reporting programs.

We are not finalizing our proposal to adopt the Medication Continuation following Inpatient Psychiatric Discharge measure for FY 2020 payment determination and subsequent years.

3. Summary of Costs and Benefits

• *Adjustment for MS–DRG Documentation and Coding Changes.* Section 414 of the MACRA replaced the single positive adjustment we intended to make in FY 2018 once the recoupment required by section 631 of the ATRA was complete with a 0.5 percent positive adjustment to the standardized amount of Medicare payments to acute care hospitals for FYs 2018 through 2023. The FY 2018 adjustment was subsequently adjusted to 0.4588 percent by section 15005 of the 21st Century Cures Act (Pub. L. 114–255). For FY 2018, we are making the 0.4588 percent positive adjustment to the standardized amount as required by these provisions.

• *Adjustment to IPPS Payment Rates as a Result of the 2-Midnight Policy.* The removal of the adjustment to IPPS rates resulting from the 2-midnight policy will decrease IPPS payment rates by (1/1.006) for FY 2018. The (1/1.006) is a one-time factor that will be applied to the standardized amount, the hospital-specific rates, and the national capital Federal rate for FY 2018 only.

• *Medicare DSH Payment Adjustment and Additional Payment for Uncompensated Care.* Under section 1886(r) of the Act (as added by section 3133 of the Affordable Care Act), DSH payments to hospitals under section 1886(d)(5)(F) of the Act are reduced and an additional payment for uncompensated care is made to eligible hospitals beginning in FY 2014. Hospitals that receive Medicare DSH payments receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments in section 1886(d)(5)(F) of the Act. The remainder, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, is the basis for determining the additional payments for uncompensated care after the amount is reduced for changes in the percentage of individuals that are uninsured and additional statutory adjustments. Each hospital that receives Medicare DSH payments will receive an additional payment for uncompensated care based on its share of the total uncompensated care amount reported by Medicare DSHs. The reduction to Medicare DSH payments is not budget neutral.

For FY 2018, we are providing that the 75 percent of what otherwise would have been paid for Medicare DSH will be adjusted to approximately 58.01 percent of the amount to reflect changes in the percentage of individuals that are uninsured and additional statutory adjustments. In other words, approximately 43.51 percent (the product of 75 percent and 58.01 percent) of our estimate of Medicare DSH payments, prior to the application of section 3133 of the Affordable Care Act, will be available to make additional payments to hospitals for their relative share of the total amount of uncompensated care.

We project that estimated Medicare DSH payments, and additional payments for uncompensated care made for FY 2018, will increase payments overall by approximately 0.6 percent as compared to the estimate of overall payments, including Medicare DSH payments and uncompensated care payments that will be distributed in FY 2017. The additional payments have redistributive effects based on a hospital's uncompensated care amount relative to the uncompensated care amount for all hospitals that are estimated to receive Medicare DSH payments, and the calculated payment amount is not directly tied to a hospital's number of discharges.

• *Changes to the Hospital Readmissions Reduction Program.* For FY 2018 and subsequent years, the reduction is based on a hospital's risk-adjusted readmission rate during a 3-year period for acute myocardial infarction (AMI), heart failure (HF), pneumonia, chronic obstructive pulmonary disease (COPD), total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG). Overall, in this final rule, we estimate that 2,591 hospitals will have their base operating DRG payments reduced by their determined proxy FY 2018 hospital-specific readmission adjustment. As a result, we estimate that the Hospital Readmissions Reduction Program will save approximately $564 million in FY 2018, an increase of approximately $27 million over the estimated FY 2017 savings.

• *Value-Based Incentive Payments Under the Hospital VBP Program.* We estimate that there will be no net financial impact to the Hospital VBP Program for the FY 2018 program year in the aggregate because, by law, the amount available for value-based incentive payments under the program in a given year must be equal to the total amount of base operating MS–DRG payment amount reductions for that year, as estimated by the Secretary. The estimated amount of base operating MS–DRG payment amount reductions for the FY 2018 program year and, therefore, the estimated amount available for value-based incentive payments for FY 2018 discharges is approximately $1.9 billion.

• *Changes to the HAC Reduction Program.* A hospital's Total HAC score and its ranking in comparison to other hospitals in any given year depends on several different factors. Any significant impact due to the HAC Reduction Program changes for FY 2018, including which hospitals will receive the adjustment, will depend on actual experience.

• *Update to the LTCH PPS Payment Rates and Other Payment Factors.* Based on the best available data for the 415 LTCHs in our database, we estimate that the changes to the payment rates and factors that we are presenting in the preamble and Addendum of this final rule, which reflects the rolling end to the transition of the statutory application of the site neutral payment rate required by section 1886(m)(6)(A) of the Act, the update to the LTCH PPS standard Federal payment rate for FY 2018, and estimated changes to the site neutral payment rate and high-cost outlier (HCO) payments will result in an estimated decrease in payments from FY 2017 of approximately $195 million.

• *Changes to the 25-Percent Threshold Policy.* In this final rule, we estimate our adoption of a 1-year regulatory delay of the full implementation of the 25-percent threshold policy for discharges occurring in FY 2018 will increase payments to LTCHs in FY 2018 by $70 million.

• *Changes to the Hospital Inpatient Quality Reporting (IQR) Program.* Across 3,300 IPPS hospitals, we

estimate that our finalized requirements for the Hospital IQR Program will result in the following changes to costs and benefits in this program compared to previously finalized requirements: (1) A cost reduction of $613,864 for the FY 2019 payment determination due to the updates to the eCQM reporting requirements; (2) a total net cost reduction of $866,277 for the FY 2020 payment determination due to the updates to the eCQM reporting requirements, the updates to the eCQM validation procedures, and the voluntary reporting of the new Hybrid Hospital-Wide Readmission measure; and (3) a total cost reduction of $255,104 for the FY 2021 payment determination due to the updates to the eCQM validation procedures.

• *Changes Related to the LTCH QRP.* In this final rule, we are adopting one outcome measure related to pressure ulcers and two new measures (one process and one outcome) related to ventilator weaning. We also are specifying the use of certain standardized patient assessment data as required under section 1899B(b)(1)(B) of the Act and policies regarding public display of measure data. Overall, the cost associated with the changes to the LTCH QRP is estimated at a reduction of $893.14 per LTCH annually or $380,480 for all LTCHs.

• *Changes to the IPFQR Program.* In this final rule, we are not adopting the one claims-based measure we proposed. However, we are updating our ECE process; changing the specification of the data submission period; aligning the timeframe for submission of the NOP or program withdrawal with the data submission period; and establishing factors to evaluate measures for retention or removal. We do not believe that these policies will have any impact on the IPFQR program burden.

B. Summary

1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)

Section 1886(d) of the Social Security Act (the Act) sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires the Secretary to use a prospective payment system (PPS) to pay for the capital-related costs of inpatient hospital services for these ''subsection (d) hospitals.'' Under these PPSs, Medicare payment for hospital inpatient operating and capital-related costs is made at predetermined, specific rates for each hospital discharge. Discharges are classified according to a list of diagnosis-related groups (DRGs).

The base payment rate is comprised of a standardized amount that is divided into a labor-related share and a nonlabor-related share. The labor-related share is adjusted by the wage index applicable to the area where the hospital is located. If the hospital is located in Alaska or Hawaii, the nonlabor-related share is adjusted by a cost-of-living adjustment factor. This base payment rate is multiplied by the DRG relative weight.

If the hospital treats a high percentage of certain low-income patients, it receives a percentage add-on payment applied to the DRG-adjusted base payment rate. This add-on payment, known as the disproportionate share hospital (DSH) adjustment, provides for a percentage increase in Medicare payments to hospitals that qualify under either of two statutory formulas designed to identify hospitals that serve a disproportionate share of low-income patients. For qualifying hospitals, the amount of this adjustment varies based on the outcome of the statutory calculations. The Affordable Care Act revised the Medicare DSH payment methodology and provides for a new additional Medicare payment that considers the amount of uncompensated care beginning on October 1, 2013.

If the hospital is training residents in an approved residency program(s), it receives a percentage add-on payment for each case paid under the IPPS, known as the indirect medical education (IME) adjustment. This percentage varies, depending on the ratio of residents to beds.

Additional payments may be made for cases that involve new technologies or medical services that have been approved for special add-on payments. To qualify, a new technology or medical service must demonstrate that it is a substantial clinical improvement over technologies or services otherwise available, and that, absent an add-on payment, it would be inadequately paid under the regular DRG payment.

The costs incurred by the hospital for a case are evaluated to determine whether the hospital is eligible for an additional payment as an outlier case. This additional payment is designed to protect the hospital from large financial losses due to unusually expensive cases. Any eligible outlier payment is added to the DRG-adjusted base payment rate, plus any DSH, IME, and new technology or medical service add-on adjustments.

Although payments to most hospitals under the IPPS are made on the basis of the standardized amounts, some categories of hospitals are paid in whole or in part based on their hospital-specific rate, which is determined from their costs in a base year. For example, sole community hospitals (SCHs) receive the higher of a hospital-specific rate based on their costs in a base year (the highest of FY 1982, FY 1987, FY 1996, or FY 2006) or the IPPS Federal rate based on the standardized amount. SCHs are the sole source of care in their areas. Specifically, section 1886(d)(5)(D)(iii) of the Act defines an SCH as a hospital that is located more than 35 road miles from another hospital or that, by reason of factors such as isolated location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of hospital inpatient services reasonably available to Medicare beneficiaries. In addition, certain rural hospitals previously designated by the Secretary as essential access community hospitals are considered SCHs.

Under current law, the Medicare-dependent, small rural hospital (MDH) program is effective through FY 2017. Through and including FY 2006, an MDH received the higher of the Federal rate or the Federal rate plus 50 percent of the amount by which the Federal rate was exceeded by the higher of its FY 1982 or FY 1987 hospital-specific rate. For discharges occurring on or after October 1, 2007, but before October 1, 2017, an MDH receives the higher of the Federal rate or the Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the highest of its FY 1982, FY 1987, or FY 2002 hospital-specific rate. MDHs are a major source of care for Medicare beneficiaries in their areas. Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area, has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (not less than 60 percent of its inpatient days or discharges in its cost reporting year beginning in FY 1987 or in two of its three most recently settled Medicare cost reporting years).

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient hospital services in accordance with a prospective payment system established by the Secretary. The basic methodology for determining capital prospective payments is set forth in our regulations at 42 CFR 412.308 and 412.312. Under the capital IPPS, payments are adjusted by the same DRG for the case as they are under the operating IPPS. Capital IPPS payments are also adjusted for IME and DSH, similar to the adjustments made under the operating IPPS. In addition, hospitals may receive outlier payments

for those cases that have unusually high costs.

The existing regulations governing payments to hospitals under the IPPS are located in 42 CFR part 412, subparts A through M.

2. Hospitals and Hospital Units Excluded From the IPPS

Under section 1886(d)(1)(B) of the Act, as amended, certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: Inpatient rehabilitation facility (IRF) hospitals and units; long-term care hospitals (LTCHs); psychiatric hospitals and units; children's hospitals; cancer hospitals; extended neoplastic disease care hospitals (referred to as ''long-term care neoplastic disease hospitals'' in the proposed rule and renamed for this final rule, which were formerly LTCHs classified under section 1886(d)(1)(B)(iv)(II) of the Act and redesignated by section 15008 of Pub. L 114–255) and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS. Various sections of the Balanced Budget Act of 1997 (BBA, Pub. L. 105–33), the Medicare, Medicaid and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 (BBRA, Pub. L. 106–113), and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA, Pub. L. 106–554) provide for the implementation of PPSs for IRF hospitals and units, LTCHs, and psychiatric hospitals and units (referred to as inpatient psychiatric facilities (IPFs)). (We note that the annual updates to the LTCH PPS are included along with the IPPS annual update in this document. Updates to the IRF PPS and IPF PPS are issued as separate documents.) Children's hospitals, cancer hospitals, hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa), and RNHCIs continue to be paid solely under a reasonable cost-based system subject to a rate-of-increase ceiling on inpatient operating costs.

The existing regulations governing payments to excluded hospitals and hospital units are located in 42 CFR parts 412 and 413.

3. Long-Term Care Hospital Prospective Payment System (LTCH PPS)

The Medicare prospective payment system (PPS) for LTCHs applies to hospitals described in section 1886(d)(1)(B)(iv) of the Act effective for cost reporting periods beginning on or after October 1, 2002. The LTCH PPS was established under the authority of sections 123 of the BBRA and section 307(b) of the BIPA (as codified under section 1886(m)(1) of the Act). During the 5-year (optional) transition period, a LTCH's payment under the PPS was based on an increasing proportion of the LTCH Federal rate with a corresponding decreasing proportion based on reasonable cost principles. Effective for cost reporting periods beginning on or after October 1, 2006, all LTCHs are paid 100 percent of the Federal rate. Section 1206(a) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) established the site neutral payment rate under the LTCH PPS, which made the LTCH PPS a dual rate payment system beginning in FY 2016. Under this statute, based on a rolling effective date that is linked to the date on which a given LTCH's Federal FY 2016 cost reporting period begins, LTCHs are paid for discharges at the site neutral payment rate unless the discharge meets the patient criteria for payment at the LTCH PPS standard Federal payment rate. The existing regulations governing payment under the LTCH PPS are located in 42 CFR part 412, subpart O. Beginning October 1, 2009, we issue the annual updates to the LTCH PPS in the same documents that update the IPPS (73 FR 26797 through 26798).

4. Critical Access Hospitals (CAHs)

Under sections 1814(l), 1820, and 1834(g) of the Act, payments made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services are generally based on 101 percent of reasonable cost. Reasonable cost is determined under the provisions of section 1861(v) of the Act and existing regulations under 42 CFR part 413.

5. Payments for Graduate Medical Education (GME)

Under section 1886(a)(4) of the Act, costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act. The amount of payment for direct GME costs for a cost reporting period is based on the hospital's number of residents in that period and the hospital's costs per resident in a base year. The existing regulations governing payments to the various types of hospitals are located in 42 CFR part 413.

C. Summary of Provisions of Recent Legislation Implemented in This Final Rule

1. The American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240), the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10), and the 21st Century Cures Act (Pub. L. 114–255)

Section 631 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240) amended section 7(b)(1)(B) of Public Law 110–90 to require CMS to make a recoupment adjustment to the standardized amounts under section 1886(d) of the Act based upon the Secretary's estimates for discharges occurring from FYs 2014 through FY 2017 to fully offset $11 billion. Once the recoupment required under section 631 of the ATRA was completed, CMS had anticipated making a single positive adjustment in FY 2018 to offset the reductions required to recoup the $11 billion under section 631 of the ATRA. However, section 414 of the MACRA replaced the single positive adjustment CMS intended to make in FY 2018 with a 0.5 percent positive adjustment for each of FYs 2018 through 2023. Section 15005 of the 21st Century Cures Act (Pub. L. 114–255, enacted December 13, 2016) further amended Public Law 110–90 to reduce the adjustment for FY 2018 from 0.5 percent point to 0.4588 percentage point.

2. Pathway for SGR Reform Act of 2013 (Pub. L. 113–67)

The Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) introduced new payment rules in the LTCH PPS. Under section 1206 of this law, discharges in cost reporting periods beginning on or after October 1, 2015 under the LTCH PPS will receive payment under a site neutral rate unless the discharge meets certain patient-specific criteria. In this final rule, we are continuing to update certain policies that implemented provisions under section 1206 of the Pathway for SGR Reform Act.

3. Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185)

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act (Pub. L. 113–185), enacted on October 6, 2014, made a number of changes that affect the Long-Term Care

Quality Reporting Program (LTCH QRP). In this final rule, we are continuing to implement portions of section 1899B of the Act, as added by section 2(a) of the IMPACT Act, which, in part, requires LTCHs, among other postacute care providers, to report standardized patient assessment data, data on quality measures, and data on resource use and other measures.

4. The Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10)

Section 411(g) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA, Pub. L. 114–10) sets the annual update under the LTCH PPS to 1.0 percent for FY 2018. In this final rule, consistent with this requirement, we are updating the LTCH standard Federal payment rate by 1.0 percent for FY 2018.

The MACRA also extended the MDH program and temporary changes to the payment adjustment for low-volume hospitals through FY 2017. In this final rule, we discuss the expiration of the MDH program and the expiration of the temporary changes to the low-volume hospital payment adjustment under current law.

5. The 21st Century Cures Act (Pub. L. 114–255)

The 21st Century Cures Act (Pub. L. 114–255), enacted on December 13, 2016, contains a number of provisions affecting payments under the LTCH PPS, the Hospital Readmissions Reduction Program and the Medicare EHR Incentive Program, which we are implementing in this final rule:

- Section 4002(b)(1)(A) amended section 1848(a)(7)(B) of the Act to provide that the Secretary shall exempt an eligible professional from the application of the payment adjustment under section 1848(a)(7)(A) of the Act with respect to a year, subject to annual renewal, if the Secretary determines that compliance with the requirement for being a meaningful EHR user is not possible because the certified EHR technology used by such eligible professional has been decertified under the Office of the National Coordinator for Health Information Technology's (ONC) Health IT Certification Program.
- Section 4002(b)(2) amended section 1886(b)(3)(B)(ix)(II) of the Act to provide that the Secretary shall exempt a hospital from the application of the payment adjustment under section 1886(b)(3)(B)(ix)(I) with respect to a fiscal year, subject to annual renewal, if the Secretary determines that compliance with the requirement for being a meaningful EHR user is not possible because the certified EHR technology used by the hospital is decertified under ONC's Health IT Certification Program.
- Section 15002, which amended section 1886(q)(3) of the Act by adding subparagraphs (D) and (E), which requires the Secretary to develop a methodology for the calculating the excess readmissions adjustment factor for the Hospital Readmissions Reduction Program based on cohorts defined by the percentage of dual eligible patients (that is, patients who are eligible for both Medicare and full-benefit Medicaid coverage) cared for by a hospital. In this final rule, we are implementing changes to the payment adjustment factor to assess penalties based on a hospital's performance relative to other hospitals treating a similar proportion of dual-eligible patients.
- Section 15004(a), which further amended section 114(d)(7) of the MMSEA (as amended) by striking ''The moratorium under paragraph (1)(A)'' and inserting ''[a]ny moratorium under paragraph (1)'' and specified that such amendment shall take effect as if included in the enactment of section 112 of the PAMA. We are implementing the exceptions to the current statutory moratorium, which is in effect through September 30, 2017, on increasing beds in an existing LTCH or an existing LTCH satellite as provided by Section 15004(a).
- Section 15004(b), which modifies high cost outlier payments to LTCH standard Federal rate cases beginning in FY 2018.
- Section 15006, which further amended section 114(c)(1)(A) of the MMSEA (as amended) by extending the moratorium on the full implementation of the 25-percent threshold policy through June 30, 2016, and for discharges occurring on or after October 1, 2016 and before October 1, 2017. In this final rule, we are implementing the moratorium on the full implementation of the 25-percent threshold policy for discharges occurring on or after October 1, 2016, through September 30, 2017, as provided by section 15006.
- Section 15007, which amended section 1206(a)(3) of the Pathway for SGR Reform Act by extending the exclusion for of Medicare Advantage plans' and site neutral payment rate discharges from the calculation of the average length-of-stay to all LTCHs, for discharges occurring in cost reporting periods beginning on or after October 1, 2015.
- Section 15008, which provided for a change in Medicare classification for ''subclause (II)'' LTCHs by redesignating such hospitals from section 1886(d)(1)(B)(iv)(II) to section 1886(d)(1)(B)(vi) of the Act. In this final rule, we are implementing the reclassification of hospitals which had previously been classified as ''subclause (II)'' LTCHs as their own category of IPPS-excluded hospitals as provided by the provisions of section 15008.
- Section 15009 of Public Law 114–255, which added new subparagraph (F) to section 1886(m)(6) of the Act, providing for a temporary exception to the site neutral payment rate for certain spinal cord specialty hospitals for all discharges occurring during such LTCH's cost reporting periods that begin during FYs 2018 and 2019.
- Section 15010, which added a new subparagraph (G) to section 1886(m)(6) of the Act, to create a temporary exception to the site neutral payment rate for certain severe wound discharges from certain LTCHs during such LTCH's cost reporting period beginning during FY 2018.
- Section 16003 amended section 1848(a)(7)(D) of the Act to provide that no payment adjustment may be made under section 1848(a)(7)(A) of the Act for 2017 and 2018 in the case of an eligible professional who furnishes substantially all of his or her covered professional services in an ambulatory surgical center (ASC). Section 1848(a)(7)(D)(iii) of the Act provides that determinations of whether an eligible professional is ASC-based may be made based on the site of service as defined by the Secretary or an attestation, but shall be made without regard to any employment or billing arrangement between the eligible professional and any other supplier or provider of services. Section 1848(a)(7)(D)(iv) of the Act provides that the ASC-based exception shall no longer apply as of the first year that begins more than 3 years after the date on which the Secretary determines, through notice-and-comment rulemaking, that certified EHR technology applicable to the ASC setting is available.

D. Issuance of a Notice of Proposed Rulemaking

In the proposed rule that appeared in the **Federal Register** on April 28, 2017 (82 FR 19796), we set forth proposed payment and policy changes to the Medicare IPPS for FY 2018 operating costs and for capital-related costs of acute care hospitals and certain hospitals and hospital units that are excluded from IPPS. In addition, we set forth proposed changes to the payment rates, factors, and other payment and policy-related changes to programs

associated with payment rate policies under the LTCH PPS for FY 2018.

Below is a summary of the major changes that we proposed to make.

1. Proposed Changes to MS–DRG Classifications and Recalibrations of Relative Weights

In section II. of the preamble of the proposed rule, we included—

- Proposed changes to MS–DRG classifications based on our yearly review for FY 2018.
- Proposed adjustment to the standardized amounts under section 1886(d) of the Act for FY 2018 in accordance with the amendments made to section 7(b)(1)(B) of Public Law 110–90 by section 414 of the MACRA and section 15005 of the 21st Century Cures Act.
- Proposed recalibration of the MS–DRG relative weights.
- A discussion of the FY 2018 status of new technologies approved for add-on payments for FY 2017 and a presentation of our evaluation and analysis of the FY 2018 applicants for add-on payments for high-cost new medical services and technologies (including public input, as directed by Pub. L. 108–173, obtained in a town hall meeting).

2. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

In section III. of the preamble to the proposed rule, we proposed to make revisions to the wage index for acute care hospitals and the annual update of the wage data. Specific issues addressed include, but are not limited to, the following:

- The proposed FY 2018 wage index update using wage data from cost reporting periods beginning in FY 2014.
- Clarification of other wage-related costs in the wage index.
- Calculation of the proposed occupational mix adjustment for FY 2018 based on the 2013 Occupational Mix Survey.
- Analysis and implementation of the proposed FY 2018 occupational mix adjustment to the wage index for acute care hospitals.
- Proposed application of the rural floor and the frontier State floor and the proposed expiration of the imputed floor.
- Proposed revisions to the wage index for acute care hospitals based on hospital redesignations and reclassifications under sections 1886(d)(8)(B), (d)(8)(E), and (d)(10) of the Act.
- Proposal to require documentation of SCH and RRC classification status approvals to be submitted to the MGCRB by the first business day after January 1.
- Clarification of special rules for SCHs and RRCs reclassifying to geographic home areas.
- Proposed changes to the 45-day notification rule.
- The proposed adjustment to the wage index for acute care hospitals for FY 2018 based on commuting patterns of hospital employees who reside in a county and work in a different area with a higher wage index.
- Determination of the labor-related share for the proposed FY 2018 wage index.

3. Proposed Rebasing and Revising of Hospital Market Basket

In section IV. of the proposed rule, we proposed to revise and rebase the hospital market baskets for acute care hospitals and update the labor-related share.

4. Other Decisions and Proposed Changes to the IPPS for Operating Costs

In section V. of the preamble of the proposed rule, we discussed proposed changes or clarifications of a number of the provisions of the regulations in 42 CFR parts 412 and 413, including the following:

- Proposed changes to MS–DRGs subject to the postacute care transfer policy.
- Proposed changes to the inpatient hospital update for FY 2018.
- Proposed changes to the volume decrease adjustment for SCHs.
- Proposed updated national and regional case-mix values and discharges for purposes of determining RRC status.
- Expiration of the temporary changes to the payment adjustment for low-volume hospitals at the end of FY 2017.
- Proposed parallel low-volume hospital payment adjustment concerning hospitals operated by the Indian Health Service (IHS) or a Tribe.
- The statutorily required IME adjustment factor for FY 2018.
- Proposed changes to the methodologies for determining Medicare DSH payments and the additional payments for uncompensated care.
- Discussion of expiration of the MDH program at the end of FY 2017 and our policy to allow MDHs to apply for SCH status in advance of the expiration of the MDH program and be paid as such under certain conditions.
- Proposed changes to the rules for payment adjustments under the Hospital Readmissions Reduction Program based on hospital readmission measures and the process for hospital review and correction of those rates for FY 2018.
- Proposed changes to the requirements and provision of value-based incentive payments under the Hospital Value-Based Purchasing Program.
- Proposed requirements for payment adjustments to hospitals under the HAC Reduction Program for FY 2018.
- Discussion of and proposals relating to the additional 5-year extension of the Rural Community Hospital Demonstration Program.
- Proposals related to the provider-based status of IHS and Tribal facilities and organizations that would remove the regulatory date limitation that restricted the grandfathering provision to IHS or Tribal facilities and organizations furnishing services on or before April 7, 2000. We also proposed to make a technical change to make the regulation text more consistent with our current rules that require these facilities to comply with all applicable Medicare conditions of participation that apply to the main provider.

5. Proposed FY 2018 Policy Governing the IPPS for Capital-Related Costs

In section VI. of the preamble to the proposed rule, we discussed the proposed payment policy requirements for capital-related costs and capital payments to hospitals for FY 2018.

6. Proposed Changes to the Payment Rates for Certain Excluded Hospitals: Rate-of-Increase Percentages

In section VII. of the preamble of the proposed rule, we discussed—

- Proposed changes to payments to certain excluded hospitals for FY 2018.
- Proposed policy changes relating to payments to hospitals-within-hospitals.
- Proposed continued implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration.

7. Proposed Changes to the LTCH PPS

In section VIII. of the preamble of the proposed rule, we set forth—

- Proposed changes to the LTCH PPS Federal payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2018.
- Proposed changes to the short-stay outlier (SSO) policy.
- Proposed 1-year regulatory delay of the full implementation of the 25-percent threshold policy for discharges occurring in FY 2018.
- Proposed changes to implement the temporary exception to the site neutral payment rate for certain spinal cord specialty hospitals and for certain discharges with severe wounds from certain LTCHs, as provided under sections 15009 and 15010 of Public Law 114–255, respectively.

• Proposed change to the average length of stay criterion to implement section 15007 of Public Law 114–255.
• Proposed change in Medicare classification for certain hospitals to implement section 15008 of Public Law 114–255.

8. Proposed Changes Relating to Quality Data Reporting for Specific Providers and Suppliers

In section IX. of the preamble of the proposed rule, we addressed—
• Proposed requirements for the Hospital Inpatient Quality Reporting (IQR) Program.
• Proposed changes to the requirements for the quality reporting program for PPS-exempt cancer hospitals (PCHQR Program).
• Proposed changes to the requirements under the LTCH Quality Reporting Program (LTCH QRP).
• Proposed changes to the requirements under the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program.
• Proposed changes to requirements pertaining to the clinical quality measurement of eligible hospitals and CAHs as well as EPs participating in the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs.

9. Proposed Changes Relating to Medicare Cost Reporting and Provider Requirements

In section X. of the preamble of the proposed rule, we presented our proposals to revise the regulations to allow providers to use an electronic signature to sign the Certification and Settlement Summary page of the Medicare cost report and submit this page electronically, and clarify the rules relating to the sale or scrapping of depreciable assets disposed of on or after December 1, 1997.

10. Proposed Changes Relating to Survey and Certification Requirements

In section XI. of the preamble of the proposed rule, we present our proposals for allowing transparency in accrediting organization survey reports and plans of correction and for changing the requirement for providers to publish self-termination notices in newspapers.

11. Determining Prospective Payment Operating and Capital Rates and Rate-of-Increase Limits for Acute Care Hospitals

In section V. of the Addendum to the proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2018 prospective payment rates for operating costs and capital-related costs for acute care hospitals. We proposed to establish the threshold amounts for outlier cases. In addition, we addressed the update factors for determining the rate-of-increase limits for cost reporting periods beginning in FY 2018 for certain hospitals excluded from the IPPS.

12. Determining Prospective Payment Rates for LTCHs

In the Addendum to the proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2018 LTCH PPS standard Federal payment rate and other factors used to determine LTCH PPS payments under both the LTCH PPS standard Federal payment rate and the site neutral payment rate in FY 2018. We proposed to establish the adjustments for wage levels, the labor-related share, the cost-of-living adjustment, and high-cost outliers, including the applicable fixed-loss amounts and the LTCH cost-to-charge ratios (CCRs) for both payment rates.

13. Impact Analysis

In Appendix A of the proposed rule, we set forth an analysis of the impact that the proposed changes would have on affected acute care hospitals, CAHs, LTCHs, PCHs, and IPFs.

14. Recommendation of Update Factors for Operating Cost Rates of Payment for Hospital Inpatient Services

In Appendix B of the proposed rule, as required by sections 1886(e)(4) and (e)(5) of the Act, we provided our recommendations of the appropriate percentage changes for FY 2018 for the following:
• A single average standardized amount for all areas for hospital inpatient services paid under the IPPS for operating costs of acute care hospitals (and hospital-specific rates applicable to SCHs).
• Target rate-of-increase limits to the allowable operating costs of hospital inpatient services furnished by certain hospitals excluded from the IPPS.
• The LTCH PPS standard Federal payment rate and the site neutral payment rate for hospital inpatient services provided for LTCH PPS discharges.

15. Discussion of Medicare Payment Advisory Commission Recommendations

Under section 1805(b) of the Act, MedPAC is required to submit a report to Congress, no later than March 15 of each year, in which MedPAC reviews and makes recommendations on Medicare payment policies. MedPAC's March 2017 recommendations concerning hospital inpatient payment policies address the update factor for hospital inpatient operating costs and capital-related costs for hospitals under the IPPS. We addressed these recommendations in Appendix B of the proposed rule. For further information relating specifically to the MedPAC March 2017 report or to obtain a copy of the report, contact MedPAC at (202) 220–3700 or visit MedPAC's Web site at: *http://www.medpac.gov*.

II. Changes to Medicare Severity Diagnosis-Related Group (MS–DRG) Classifications and Relative Weights

A. Background

Section 1886(d) of the Act specifies that the Secretary shall establish a classification system (referred to as diagnosis-related groups (DRGs)) for inpatient discharges and adjust payments under the IPPS based on appropriate weighting factors assigned to each DRG. Therefore, under the IPPS, Medicare pays for inpatient hospital services on a rate per discharge basis that varies according to the DRG to which a beneficiary's stay is assigned. The formula used to calculate payment for a specific case multiplies an individual hospital's payment rate per case by the weight of the DRG to which the case is assigned. Each DRG weight represents the average resources required to care for cases in that particular DRG, relative to the average resources used to treat cases in all DRGs. Section 1886(d)(4)(C) of the Act requires that the Secretary adjust the DRG classifications and relative weights at least annually to account for changes in resource consumption. These adjustments are made to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources.

B. MS–DRG Reclassifications

For general information about the MS–DRG system, including yearly reviews and changes to the MS–DRGs, we refer readers to the previous discussions in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43764 through 43766) and the FYs 2011 through 2017 IPPS/LTCH PPS final rules (75 FR 50053 through 50055; 76 FR 51485 through 51487; 77 FR 53273; 78 FR 50512; 79 FR 49871; 80 FR 49342; and 81 FR 56787 through 56872, respectively).

C. Adoption of the MS–DRGs in FY 2008

For information on the adoption of the MS–DRGs in FY 2008, we refer readers to the FY 2008 IPPS final rule

with comment period (72 FR 47140 through 47189).

D. FY 2018 MS–DRG Documentation and Coding Adjustment

1. Background on the Prospective MS–DRG Documentation and Coding Adjustments for FY 2008 and FY 2009 Authorized by Public Law 110–90

In the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189), we adopted the MS–DRG patient classification system for the IPPS, effective October 1, 2007, to better recognize severity of illness in Medicare payment rates for acute care hospitals. The adoption of the MS–DRG system resulted in the expansion of the number of DRGs from 538 in FY 2007 to 745 in FY 2008. By increasing the number of MS–DRGs and more fully taking into account patient severity of illness in Medicare payment rates for acute care hospitals, MS–DRGs encourage hospitals to improve their documentation and coding of patient diagnoses.

In the FY 2008 IPPS final rule with comment period (72 FR 47175 through 47186), we indicated that the adoption of the MS–DRGs had the potential to lead to increases in aggregate payments without a corresponding increase in actual patient severity of illness due to the incentives for additional documentation and coding. In that final rule with comment period, we exercised our authority under section 1886(d)(3)(A)(vi) of the Act, which authorizes us to maintain budget neutrality by adjusting the national standardized amount, to eliminate the estimated effect of changes in coding or classification that do not reflect real changes in case-mix. Our actuaries estimated that maintaining budget neutrality required an adjustment of −4.8 percentage points to the national standardized amount. We provided for phasing in this −4.8 percentage point adjustment over 3 years. Specifically, we established prospective documentation and coding adjustments of −1.2 percentage points for FY 2008, −1.8 percentage points for FY 2009, and −1.8 percentage points for FY 2010.

On September 29, 2007, Congress enacted the TMA [Transitional Medical Assistance], Abstinence Education, and QI [Qualifying Individuals] Programs Extension Act of 2007 (Public Law 110–90). Section 7(a) of Public Law 110–90 reduced the documentation and coding adjustment made as a result of the MS–DRG system that we adopted in the FY 2008 IPPS final rule with comment period to −0.6 percentage point for FY 2008 and −0.9 percentage point for FY 2009.

As discussed in prior year rulemaking, and most recently in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56780 through 56782), we implemented a series of adjustments required under sections 7(b)(1)(A) and 7(b)(1)(B) of Public Law 110–90, based on a retrospective review of FY 2008 and FY 2009 claims data. We completed these adjustments in FY 2013, but indicated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53274 through 53275) that delaying full implementation of the adjustment required under section 7(b)(1)(A) of Public Law 110–90 until FY 2013 resulted in payments in FY 2010 through FY 2012 being overstated, and that these overpayments could not be recovered.

2. Recoupment or Repayment Adjustment Authorized by Section 631 of the American Taxpayer Relief Act of 2012 (ATRA)

Section 631 of the ATRA amended section 7(b)(1)(B) of Public Law 110–90 to require the Secretary to make a recoupment adjustment or adjustments totaling $11 billion by FY 2017. This adjustment represented the amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013. As discussed earlier, this delay in implementation resulted in overstated payment rates in FYs 2010, 2011, and 2012. The resulting overpayments could not have been recovered under Public Law 110–90.

Similar to the adjustments authorized under section 7(b)(1)(B) of Public Law 110–90, the adjustment required under section 631 of the ATRA was a one-time recoupment of a prior overpayment, not a permanent reduction to payment rates. Therefore, we anticipated that any adjustment made to reduce payment rates in one year would eventually be offset by a positive adjustment in 2018, once the necessary amount of overpayment was recovered. However, section 414 of the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, Public Law 114–10, enacted on April 16, 2015, replaced the single positive adjustment we intended to make in FY 2018 with a 0.5 percentage point positive adjustment for each of FYs 2018 through 2023. We stated in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49345) that we would address this MACRA provision in future rulemaking. However, section 15005 of the 21st Century Cures Act (Pub. L. 114–255), enacted on December 13, 2016, reduced the adjustment for FY 2018 from 0.5 percentage points to 0.4588 percentage points. We are addressing these provisions of MACRA and the 21st Century Cures Act in section II.D.3. of the preamble of this final rule.

As we stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50515 through 50517), our actuaries estimated that a −9.3 percentage point adjustment to the standardized amount would be necessary if CMS were to fully recover the $11 billion recoupment required by section 631 of the ATRA in FY 2014. It is often our practice to phase in payment rate adjustments over more than one year, in order to moderate the effect on payment rates in any one year. Therefore, consistent with the policies that we have adopted in many similar cases, and after consideration of the public comments we received, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50515 through 50517), we implemented a −0.8 percentage point recoupment adjustment to the standardized amount in FY 2014. We estimated that if adjustments of approximately −0.8 percentage point were implemented in FYs 2014, 2015, 2016, and 2017, using standard inflation factors, the entire $11 billion would be accounted for by the end of the statutory 4-year timeline. As estimates of any future adjustments are subject to variations in total savings, we did not provide for specific adjustments for FYs 2015, 2016, or 2017 at that time.

Consistent with the approach discussed in the FY 2014 rulemaking for recouping the $11 billion required by section 631 of the ATRA, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49874) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49345), we implemented additional −0.8 percentage point recoupment adjustments to the standardized amount in FY 2015 and FY 2016, respectively. We estimated that these adjustments, combined with leaving the prior −0.8 percentage point adjustments in place, would recover up to $2 billion in FY 2015 and another $3 billion in FY 2016. When combined with the approximately $1 billion adjustment made in FY 2014, we estimated that approximately $5 to $6 billion would be left to recover under section 631 of the ATRA by the end of FY 2016.

As indicated in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24966), due to lower than previously estimated inpatient spending, we determined that an adjustment of −0.8 percentage point in FY 2017 would not recoup the $11 billion under section 631 of the ATRA. For the FY 2017 IPPS/LTCH PPS final rule (81 FR 56785), based on the Midsession Review of the President's FY 2017 Budget, our actuaries estimated

that, to the nearest tenth of a percentage point, the FY 2017 documentation and coding adjustment factor that will recoup as closely as possible $11 billion from FY 2014 through FY 2017 without exceeding this amount is −1.5 percentage points. Based on those updated estimates by the Office of the Actuary using the Midsession Review of the President's FY 2017 Budget, we made a −1.5 percentage point adjustment for FY 2017 as the final adjustment required under section 631 of the ATRA. The estimates by our actuaries related to this finalized adjustment were included in a memorandum that we made publicly available on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2017-IPPS-Final-Rule-Home-Page-Items/FY2017-IPPS-Final-Rule-OACT.html.*

3. Adjustment for FY 2018 Required Under Section 414 of Public Law 114–10 (MACRA) and Section 15005 of Public Law 114–255

As stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56785), once the recoupment required under section 631 of the ATRA was complete, we had anticipated making a single positive adjustment in FY 2018 to offset the reductions required to recoup the $11 billion under section 631 of the ATRA. However, section 414 of the MACRA (which was enacted on April 16, 2015) replaced the single positive adjustment we intended to make in FY 2018 with a 0.5 percentage point positive adjustment for each of FYs 2018 through 2023. In the FY 2017 rulemaking, we indicated that we would address the adjustments for FY 2018 and later fiscal years in future rulemaking. As noted previously, section 15005 of the 21st Century Cures Act (Pub. L. 114–255), which was enacted on December 13, 2016, amended section 7(b)(1)(B) of the TMA, as amended by section 631 of the ATRA and section 414 of the MACRA, to reduce the adjustment for FY 2018 from a 0.5 percentage point to a 0.4588 percentage point. We believe the directive under section 15005 of Public Law 114–255 is clear. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19816) for FY 2018, we proposed to implement the required +0.4588 percentage point adjustment to the standardized amount. This is a permanent adjustment to payment rates. While we did not propose future adjustments required under section 414 of the MACRA and section 15005 of Public Law 114–255 at that time, we stated in the proposed rule that we expect to propose positive 0.5 percentage point adjustments to the standardized amounts for FYs 2019 through 2023.

Comment: Several commenters reiterated their disagreement with the −1.5 percentage point adjustment that CMS made for FY 2017 under section 631 of the ATRA, which exceeded the estimated adjustment of approximately −0.8 percentage point described in the FY 2014 IPPS/LTCH PPS rulemaking. Commenters contended that, as a result, hospitals would be left with a larger permanent cut than Congress intended following the enactment of MACRA. They asserted that CMS' proposal to apply a 0.4588 percent positive adjustment for FY 2018 misinterprets the relevant statutory authority, and urged CMS to align with their view of Congress' intent by restoring an additional +0.7 percentage point adjustment to the standardized amount in FY 2018; that is, the difference between the −1.5 percentage point adjustment made in FY 2017 and the initial estimate of −0.8 percentage point discussed in the FY 2014 IPPS/LTCH PPS rulemaking. Commenters also urged CMS to use its discretion under section 1886(d)(5)(I) of the Act to increase the FY 2018 adjustment by 0.7 percentage point. Other commenters requested that, despite current law, CMS ensure that adjustments totaling the full 3.9 percentage points withheld under section 631 of the ATRA be returned.

Response: As discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56783 through 56785), CMS completed the $11 billion recoupment required under section 631 of the ATRA. We continue to disagree that section 414 of the MACRA was intended to augment or limit our separate obligation under the ATRA to fully offset $11 billion by FY 2017, as we discussed in response to comments in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56784). Moreover, as we discussed in the FY 2018 IPPS/LTCH PPS proposed rule, we believe the directive regarding the applicable adjustment for FY 2018 is clear. While we had anticipated making a positive adjustment in FY 2018 to offset the reductions required to recoup the $11 billion under section 631 of the ATRA, section 414 of the MACRA requires that we not make the single positive adjustment we intended to make in FY 2018 but instead make a 0.5 percentage point positive adjustment for each of FYs 2018 through 2023. As noted by the commenters, and discussed in the FY 2017 IPPS/LTCH PPS final rule, by phasing in a total positive adjustment of only 3.0 percentage points, section 414 of the MACRA would not fully restore even the 3.2 percentage point adjustment originally estimated by CMS in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50515). Finally, Public Law 114–255, which further reduced the positive adjustment required for FY 2018 from 0.5 percentage point to 0.4588 percentage point, was enacted on December 13, 2016, after CMS proposed and finalized the −1.5 percentage point adjustment as the final adjustment required under section 631 of the ATRA in the FY 2017 rulemaking.

After consideration of the public comments we received, we are finalizing the +0.4588 percentage point adjustment to the standardized amount for FY 2018, as required under section 15005 of Public Law 114–255.

E. Refinement of the MS–DRG Relative Weight Calculation

1. Background

Beginning in FY 2007, we implemented relative weights for DRGs based on cost report data instead of charge information. We refer readers to the FY 2007 IPPS final rule (71 FR 47882) for a detailed discussion of our final policy for calculating the cost-based DRG relative weights and to the FY 2008 IPPS final rule with comment period (72 FR 47199) for information on how we blended relative weights based on the CMS DRGs and MS–DRGs. We also refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56785 through 56787) for a detailed discussion of the history of changes to the number of cost centers used in calculating the DRG relative weights. Since FY 2014, we calculate the IPPS MS–DRG relative weights using 19 CCRs, which now include distinct CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization.

2. Discussion of Policy for FY 2018

Consistent with our established policy, we calculated the final MS–DRG relative weights for FY 2018 using two data sources: The MedPAR file as the claims data source and the HCRIS as the cost report data source. We adjusted the charges from the claims to costs by applying the 19 national average CCRs developed from the cost reports. The description of the calculation of the 19 CCRs and the MS–DRG relative weights for FY 2018 is included in section II.G. of the preamble to this FY 2018 IPPS/LTCH PPS final rule. As we did with the FY 2018 IPPS/LTCH PPS proposed rule, we are providing the version of the HCRIS from which we calculated these 19 CCRs on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Click on the link on the

left side of the screen titled, ''FY 2018 IPPS Final Rule Home Page'' or ''Acute Inpatient Files for Download.''

Comment: One commenter recommended that CMS work with stakeholders to update cost reporting instructions and improve the accuracy and validity of the national average CCRs. The commenter expressed concern that the differences between hospitals' use of nonstandard cost center codes and CMS' procedures for mapping and rolling up nonstandard codes to the standard cost centers will continue to result in invalid CCRs and inaccurate payments. The commenter stressed the need for flexibility in cost reporting, to accommodate any new or unique services that certain hospitals may provide, which may not be easily captured through the cost reporting software. Finally, the commenter again recommended, as it had done in response to prior IPPS rules, that CMS pay particular attention to data used for CT scan and MRI cost centers; the commenter believed that the hospital payment rates established by CMS from the CT scan and MRI CCRs simply do not correlate with resources used for these capital-intensive services.

Response: We received a similar public comment last year and responded to it in the FY 2017 IPPS/LTCH PPS final rule. We refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56787) for our response to these issues. We note that we will continue to explore ways in which we can improve the accuracy of the cost report data and calculated CCRs used in the cost estimation process.

Comment: One commenter requested that CMS use a single diagnostic radiology CCR to set weights, rather than using the separate CT and MRI cost centers. The commenter requested that if CMS maintains the separate CT and MRI cost centers, CMS should not include cost reports from hospitals that use the ''square foot'' allocation methodology. The commenter provided an analysis to support its assertion that the CCRs for CT and MRI are incorrect and are inappropriately reducing payments under the IPPS. The commenter indicated that the charge-compression hypothesis has been shown to be false with the use of the separate CT and MRI cost centers. The commenter discussed problems with cost allocation to the CT and MRI cost centers. The commenter referenced discussions in prior IPPS/LTCH PPS rules about this issue. The commenter acknowledged that CMS did not include a specific proposal in the FY 2018 proposed rule regarding this issue.

Response: As the commenter noted, we did not make any proposals for FY 2018 relating to the number of cost centers used to calculate the relative weights. As noted previously and discussed in detail in prior rulemaking, we have calculated the IPPS MS–DRG relative weights using 19 CCRs, including distinct CCRs for MRIs and CT scans, since FY 2014. We refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56785) for a detailed discussion of the basis for establishing these 19 CCRs. We further note that in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50518 through 50523), we presented data analyses using distinct CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization. As we noted, we will continue to explore ways in which we can improve the accuracy of the cost report data and calculated CCRs used in the cost estimation process.

F. Changes to Specific MS–DRG Classifications

1. Discussion of Changes to Coding System and Basis for FY 2018 MS–DRG Updates

a. Conversion of MS–DRGs to the International Classification of Diseases, 10th Revision (ICD–10)

As of October 1, 2015, providers use the International Classification of Diseases, 10th Revision (ICD–10) coding system to report diagnoses and procedures for Medicare hospital inpatient services under the MS–DRG system instead of the ICD–9–CM coding system, which was used through September 30, 2015. The ICD–10 coding system includes the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, as well as the Official ICD–10–CM and ICD–10–PCS Guidelines for Coding and Reporting. For a detailed discussion of the conversion of the MS–DRGs to ICD–10, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56787 through 56789).

b. Basis for FY 2018 MS–DRG Updates

CMS has previously encouraged input from our stakeholders concerning the annual IPPS updates when that input is made available to us by December 7 of the year prior to the next annual proposed rule update. For example, to be considered for any updates or changes in FY 2018, comments and suggestions should have been submitted by December 7, 2016. The comments that were submitted in a timely manner for FY 2018 are discussed in this section of the preamble of this final rule. As CMS works with the public to examine the ICD–10 claims data used for updates to the ICD–10 MS–DRGs, we would like to examine areas where the MS–DRGs can be improved. This will require additional time for us to review requests from the public to make specific updates, analyze claims data, and consider any proposed updates. As discussed in the proposed rule, given the need for more time to carefully evaluate requests and propose updates, we are changing the deadline to request updates to MS–DRGs to November 1 of each year. This will provide an additional 5 weeks for the data analysis and review process. Interested parties should submit any comments and suggestions for FY 2019 by November 1, 2017, via the CMS MS–DRG Classification Change Requests Mailbox located at: *MSDRGClassification Change@cms.hhs.gov*.

Following are the changes that we proposed to the MS–DRGs for FY 2018 in the FY 2018 IPPS/LTCH PPS proposed rule. We invited public comments on each of the MS–DRG classification proposed changes as well as our proposals to maintain certain existing MS–DRG classifications discussed in the proposed rule. In some cases, we proposed changes to the MS–DRG classifications based on our analysis of claims data. In other cases, we proposed to maintain the existing MS–DRG classification based on our analysis of claims data. For the FY 2018 proposed rule, our MS–DRG analysis was based on ICD–10 claims data from the December 2016 update of the FY 2016 MedPAR file, which contains hospital bills received through September 30, 2016, for discharges occurring through September 30, 2016. In our discussion of the proposed MS–DRG reclassification changes, we referred to our analysis of claims data from the ''December 2016 update of the FY 2016 MedPAR file''.

In this FY 2018 IPPS/LTCH PPS final rule, we summarize the public comments we received on our proposals, present our responses, and state our final policies. For this FY 2018 final rule, we performed limited additional MS–DRG analysis of claims data. Therefore, all of the data analysis is based on claims data from the December 2016 update of the FY 2016 MedPAR file, which contains hospital bills received through September 30, 2016, for discharges occurring through September 30, 2016, except where specifically noted that it is based on the

March 2017 update of the FY 2016 MedPAR file, which contains hospital bills received through March 31, 2017, for discharges occurring through September 30, 2016.

As explained in previous rulemaking (76 FR 51487), in deciding whether to propose to make further modification to the MS–DRGs for particular circumstances brought to our attention, we consider whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different than the remaining patients represented in the MS–DRG. We evaluate patient care costs using average costs and lengths of stay and rely on the judgment of our clinical advisors to determine whether patients are clinically distinct or similar to other patients represented in the MS–DRG. In evaluating resource costs, we consider both the absolute and percentage differences in average costs between the cases we select for review and the remainder of cases in the MS–DRG. We also consider variation in costs within these groups; that is, whether observed average differences are consistent across patients or attributable to cases that are extreme in terms of costs or length of stay, or both. Further, we consider the number of patients who will have a given set of characteristics and generally prefer not to create a new MS–DRG unless it would include a substantial number of cases.

In our examination of the claims data, we apply the following criteria established in FY 2008 (72 FR 47169) to determine if the creation of a new complication or comorbidity (CC) or major complication or comorbidity (MCC) subgroup within a base MS–DRG is warranted:

- A reduction in variance of costs of at least 3 percent.
- At least 5 percent of the patients in the MS–DRG fall within the CC or MCC subgroup.
- At least 500 cases are in the CC or MCC subgroup.
- There is at least a 20-percent difference in average costs between subgroups.
- There is a $2,000 difference in average costs between subgroups.

In order to warrant creation of a CC or MCC subgroup within a base MS–DRG, the subgroup must meet all five of the criteria.

Comment: Several commenters expressed concern regarding the use of ICD–10 claims data for proposed updates to the FY 2018 ICD–10 MS–DRGs Version 35 and in recalibrating the proposed FY 2018 MS–DRG relative weights. Commenters reported that the proposed relative weights for certain MS–DRGs had large reductions when compared to the current FY 2017 ICD–10 MS–DRG Version 34 relative weights. Specifically, commenters noted that MS–DRG 215 (Other Heart Assist System Implant) appeared to have the largest decrease by approximately 35% although it was not the subject of a new proposal in the FY 2018 IPPS/LTCH PPS proposed rule. According to the commenters, the proposed reductions for certain relative weights are a direct result of the transition from ICD–9 to ICD–10 coded claims data that was utilized in setting the proposed FY 2018 MS–DRG relative weights. The commenters stated that, if finalized as proposed, these reductions could limit access to the necessary services for Medicare beneficiaries and urged CMS to consider phasing in these significant fluctuations that they asserted cause instability of the weights and hinder providers in their ability to project anticipated payment rates. Many commenters also recommended that CMS limit the percentage by which an MS–DRG's relative weight can be reduced.

Commenters also believed that the fluctuations in the proposed relative weights do not appear to be consistent with the deliberate approach CMS has taken to ensure a smooth transition from ICD–9 to ICD–10. The commenters noted that, in the past, CMS has appropriately recognized and made efforts to maintain stability within the IPPS during the transition, such as providing several versions of the ICD–10 MS–DRG Grouper for review, contracting for studies to evaluate the impact of converting the MS–DRGs to ICD–10 and assembling various public meetings. The commenters also noted that CMS has observed broader principles in prior rulemaking with regard to payment stability such as during the transition from charge-based weights to cost-based weights in FY 2007 and the conversion of the CMS DRGs to MS–DRGs in FY 2008. Consistent with those past policy refinements and the steps taken to mitigate fluctuations potentially affecting IPPS payment, commenters requested that CMS once again exercise its authority to do so. We refer readers to section II.G. of the preamble of this FY 2018 IPPS/LTCH PPS final rule for further discussion regarding recalibration of the FY 2018 MS–DRG relative weights, including our response to comments requesting a transition period for substantial reductions in relative weights in order to facilitate payment stability.

As stated above, commenters noted that MS–DRG 215 (Other Heart Assist System Implant) appeared to have the largest decrease by approximately 35% although it was not the subject of a new proposal in the FY 2018 IPPS/LTCH PPS proposed rule. We received multiple comments stating that the American Hospital Association published Coding Clinic advice that changed coding guidance for external heart assist devices and that this will result in higher-cost patients with more ICU days and increased lengths of stay that are assigned to MS–DRG 215 in FY 2018. The commenters noted there will be a substantial difference in coding for this patient population that is not reflected in the current cost data used to set the FY 2018 payment rates and a commenter urged CMS to revise the structure of MS–DRG 215 as an alternative option to address the decrease in the FY 2018 proposed relative weight for this MS–DRG. According to the commenter, restructuring this MS–DRG would more accurately reflect the resources required for cases that will be assigned to this MS–DRG in FY 2018 and is consistent with the agency's continuing efforts to ensure accurate replication between the ICD–9 and ICD–10 based MS–DRGs.

The commenter noted that currently, patients who receive heart assist devices may be assigned to the Pre-MDC MS–DRGs 001 and 002 (Heart Transplant or Implant of Heart Assist System) or MS–DRG 215 (Other Heart Assist System Implant). The commenter asserted that the transition from using ICD–9 codes to ICD–10 codes as the basis for MS–DRG assignment has been impacted by the significant increase in the number of codes relevant to the assignment of a MS–DRG because ICD–10 is more granular. This commenter recommended that CMS revise the assignments for the ICD–10 procedure codes grouping to MS–DRG 215 to accurately replicate the logic used to assign ICD–9 procedure codes to MS–DRG 215.

An example of how the MS–DRG assignment has been impacted by the transition to ICD–10 was provided by the commenter who noted that under the ICD–9 based MS–DRGs, procedure code 37.62 (Insertion of temporary non-implantable extracorporeal circulatory assist device) was reported for both the insertion and removal of an external heart assist device and was assigned to MS–DRG 215. However, under ICD–10, two codes are required, one for the insertion and one for the removal of the device where the logic for the combination of those two codes results in assignment to Pre-MDC MS–DRGs 001 and 002 (Heart transplant or Implant of Heart Assist System).

Another example offered by the commenter included ICD–9 procedure code 37.63 (Repair of heart assist system) where, under ICD–10, these cases could be reported with a code describing revision of an external heart assist device or these cases could be reported with a combination of codes, one for the removal and one for the revision of an external heart assist device. The commenter suggested that the combinations of insertion and removal codes and the combinations of removal and revision codes be reassigned from the Pre-MDC MS–DRGs 001 and 002 to MS–DRG 215 to accurately replicate the logic that was used in the ICD–9 based MS–DRGs.

The commenter performed its own analysis of MS–DRG 215 using the FY 2016 MedPAR data and noted that its findings indicated there was a decrease in the volume of procedures involving a repair or revision of a heart assist system device and an increase in the number of insertion or implantation of heart assist system devices when compared to the FY 2015 MedPAR data. The commenter's findings also indicated that there was a decrease in the average total standardized charges, as well as a decrease in the severity of illness of the patients grouping to this MS–DRG in FY 2016 compared to FY 2015. For example, the commenter noted that its analysis showed approximately 95 percent of insertion or implant of heart assist system cases also reported a secondary diagnosis of an MCC in FY 2015; however, this number dropped to 84 percent in FY 2016. Additionally, the commenter reported that approximately 73 percent of the revision of heart assist system cases also reported a secondary diagnosis of an MCC in FY 2015; however, this number dropped to 67 percent in FY 2016. The commenter stated that the clinical and usage changes for these devices do not account for this dramatic 1-year reversal.

Response: We agree with the commenter that under the ICD–9 based MS–DRGs, procedure code 37.62 (Insertion of temporary non-implantable extracorporeal circulatory assist device) was reported for both the insertion and removal of an external heart assist device and was assigned to MS–DRG 215. We also agree with the commenter that, under ICD–10, two codes are currently required to describe this same procedure, one for the insertion and one for the removal of the device where the logic for the combination of those two codes results in assignment to Pre-MDC MS–DRGs 001 and 002 (Heart transplant or Implant of Heart Assist System). Lastly, we agree with the example offered by the commenter that included ICD–9 procedure code 37.63 (Repair of heart assist system) where under ICD–10, these cases could be reported with a code describing revision of a heart assist device or these cases could be reported with a combination of codes, one for the removal and one for the revision of a heart assist device.

We also are aware that the American Hospital Association published Coding Clinic advice that clarified coding and reporting for certain external heart assist devices due to the technology being approved for new indications. We point out that coding advice is issued independently from payment policy. That is, in our annual IPPS rulemaking, in considering updates to the MS–DRGs, it is typically not our process to analyze changes in published coding advice. We generally do not make proposals for MS–DRG reclassification changes in the absence of data and clinical input from our clinical advisors.

In response to the commenters' request to ensure accurate replication between the ICD–9 and ICD–10 based MS–DRGs for external heart assist devices in conjunction with the public comments requesting that we maintain stability in the MS–DRG relative payment weights, we note that, for FY 2018 and beyond, we are no longer replicating the ICD–9 MS–DRGs. As stated in the FY 2018 IPPS/LTCH PPS proposed rule and this final rule, we are using ICD–10 coded claims data for the first time to propose changes to the ICD–10 MS–DRG classifications and to compute the relative weights. Therefore, our proposals and final policies for FY 2018 are based only on the ICD–10 claims data from the FY 2016 MedPAR file. However, similar to our efforts in identifying areas where improvements could be made to better account for severity of illness and resource utilization during the transition from the CMS DRGs to the MS–DRGs, we are making concerted efforts to continue refining the ICD–10 MS–DRGs after transitioning from the ICD–9 MS–DRGs.

We appreciate the commenters' acknowledgement of our efforts to maintain stability within the IPPS during the transition period to ICD–10 as noted above. We also acknowledge and appreciate the analysis that was conducted by the commenter for MS–DRG 215. We believe it is important to be able to fully evaluate the effects and the impact of restructuring any MS–DRGs for which all heart assist system procedures are currently assigned under ICD–10. As part of this evaluation, we believe it would be advantageous to consider additional ICD–10 coded claims data as well as changes in a hospital's case-mix (for example, patient characteristics) to determine if the patients undergoing a heart assist system procedure or a combination of heart assist system procedures demonstrate a greater severity of illness and/or increased treatment difficulty as a result of the surgical approach that is used (for example, open, percutaneous, percutaneous endoscopic, among others). Finally, consultation with our clinical advisors is also important to properly analyze the appropriateness of any modifications to the MS–DRGs where a heart assist device is currently assigned.

Therefore, in response to the public comments received, we are planning to review for FY 2019 the current ICD–10 logic for Pre-MDC MS–DRGs 001 and 002 (Heart Transplant or Implant of Heart Assist System with and without MCC, respectively), MS–DRG 215 (Other Heart Assist System Implant) and MS–DRGs 268 and 269 (Aortic and Heart Assist Procedures Except Pulsation Balloon with and without MCC, respectively) where procedures involving the heart assist devices are currently assigned. We refer the reader to the ICD–10 MS–DRG Definitions Manual version 34, which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2017-IPPS-Final-Rule-Home-Page-Items/FY2017-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending* for complete documentation of the GROUPER logic for Pre-MDC MS–DRGs 001 and 002, MS–DRG 215, and MS–DRGs 268 and 269. We also encourage the public to submit any comments on restructuring the MS–DRGs for heart assist system procedures to the CMS MS–DRG Classification Change Request Mailbox located at: *MSDRGClassificationChange@cms.hhs.gov* by November 1, 2017.

As previously stated, we are making concerted efforts to continue refining the ICD–10 MS–DRGs after transitioning from the ICD–9 MS–DRGs. We believe that it is important to include the Pre-MDC MS–DRGs and the other MS–DRGs comprised of heart assist system procedures as part of our comprehensive review of each MDC and the corresponding MS–DRGs assigned to them. After consideration of the public comments we received, we are maintaining the current structure of MS–DRG 215 for FY 2018, under the ICD–10 MS–DRGs Version 35.

We are making the FY 2018 ICD–10 MS–DRG GROUPER and Medicare Code Editor (MCE) Software Version 35 available to the public on our CMS Web

site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* through the FY 2018 IPPS Final Rule Home Page.

2. MDC 1 (Diseases and Disorders of the Nervous System)

a. Functional Quadriplegia

We received a request to reassign cases identified by diagnosis code R53.2 (Functional quadriplegia) from MS–DRGs 052 and 053 (Spinal Disorders and Injuries with and without CC/MCC, respectively). The requestor stated that because functional quadriplegia does not involve any spinal injury or pathology, cases identified by the diagnosis code should not be assigned to MS–DRGs 052 and 053. However, the requestor did not suggest an alternative MS–DRG assignment.

Section I.C.18.f. of the FY 2017 ICD–10–CM Official Coding Guidelines addresses the coding for the diagnosis of functional quadriplegia. Section I.C.18.f. states that functional quadriplegia (described by diagnosis code R53.2) is the lack of ability to use one's limbs or to ambulate due to extreme debility. The condition is not associated with neurologic deficit or injury, and diagnosis code R53.2 should not be used to identify cases of neurologic quadriplegia. In addition, the Guidelines state that the diagnosis code should only be assigned if functional quadriplegia is specifically documented by a physician in the medical record, and the diagnosis of functional quadriplegia is not associated with a neurologic deficit or injury. A physician may document the diagnosis of functional quadriplegia as occurring with a variety of conditions.

As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19817 through 19818), we examined claims data from the December 2016 update of the FY 2016 MedPAR file on cases reporting diagnosis code R53.2 in MS–DRGs 052 and 053. Our findings are shown in the table below.

CASES REPORTING FUNCTIONAL QUADRIPLEGIA IN MS–DRGS 052 AND 053

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 052—All cases	865	5.4	$10,247
MS–DRG 052—Cases reporting diagnosis code R53.2	63	4.9	6,420
MS–DRG 053—All cases	239	3.3	6,326
MS–DRG 053— Cases reporting diagnosis code R53.2	16	3.3	2,318

As shown in the table above, for MS–DRG 052, there were a total of 865 cases with an average length of stay of 5.4 days and average costs of $10,247. Of the 865 cases in MS–DRG 052, there were 63 cases that reported a principal diagnosis of functional quadriplegia, with an average length of stay of 4.9 days and average costs of $6,420. For MS–DRG 053, there were a total of 239 cases, with an average length of stay of 3.3 days and average costs of $6,326. Of the 239 cases in MS–DRG 053, there were 16 cases that reported a principal diagnosis of functional quadriplegia, with an average length of stay of 3.3 days and average costs of $2,318.

To address the request to reassign cases reporting a diagnosis of functional quadriplegia to a different MS–DRG, we reviewed the data for a total of 79 cases (63 cases in MS–DRG 052 and 16 cases in MS–DRG 053) that reported a principal diagnosis of functional quadriplegia in MS–DRGs 052 and 053. As shown in the table above, our data analysis demonstrates that the average costs for these 79 cases are lower than the average costs of all cases in MS–DRGs 052 and 053 ($6,420 compared to $10,247 for all cases in MS–DRG 052, and $2,318 compared to $6,326 for all cases in MS–DRG 053), and the average lengths of stay are shorter for cases reporting a diagnosis of functional quadriplegia in MS–DRG 052 (4.9 days compared to 5.4 days for all cases in MS–DRG 052), but equal for cases in MS–DRG 053 (3.3 days for cases reporting a diagnosis of functional quadriplegia and for all cases).

As we discussed in the proposed rule, our clinical advisors reviewed this issue and agreed that a diagnosis of functional quadriplegia does not involve a spinal disorder or injury, and may be associated with, or the result of, a variety of underlying conditions. Our clinical advisors also agreed that it is not clinically appropriate to include cases reporting a diagnosis of functional quadriplegia within MS–DRGs 052 and 053 because these cases do not involve a spinal disorder or injury. Therefore, given the fact that functional quadriplegia can be the result of a variety of other conditions, we reviewed the MS–DRGs in order to identify a more appropriate placement for cases reporting this diagnosis. Our clinical advisors recommended assigning cases representing a diagnosis of functional quadriplegia from MS–DRGs 052 and 053 to MS–DRGs 091, 092, and 093 (Other Disorders of Nervous System with MCC, with CC, and without CC/MCC, respectively). Within each MDC, there are MS–DRGs that describe a variety of other conditions that do not have the clinical characteristics of the more specific MS–DRGs. In this case, MS–DRGs 091, 092, and 093 describe a variety of other disorders of the nervous system that are not clinically similar in characteristics to the disorders described by MS–DRGs 052 and 053. We stated in the proposed rule that our clinical advisors believe that MS–DRGs 091, 092, and 093 are more appropriate MS–DRG assignments for cases representing a diagnosis of functional quadriplegia.

We examined claims data from the December 2016 update of the FY 2016 MedPAR file on cases in MS–DRGs 091, 092, and 093. Our findings are shown in the table below.

CASES IN MS–DRGS 091, 092, AND 093

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 091—All cases	12,607	5.6	$10,815
MS–DRG 092—All cases	19,392	3.9	6,706

CASES IN MS–DRGS 091, 092, AND 093—Continued

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 093—All cases	8,120	2.7	5,253

As shown in the table above, for MS–DRG 091, there were a total of 12,607 cases, with an average length of stay of 5.6 days and average costs of $10,815. For MS–DRG 092, there were a total of 19,392 cases, with an average length of stay of 3.9 days and average costs of $6,706. For MS–DRG 093, there were a total of 8,120 cases, with an average length of stay of 2.7 days and average costs of $5,253. As stated earlier, of the 865 total cases in MS–DRG 052, there were 63 cases that reported a principal diagnosis of functional quadriplegia, with an average length of stay of 4.9 days and average costs of $6,420. Of the 239 total cases in MS–DRG 053, there were 16 cases that reported a principal diagnosis of functional quadriplegia, with an average length of stay of 3.3 days and average costs of $2,318. The average lengths of stay for cases reporting a diagnosis of functional quadriplegia in MS–DRGs 052 and 053 are similar to the average lengths of stay for cases found in MS–DRGs 091, 092 and 093 (4.9 days and 3.3 days for cases in MS–DRGs 052 and 053, respectively, compared to 5.6 days, 3.9 days, and 2.7 days, respectively, for cases in MS–DRGs 091, 092, and 093). The average costs for cases reporting a diagnosis of functional quadriplegia in MS–DRGs 052 and 053 are $6,420 and $2,318, respectively, compared to $10,815, $6,706, and $5,253 for all cases in MS–DRGs 091, 092, and 093. The average costs for cases reporting a diagnosis of functional quadriplegia in MS–DRG 053 are lower than the average costs for all cases in MS–DRG 093 without a CC or MCC ($2,318 compared to $5,253, respectively). The average costs for cases reporting a diagnosis of functional quadriplegia in MS–DRG 052 are $6,420, which is lower than the average costs of $10,815 for all cases in MS–DRG 091, but close to the average costs of $6,706 for all cases in MS–DRG 092. We stated in the proposed rule that while we acknowledge that the average costs for cases reporting a diagnosis of functional quadriplegia are lower than those cases within MS–DRGs 091, 092, and 093, as stated earlier, the average costs of cases reporting a diagnosis of functional quadriplegia also are lower than the average costs of all cases in MS–DRGs 052 and 053 where these cases are currently assigned.

Our clinical advisors reviewed the clinical issues as well as the claims data for MS–DRGs 052, 053, 091, 092, and 093. As a result of this review, they recommended that cases reporting a diagnosis of functional quadriplegia be reassigned from MS–DRGs 052 and 053 to MS–DRGs 091, 092, and 093 because the current MS–DRG assignment is not clinically appropriate. We stated in the proposed rule that our clinical advisors stated that reassigning these cases to MS–DRGs 091, 092, and 093 is more appropriate because this set of MS–DRGs includes a variety of nervous system disorders that are not appropriately classified to more specific MS–DRGs within MDC 1. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19817 through 19818), we proposed to reassign cases identified by diagnosis code R53.2 from MS–DRGs 052 and 053 to MS–DRGs 091, 092, and 093 for FY 2018.

We invited public comments on our proposal.

Comment: Several commenters supported CMS' statement that diagnosis code R53.2 does not belong in MS–DRGs 052 and 053 because this condition does not involve a spinal disorder or injury. The commenters supported reassigning the code from MS–DRGs 052 and 053. However, one commenter suggested that instead of assigning diagnosis code R53.2 to MS DRGs 091, 092, and 093 (Other Disorders of Nervous System with MCC, with CC, and without CC/MCC, respectively) for FY 2018, CMS instead reassign it to MS–DRGs 947 and 948 (Signs and Symptoms with MCC and without MCC, respectively). The commenter stated that the ICD–10–CM code for functional quadriplegia, R53.2, is located in Chapter 18, Symptoms, Signs and Abnormal Findings because it can be the result of a variety of underlying conditions. Therefore, the commenter believed it was not appropriate to classify this diagnosis as a nervous system disorder. The commenter pointed out that other codes in ICD–10–CM category R53 are assigned to MS–DRGs 947 and 948. Therefore, the commenter believed that it was appropriate to reassign code R53.2 from MS–DRGs 052 and 053 to MS–DRGs 947 and 948.

Response: We agree with the commenter that diagnosis code R53.2 is located in Chapter 18, Symptoms, Signs and Abnormal Findings because it can be the result of a variety of underlying conditions. We also agree that this code cannot be labeled as a nervous system disorder. Therefore, we agree that there is merit in reassigning diagnosis code R53.2 where other codes in category R53 are assigned in MS–DRGs 947 and 948. We examined claims data from the December 2016 update of the FY 2016 MedPAR file on cases in MS–DRGs 947 and 948. Our findings are shown in the table below.

CASES IN MS–DRGS 947 AND 948

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 947–All cases	10,799	4.7	$8,225
MS–DRG 948–All cases	36,123	3.3	5,494

As stated earlier, of the 865 total cases in MS–DRG 052, there were 63 cases that reported a principal diagnosis of functional quadriplegia, with an average length of stay of 4.9 days and average costs of $6,420. This compares to all cases in MS–DRG 947 which had an average length of stay of 4.7 days and average costs of $8,225. Therefore, the average length of stay for functional quadriprlegia cases in MS–DRG 052 was 0.2 days longer and the average costs

were $1,805 lower than all cases in MS–DRG 947. Of the 239 total cases in MS–DRG 053, there were 16 cases that reported a principal diagnosis of functional quadriplegia, with an average length of stay of 3.3 days and average costs of $2,318. This compares to all cases in MS–DRG 948 which had an average length of stay of 3.3 days and average costs of $5,494. Therefore, the average length of stay for functional quadriprlegia cases in MS–DRG 053 is the same as all cases in MS–DRG 948 and the average costs are $3,176 lower than all cases in MS–DRG 948. The average costs of functional quadriplegia cases are lower than all cases in MS–DRGs 091, 092, and 093 as well as in MS–DRGs 947 and 948. The average length of stay of functional quadriplegia cases are similar to those in MS–DRGs 947 and 948. We agree with the commenter that the more appropriate MS–DRG assignment would be MS–DRGs 947 and 948 because these MS–DRGs capture similar symptom codes.

Our clinical advisors reviewed this clinical issue along with the claims data for MS–DRGs 947 and 948. Our clinical advisors agree that because diagnosis code R53.2 is a symptom code that could be the result of a variety of underlying conditions, it would not be appropriate to assign it to nervous system MS–DRGs such as MS DRGs 091, 092, and 093 as we proposed. Our clinical advisors agreed with the commenter that this symptom code should be assigned to MS–DRGs 947 and 948 where other symptom codes are assigned.

After consideration of the public comments that we received and the advice of our clinical advisors, we are finalizing the assignment of code R53.2 (Functional quadriplegia) to MS–DRGs 947 and 948 (Signs and Symptoms with MCC and without MCC, respectively).

b. Responsive Neurostimulator (RNS©) System

We received a request to modify the MS–DRG assignment for cases involving the use of the RNS© neurostimulator, a cranially implanted neurostimulator that is a treatment option for persons diagnosed with medically intractable epilepsy. Cases involving the use of the RNS© neurostimulator are assigned to MS–DRG 023 (Craniotomy with Major Device Implant or Acute Complex Central Nervous System (CNS) Principal Diagnosis (PDX) with MCC or Chemo Implant) and MS–DRG 024 (Craniotomy with Major Device Implant or Acute Complex Central Nervous System (CNS) Principal Diagnosis (PDX) without MCC).

Cases involving the use of the RNS© neurostimulator generator and leads are captured within the descriptions of four ICD–10–PCS codes. ICD–10–PCS code 0NH00NZ (Insertion of neurostimulator generator into skull, open approach) captures the use of the neurostimulator generator, and the other three ICD–10–PCS codes, 00H00MZ (Insertion of neurostimulator lead into brain, open approach), 00H03MZ (Insertion of neurostimulator lead into brain, percutaneous approach), and 00H04MZ (Insertion of neurostimulator lead into brain, percutaneous endoscopic approach) describe the insertions of the leads, depending on the approach used. The combination of an ICD–10–PCS code capturing the use of the generator and another ICD–10–PCS code describing the specific approach used to insert the leads would capture the performance of the entire procedure.

The requestor stated that the RNS© neurostimulator received FDA pre-market approval on November 14, 2013. The RNS© neurostimulator includes a cranially implanted programmable neurostimulator connected to one or two depth and/or subdural cortical strip leads that are surgically placed in or on the brain at the seizure focus. The neurostimulator and leads are typically implanted during a single acute inpatient hospital procedure at a Comprehensive Epilepsy Center (CEC). The implanted neurostimulator continuously monitors brain electrical activity and is programmed by a physician to detect abnormal patterns of electrical activity that the physician believes may lead to seizures (epileptiform activity). In response to the detection of epileptiform activity, the device delivers brief, mild electrical pulses (responsive stimulation) to one or two epileptic foci. Detection and stimulation parameters are adjusted noninvasively by the physician to optimize control of epileptic seizures for each patient.

As the neurostimulator monitors brain activity, electrocorticograms (ECoGs) recorded immediately before and after certain events are stored for later review by the physician. The physician reviews the stored recordings to see the detections and the effects of stimulation. The physician can reprogram the neurostimulator at an in-person office appointment to change detection and stimulation settings based on this information, as well as review the patient's seizures.

The RNS© neurostimulator was approved for new technology add-on payments for FY 2015 and FY 2016, and new technology add-on payments were discontinued for FY 2017. The new technology add-on payment application was discussed in the FY 2015 IPPS/LTCH PPS proposed and final rules (79 FR 28051 through 28054 and 79 FR 49946 through 49950, respectively), the FY 2016 IPPS/LTCH PPS proposed and final rules (80 FR 24427 through 24448 and 80 FR 49442 through 49443, respectively), and the FY 2017 IPPS/LTCH PPS proposed and final rules (81 FR 25036 through 25037 and 81 FR 56882 through 56884, respectively).

The requestor suggested the following three options for MS–DRG assignment updates for cases involving the RNS© neurostimulator:

- Create new MS–DRGs for cases involving the use of the RNS© neurostimulator. The requestor suggested MS–DRG XXX (Cranially Implanted Neurostimulators with MCC) and MS–DRG XXX (Cranially Implanted Neurostimulators without MCC) as possible MS–DRG titles. The requestor acknowledged that the number of cases assigned to this MS–DRG would be low, but anticipated that the number of cases would increase in the future.
- Reassign cases involving the use of the RNS© neurostimulator to MS–DRGs 020 and 021 (Intracranial Vascular Procedures with Principal Diagnosis of Hemorrhage with MCC, with CC, respectively) and update the MS–DRG logic and titles. The requestor asked CMS to reassign all cases involving the use of the RNS© neurostimulator that currently map to MS–DRG 023 (Craniotomy with Major Device Implant/Acute Complex CNS Principal Diagnosis with MCC or Chemo Implant) to MS–DRG 20, and change the title of MS–DRG 20 to ''Intracranial Vascular Procedures with Principal Diagnosis of Hemorrhage or Cranially Implanted Neurostimulator with MCC.'' In addition, the requestor asked CMS to reassign all cases involving the use of the RNS© neurostimulator that currently map to MS–DRG 024 (Craniotomy with Major Device Implant/Acute Complex CNS Principal Diagnosis without MCC) to MS–DRG 021, and change the title of MS–DRG 021 to ''Intracranial Vascular Procedures with Principal Diagnosis of Hemorrhage with CC or Cranially Implanted Neurostimulator without MCC''. The requestor believed that the majority of cases involving the use of the RNS© neurostimulator that map to MS–DRG 024 do not include a secondary diagnosis that is classified as a CC, and the average cost of cases involving the use of the RNS© neurostimulator without a CC is significantly higher than the average cost of all cases in MS–DRG 022 (Intracranial Vascular Procedures with Principal Diagnosis of Hemorrhage

without CC/MCC). Therefore, the requestor stated that it would not be adequate to assign cases involving the use of the RNS© neurostimulator without a CC to MS–DRG 022.

- Reassign cases involving the use of the RNS© neurostimulator to other higher paying MS–DRGs that would provide adequate payment.

The requestor stated that it had analyzed data from two sources, which demonstrated that the average cost of cases involving the use of the RNS© neurostimulator was higher than the average cost of all cases in MS–DRGs 023 and 024 (the current MS–DRGs for cases involving the use of the RNS© neurostimulator). The requestor indicated that the data used for its analysis was obtained from hospitals performing the procedure, as well as from the FY 2015 MedPAR file.

The requestor also asked that CMS examine the cases representing cranially implanted neurostimulators and leads that were inserted for the treatment of epilepsy. The requestor pointed out that neurostimulators also are used in the treatment of movement disorders such as Parkinson's disease, essential tremor, or dystonia. The requestor asked that CMS identify those cases with a principal diagnosis of epilepsy, and identified the following ICD–10–CM codes that it believed were representative of potential epilepsy cases.

ICD–10–CM code	ICD–10–CM code title
G40.001	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable, with status epilepticus.
G40.009	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable, without status epilepticus.
G40.011	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, with status epilepticus.
G40.019	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, without status epilepticus.
G40.101	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, with status epilepticus.
G40.119	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, without status epilepticus.
G40.201	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, not intractable, with status epilepticus.
G40.209	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, not intractable, without status epilepticus.
G40.211	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, with status epilepticus.
G40.219	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, without status epilepticus.
G40.301	Generalized idiopathic epilepsy and epileptic syndromes, not intractable, with status epilepticus.
G40.309	Generalized idiopathic epilepsy and epileptic syndromes, not intractable, without status epilepticus.
G40.311	Generalized idiopathic epilepsy and epileptic syndromes, intractable, with status epilepticus.
G40.319	Generalized idiopathic epilepsy and epileptic syndromes, intractable, without status epilepticus.
G40.401	Other generalized epilepsy and epileptic syndromes, not intractable, with status epilepticus.
G40.409	Other generalized epilepsy and epileptic syndromes, not intractable, without status epilepticus.
G40.411	Other generalized epilepsy and epileptic syndromes, intractable, with status epilepticus.
G40.419	Other generalized epilepsy and epileptic syndromes, intractable, without status epilepticus.
G40.501	Epileptic seizures related to external causes, not intractable, with status epilepticus.
G40.509	Epileptic seizures related to external causes, not intractable, without status epilepticus.
G40.801	Other epilepsy, not intractable, with status epilepticus.
G40.802	Other epilepsy, not intractable, without status epilepticus.
G40.803	Other epilepsy, intractable, with status epilepticus.
G40.804	Other epilepsy, intractable, without status epilepticus.
G40.811	Lennox-Gastaut syndrome, not intractable, with status epilepticus.
G40.812	Lennox-Gastaut syndrome, not intractable, without status epilepticus.
G40.813	Lennox-Gastaut syndrome, intractable, with status epilepticus.
G40.814	Lennox-Gastaut syndrome, intractable, without status epilepticus.
G40.821	Epileptic spasms, not intractable, with status epilepticus.
G40.822	Epileptic spasms, not intractable, without status epilepticus.
G40.823	Epileptic spasms, intractable, with status epilepticus.
G40.824	Epileptic spasms, intractable, without status epilepticus.
G40.89	Other seizures.
G40.901	Epilepsy, unspecified, not intractable, with status epilepticus.
G40.909	Epilepsy, unspecified, not intractable, without status epilepticus.
G40.911	Epilepsy, unspecified, intractable, with status epilepticus.
G40.919	Epilepsy, unspecified, intractable, without status epilepticus.

MS–DRGs 023 and 024 contain a number of cases representing neurostimulator generator and lead code combinations that are captured under a list referred to as ''Major Device Implant.'' The neurostimulator generators on this list are inserted into the skull, as well as into the subcutaneous areas of the chest, back, or abdomen. The leads are all inserted into the brain. The RNS© neurostimulator generators are inserted into the skull and the leads are inserted into the brain. The following three ICD–10–PCS code combinations capture the use of the

RNS© neurostimulator and leads that would determine an assignment of a case to MS–DRGs 023 and 024, as shown in the ''Major Device Implant'' list:

- 0NH00NZ (Insertion of neurostimulator generator into skull, open approach), in combination with 00H00MZ (Insertion of neurostimulator lead into brain, open approach);
- 0NH00NZ (Insertion of neurostimulator generator into skull, open approach), in combination with 00H03MZ (Insertion of neurostimulator lead into brain, percutaneous approach); and
- 0NH00NZ (Insertion of neurostimulator generator into skull, open approach), in combination with 00H04MZ (Insertion of neurostimulator lead into brain, percutaneous endoscopic approach).

As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19818 through 19822), we examined claims data from the December 2016 update of the FY 2016 MedPAR file for all cases representing the use of a neurostimulator in MS–DRGs 023 and 024 listed under the ''Major Device Implant'' list. As requested, we also examined the cases represented by the three neurostimulator code combinations, which capture the use of the RNS© neurostimulator that are a subset of the cases listed on the ''Major Device Implant'' list using the code combinations listed above, and that had a principal diagnosis of epilepsy from the list supplied by the requestor. The following tables show our findings for those cases in MS–DRGs 023 and 024 as well as findings for cases in MS–DRGs 020 and 021.

MS–DRGs 023 and 024

[Neurostimulator Cases]

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 023—All cases	6,723	10.9	$39,014
MS–DRG 023—Cases with neurostimulators (Major Device Implant list cases)	21	6.7	48,821
MS–DRG 023—Cases with neurostimulator generators inserted into skull (includes cases involving the use of the RNS© neurostimulator) and cases with a principal diagnosis of epilepsy	7	8.0	63,365
MS–DRG 024—All cases	2,275	5.5	27,574
MS–DRG 024—Cases with neurostimulators (Major Device Implant list cases)	394	2.1	31,669
MS–DRG 024—Cases with neurostimulator generators inserted into skull (includes cases involving the use of the RNS© neurostimulator) and cases with a principal diagnosis of epilepsy	54	4.3	51,041

Cases in MS–DRGs 020 and 021

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 020–All cases	1,372	16.7	$72,926
MS–DRG 021–All cases	336	13.5	54,385

As shown by the table above, for MS–DRG 023, we identified a total of 6,723 cases, with an average length of stay of 10.9 days and average costs of $39,014. Of the 6,723 cases in MS–DRG 023, there were 21 cases representing the implantation of any type of neurostimulator generator with an average length of stay of 6.7 days, and average costs of $48,821. Of the 21 neurostimulator generator cases, there were 7 cases with the neurostimulator generators inserted into skull (including cases involving the use of the RNS© neurostimulator) and a principal diagnosis of epilepsy with an average length of stay of 8.0 days and average costs of $63,365. For MS–DRG 024, we identified a total of 2,275 cases, with an average length of stay of 5.5 days and average costs of $27,574. Of the 2,275 cases in MS–DRG 024, there were 394 cases representing the implantation of any type of neurostimulator generator with an average length of stay of 2.1 days and average costs of $31,669. Of the 394 neurostimulator generator cases, there were 54 cases with the neurostimulator generators inserted into skull (including cases involving the use of the RNS© neurostimulator) and a principal diagnosis of epilepsy with an average length of stay of 4.3 days and average costs of $51,041.

There were only 61 cases involving the use of the RNS© neurostimulator with a principal diagnosis of epilepsy in MS–DRGs 023 and 024 (7 and 54, respectively). As we stated in the proposed rule, our clinical advisors reviewed this issue, and agreed that this number of cases is too small on which to base a rationale for creating a new MS–DRG. Basing a new MS–DRG on such a small number of cases (61) could lead to distortion in the relative payment weights for the MS–DRG because several expensive cases could impact the overall relative payment weight. Having larger clinical cohesive groups within an MS–DRG provides greater stability for annual updates to the relative payment weights.

We also examined the possibility of reassigning cases involving the use of the RNS© neurostimulator to MS–DRGs 020 and 021. As the table above shows, for MS–DRG 020, there were a total of 1,372 cases with an average length of stay of 16.7 days and average costs of $72,926. For MS–DRG 021, there were a total of 336 cases with an average length of stay of 13.5 days and average costs of $54,385. The cases in MS–DRG 023 with neurostimulator generators inserted into skull (including cases involving the use of the RNS© neurostimulator) and a principal diagnosis of epilepsy have average costs that are $9,561 lower than that for all cases in MS–DRG 020 ($63,365 compared to $72,926), and the average length of stay is 8.7 days shorter (8.0 days compared to 16.7 days). We stated in the proposed rule that we do not believe these data support reassigning the cases in MS–DRG 023 with neurostimulator generators inserted into the skull (including cases involving the use of the RNS© neurostimulator) and a principal

diagnosis of epilepsy to MS–DRG 020. While the cases in MS–DRG 024 with neurostimulator generators inserted into the skull (including cases involving the use of the RNS© neurostimulator) and a principal diagnosis of epilepsy have average costs that are similar to the average costs of cases in MS–DRG 021 ($51,041 compared to $54,385), they have an average length of stay that is 9.2 days shorter (4.3 days compared to 13.5 days). Our clinical advisors reviewed the clinical issues and the claims data and, as we discussed in the proposed rule, did not support reassigning the cases with neurostimulator generators inserted into skull (including cases involving the use of the RNS© neurostimulator) and a principal diagnosis of epilepsy from MS–DRGs 023 and 024 to MS–DRGs 020 and 021. Our clinical advisors pointed out that the cases in MS–DRGs 020 and 021 have a principal diagnosis of a hemorrhage. The RNS© neurostimulator generators are not used to treat patients with diagnosis of a hemorrhage. Therefore, our clinical advisors stated that it was inappropriate to reassign cases representing a principal diagnosis of epilepsy to an MS–DRG that contains cases that represent the treatment of intracranial hemorrhage. They also stated that the differences in average length of stay and average costs support this recommendation.

We then explored alternative MS–DRG assignments, as was requested. We noted that the 7 cases with the neurostimulator generators inserted into the skull (including cases involving the use of the RNS© neurostimulator) and a principal diagnosis of epilepsy had an average length of stay of 8.0 days and average costs of $63,365, as compared to the 6,723 cases in MS–DRG 023 that had an average length of stay of 10.9 days and average costs of $39,014. While these neurostimulator cases had average costs that were $24,351 higher than the average costs of all cases in MS–DRG 023, there were only a total of 7 cases. There may have been other factors contributing to the higher costs. We noted that the 54 cases with the neurostimulator generators inserted into skull (including cases involving the use of the RNS© neurostimulator) and a principal diagnosis of epilepsy in MS–DRG 024 had average costs of $51,041 and an average length of stay of 4.3 days, compared to average costs of $27,574 and average length of stay of 5.5 days for all cases in MS–DRG 024. By reassigning all cases with the neurostimulator generators inserted into the skull (including cases involving the use of the RNS© neurostimulator) and a principal diagnosis of epilepsy to MS DRG 023, even if there is not a MCC present, the cases would receive higher payment. The average costs of MS–DRG 023 were $39,014, compared to the average costs of $51,041 for the cases with the neurostimulator generators inserted into skull (including cases involving the use of the RNS© neurostimulator) and a principal diagnosis of epilepsy in MS–DRG 024. Our clinical advisors reviewed the clinical issues and the claims data, and supported the recommendation to reassign the cases with the neurostimulator generators inserted into skull (including cases involving the use of the RNS© neurostimulator) and a principal diagnosis of epilepsy to MS–DRG 023, even if there is not a MCC reported. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19818 through 19822), we proposed to reassign all cases with a principal diagnosis of epilepsy from the epilepsy diagnosis list provided earlier, and one of the following ICD–10–PCS code combinations capturing cases with the neurostimulator generators inserted into the skull (including cases involving the use of the RNS© neurostimulator), to MS–DRG 023, even if there is no MCC reported:

- 0NH00NZ (Insertion of neurostimulator generator into skull, open approach), in combination with 00H00MZ (Insertion of neurostimulator lead into brain, open approach);
- 0NH00NZ (Insertion of neurostimulator generator into skull, open approach), in combination with 00H03MZ (Insertion of neurostimulator lead into brain, percutaneous approach); and
- 0NH00NZ (Insertion of neurostimulator generator into skull, open approach), in combination with 00H04MZ (Insertion of neurostimulator lead into brain, percutaneous endoscopic approach).

We also proposed to change the title of MS–DRG 023 from ''Craniotomy with Major Device Implant or Acute Complex Central Nervous System (CNS) Principal Diagnosis (PDX) with MCC or Chemo Implant'' to ''Craniotomy with Major Device Implant or Acute Complex Central Nervous System (CNS) Principal Diagnosis (PDX) with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator'' to reflect the proposed modifications to MS–DRG assignments.

We invited public comments on our proposals.

Comment: Commenters supported CMS' proposal to reassign cases with insertion of a neurostimulator generator and a principal diagnosis of epilepsy to MS–DRG 023. The commenters also agreed with the proposed change in the title of MS–DRG 023. The commenters stated that the updates were necessary for Comprehensive Epilepsy Centers to be able to offer the RNS© neurostimulator. One commenter who supported this MS–DRG update recommended that codes in subcategories G40.A and G40.B be included in the list of epilepsy diagnosis codes classified to MS–DRG 023 because these subcategory codes are also epilepsy codes.

Response: We appreciate the commenters' support for our recommendations. We identified the following list of epilepsy codes that are included under categories G40.A and G40.B.

- G40.A01 Absence epileptic syndrome, not intractable, with status epilepticus
- G40.A09 Absence epileptic syndrome, not intractable, without status epilepticus
- G40.A11 Absence epileptic syndrome, intractable, with status epilepticus
- G40.A19 Absence epileptic syndrome, intractable, without status epilepticus
- G40.B01 Juvenile myoclonic epilepsy, not intractable, with status epilepticus
- G40.B09 Juvenile myoclonic epilepsy, not intractable, without status epilepticus
- G40.B11 Juvenile myoclonic epilepsy, intractable, with status epilepticus
- G40.B19 Juvenile myoclonic epilepsy, intractable, without status epilepticus

We agree that the codes listed above are also epilepsy codes and should be added to the list of epilepsy codes assigned to MS–DRG 023 because they also capture a type of epilepsy. Our clinical advisors reviewed this issue and agree with adding the additional epilepsy codes.

For FY 2018, the complete list of epilepsy codes assigned to MS–DRG 023 under our finalized policy is as follows:

ICD–10–CM code	ICD–10–CM code title
G40.001	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable, with status epilepticus.

ICD–10–CM code	ICD–10–CM code title
G40.009	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable, without status epilepticus.
G40.011	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, with status epilepticus.
G40.019	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, without status epilepticus.
G40.101	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, with status epilepticus.
G40.119	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, without status epilepticus.
G40.201	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, not intractable, with status epilepticus.
G40.209	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, not intractable, without status epilepticus.
G40.211	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, with status epilepticus.
G40.219	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, without status epilepticus.
G40.301	Generalized idiopathic epilepsy and epileptic syndromes, not intractable, with status epilepticus.
G40.309	Generalized idiopathic epilepsy and epileptic syndromes, not intractable, without status epilepticus.
G40.311	Generalized idiopathic epilepsy and epileptic syndromes, intractable, with status epilepticus.
G40.319	Generalized idiopathic epilepsy and epileptic syndromes, intractable, without status epilepticus.
G40.A01	Absence epileptic syndrome, not intractable, with status epilepticus.
G40.A09	Absence epileptic syndrome, not intractable, without status epilepticus.
G40.A11	Absence epileptic syndrome, intractable, with status epilepticus.
G40.A19	Absence epileptic syndrome, intractable, without status epilepticus.
G40.B01	Juvenile myoclonic epilepsy, not intractable, with status epilepticus.
G40.B09	Juvenile myoclonic epilepsy, not intractable, without status epilepticus.
G40.B11	Juvenile myoclonic epilepsy, intractable, with status epilepticus.
G40.B19	Juvenile myoclonic epilepsy, intractable, without status epilepticus.
G40.401	Other generalized epilepsy and epileptic syndromes, not intractable, with status epilepticus.
G40.409	Other generalized epilepsy and epileptic syndromes, not intractable, without status epilepticus.
G40.411	Other generalized epilepsy and epileptic syndromes, intractable, with status epilepticus.
G40.419	Other generalized epilepsy and epileptic syndromes, intractable, without status epilepticus.
G40.501	Epileptic seizures related to external causes, not intractable, with status epilepticus.
G40.509	Epileptic seizures related to external causes, not intractable, without status epilepticus.
G40.801	Other epilepsy, not intractable, with status epilepticus.
G40.802	Other epilepsy, not intractable, without status epilepticus.
G40.803	Other epilepsy, intractable, with status epilepticus.
G40.804	Other epilepsy, intractable, without status epilepticus.
G40.811	Lennox-Gastaut syndrome, not intractable, with status epilepticus.
G40.812	Lennox-Gastaut syndrome, not intractable, without status epilepticus.
G40.813	Lennox-Gastaut syndrome, intractable, with status epilepticus.
G40.814	Lennox-Gastaut syndrome, intractable, without status epilepticus.
G40.821	Epileptic spasms, not intractable, with status epilepticus.
G40.822	Epileptic spasms, not intractable, without status epilepticus.
G40.823	Epileptic spasms, intractable, with status epilepticus.
G40.824	Epileptic spasms, intractable, without status epilepticus.
G40.89	Other seizures.
G40.901	Epilepsy, unspecified, not intractable, with status epilepticus.
G40.909	Epilepsy, unspecified, not intractable, without status epilepticus.
G40.911	Epilepsy, unspecified, intractable, with status epilepticus.
G40.919	Epilepsy, unspecified, intractable, without status epilepticus.

After consideration of the public comments that we received, we are finalizing our proposal to reassign all cases with a principal diagnosis of epilepsy from the epilepsy diagnosis list provided above, and one of the following ICD–10–PCS code combinations capturing cases with the neurostimulator generators inserted into the skull (including cases involving the use of the RNS© neurostimulator), to MS–DRG 023, even if there is no MCC reported:

- 0NH00NZ (Insertion of neurostimulator generator into skull, open approach), in combination with 00H00MZ (Insertion of neurostimulator lead into brain, open approach);
- 0NH00NZ (Insertion of neurostimulator generator into skull, open approach), in combination with 00H03MZ (Insertion of neurostimulator lead into brain, percutaneous approach); and
- 0NH00NZ (Insertion of neurostimulator generator into skull, open approach), in combination with 00H04MZ (Insertion of neurostimulator lead into brain, percutaneous endoscopic approach).

We also finalizing our proposed change to the title of MS–DRG 023 from ''Craniotomy with Major Device Implant or Acute Complex Central Nervous System (CNS) Principal Diagnosis (PDX) with MCC or Chemo Implant'' to ''Craniotomy with Major Device Implant or Acute Complex Central Nervous System (CNS) Principal Diagnosis (PDX) with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator'' to reflect the modifications to MS–DRG assignments.

c. Precerebral Occlusion or Transient Ischemic Attack with Thrombolytic

We received a request to add the ICD–10–CM diagnosis codes currently

assigned to MS–DRGs 067 and 068 (Nonspecific CVA and Precerebral Occlusion without Infarction with MCC and without MCC, respectively) and the ICD–10–CM diagnosis codes currently assigned to MS–DRG 069 (Transient Ischemia) to the GROUPER logic for MS–DRGs 061, 062, and 063 (Acute Ischemic Stroke with Use of Thrombolytic Agent with MCC, with CC, and without CC/MCC, respectively) when those conditions are sequenced as the principal diagnosis and reported with an ICD–10–PCS procedure code describing use of a thrombolytic agent (for example, tPA).

The ICD–10–CM diagnosis codes displayed in the table below identify the conditions that are assigned to MS–DRGs 067 and 068 when reported as a principal diagnosis.

ICD–10–CM code	Code description
I65.01	Occlusion and stenosis of right vertebral artery.
I65.02	Occlusion and stenosis of left vertebral artery.
I65.03	Occlusion and stenosis of bilateral vertebral arteries.
I65.09	Occlusion and stenosis of unspecified vertebral artery.
I65.1	Occlusion and stenosis of basilar artery.
I65.21	Occlusion and stenosis of right carotid artery.
I65.22	Occlusion and stenosis of left carotid artery.
I65.23	Occlusion and stenosis of bilateral carotid arteries.
I65.29	Occlusion and stenosis of unspecified carotid artery.
I65.8	Occlusion and stenosis of other precerebral arteries.
I65.9	Occlusion and stenosis of unspecified precerebral artery.
I66.01	Occlusion and stenosis of right middle cerebral artery.
I66.02	Occlusion and stenosis of left middle cerebral artery.
I66.03	Occlusion and stenosis of bilateral middle cerebral arteries.
I66.09	Occlusion and stenosis of unspecified middle cerebral artery.
I66.11	Occlusion and stenosis of right anterior cerebral artery.
I66.12	Occlusion and stenosis of left anterior cerebral artery.
I66.13	Occlusion and stenosis of bilateral anterior cerebral arteries.
I66.19	Occlusion and stenosis of unspecified anterior cerebral artery.
I66.21	Occlusion and stenosis of right posterior cerebral artery.
I66.22	Occlusion and stenosis of left posterior cerebral artery.
I66.23	Occlusion and stenosis of bilateral posterior cerebral arteries.
I66.29	Occlusion and stenosis of unspecified posterior cerebral artery.
I66.3	Occlusion and stenosis of cerebellar arteries.
I66.8	Occlusion and stenosis of other cerebral arteries.
I66.9	Occlusion and stenosis of unspecified cerebral artery.

The ICD–10–CM diagnosis codes displayed in the table below identify the conditions that are assigned to MS–DRG 069 when reported as a principal diagnosis.

ICD–10–CM code	Code description
G45.0	Vertebro-basilar artery syndrome.
G45.1	Carotid artery syndrome (hemispheric).
G45.2	Multiple and bilateral precerebral artery syndromes.
G45.8	Other transient cerebral ischemic attacks and related syndromes.
G45.9	Transient cerebral ischemic attack, unspecified.
G46.0	Middle cerebral artery syndrome.
G46.1	Anterior cerebral artery syndrome.
G46.2	Posterior cerebral artery syndrome.
I67.81	Acute cerebrovascular insufficiency.
I67.82	Cerebral ischemia.
I67.841	Reversible cerebrovascular vasoconstriction syndrome.
I67.848	Other cerebrovascular vasospasm and vasoconstriction.
I67.89	Other cerebrovascular disease.

The ICD–10–PCS procedure codes displayed in the table below describe use of a thrombolytic agent. These procedure codes are designated as non-O.R. procedure codes affecting the MS–DRG assignment for MS–DRGs 061, 062, and 063.

ICD–10–PCS code	Code description
3E03017	Introduction of other thrombolytic into peripheral vein, open approach.
3E03317	Introduction of other thrombolytic into peripheral vein, percutaneous approach.
3E04017	Introduction of other thrombolytic into central vein, open approach.
3E04317	Introduction of other thrombolytic into central vein, percutaneous approach.
3E05017	Introduction of other thrombolytic into peripheral artery, open approach.
3E05317	Introduction of other thrombolytic into peripheral artery, percutaneous approach.
3E06017	Introduction of other thrombolytic into central artery, open approach.
3E06317	Introduction of other thrombolytic into central artery, percutaneous approach.

ICD–10–PCS code	Code description
3E08017	Introduction of other thrombolytic into heart, open approach.
3E08317	Introduction of other thrombolytic into heart, percutaneous approach.

At the onset of stroke symptoms, tPA must be given within 3 hours (or up to 4.5 hours for certain eligible patients) in an attempt to dissolve a clot and improve blood flow to the specific area affected in the brain. If, upon receiving the tPA, the stroke symptoms completely resolve within 24 hours and imaging studies (if performed) are negative, the patient has suffered what is clinically defined as a transient ischemic attack, not a stroke. According to the requestor, the current MS–DRG assignments do not account for this subset of patients who were successfully treated with tPA to prevent a stroke.

In addition, the requestor expressed concerns regarding documentation and quality of the data. For example, the requestor noted that the terms ''stroke-in-evolution'' and ''aborted stroke'' may be documented as a ''workaround'' for a patient exhibiting symptoms of a stroke who receives tPA and, regardless of the outcome, would result in assignment to MS–DRG 061, 062, or 063. Therefore, in cases where the patient's stroke symptoms completely resolved upon receiving tPA and the patient clinically suffered a precerebral occlusion or transient ischemia, this documentation practice is incorrectly labeling these patients as having had a stroke and ultimately leading to inaccurate data.

As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19822 through 19824), we analyzed claims data from the December 2016 update of the FY 2016 MedPAR file for MS–DRGs 061, 062, and 063. Our findings are shown in the tables below.

MS–DRGs for Acute Ischemic Stroke With Use of Thrombolytic Agent

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 061–All cases	4,528	6.4	$20,270
MS–DRG 062–All cases	8,600	4.2	14,124
MS–DRG 063–All cases	1,859	3.0	11,898

Our analysis also consisted of claims data for MS–DRGs 067 and 068 when reported with a procedure code describing the use of tPA. As shown in the table below, the total number of cases reported in MS–DRG 067 was 811, with an average length of stay of 4.8 days and average costs of $10,248. There were 9 cases in MS–DRG 067 with a precerebral occlusion receiving tPA, with an average length of stay of 5.2 days and average costs of $20,156. The total number of cases reported in MS–DRG 068 was 3,809, with an average length of stay of 2.8 days and average costs of $6,555. There were 33 cases in MS–DRG 068 with a precerebral occlusion receiving tPA, with an average length of stay of 4.3 days and average costs of $13,814.

MS–DRGs for Precerebral Occlusion With Use of Thrombolytic Agent

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 067—All cases	811	4.8	$10,248
MS–DRG 067—Cases with tPA	9	5.2	20,156
MS–DRG 068—All cases	3,809	2.8	6,555
MS–DRG 068—Cases with tPA	33	4.3	13,814

As we stated in the proposed rule, we recognize that while the volume of cases for patients with a diagnosis of precerebral occlusion receiving tPA in MS–DRGs 067 and 068 is relatively low, the average length of stay is longer, and the average costs for this subset of patients is approximately twice the amount of the average costs in comparison to all cases in MS–DRGs 067 and 068.

We then analyzed claims data for cases in MS–DRG 069 when reported with a procedure code describing the use of tPA. As shown in the table below, the total number of cases reported in MS–DRG 069 was 50,633, with an average length of stay of 2.5 days and average costs of $5,518. There were 554 cases of transient ischemia receiving tPA, with an average length of stay of 3.2 days and average costs of $12,481.

MS–DRG for Transient Ischemia With Use of Thrombolytic Agent

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 069—All cases	50,633	2.5	$5,518
MS–DRG 069—Cases with tPA	554	3.2	12,481

Similar to the findings for MS–DRGs 067 and 068, the number of cases for transient ischemia receiving tPA in MS–DRG 069 was relatively low in comparison to all the cases in the MS–DRG, with a longer average length of

stay and approximately twice the amount of average costs in comparison to all cases in MS–DRG 069.

We stated in the proposed rule that the results of analysis of the data and the advice of our clinical advisors support adding the ICD–10–CM diagnosis codes in MS–DRGs 067, 068, and 069 to the list of principal diagnoses in MS–DRGs 061, 062, and 063 to better account for this subset of patients who were successfully treated with tPA to prevent a stroke, to identify the increasing use of thrombolytics at the onset of symptoms of a stroke, to further encourage appropriate physician documentation for a precerebral occlusion or transient ischemic attack when patients are treated with tPA, and to reflect more appropriate payment for the resources involved in evaluating and treating these patients. We stated that we believe this approach will improve accuracy of the data and assist in addressing the concern that facilities may be reporting incorrect diagnoses for this subset of patients.

Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19824), for FY 2018, we proposed to add the ICD–10–CM diagnosis codes listed earlier in this section that are currently assigned to MS–DRGs 067 and 068 and the ICD–10–CM diagnosis codes currently assigned to MS–DRG 069 to the GROUPER logic for MS–DRGs 061, 062, and 063 when those conditions are sequenced as the principal diagnosis and reported with an ICD–10–PCS procedure code describing use of a thrombolytic agent (for example, tPA). We invited public comments on our proposal.

We also proposed to retitle MS–DRGs 061, 062, and 063 as ''Ischemic Stroke, Precerebral Occlusion or Transient Ischemia with Thrombolytic Agent with MCC, with CC and without CC/MCC'', respectively, and to retitle MS–DRG 069 as ''Transient Ischemia without Thrombolytic''.

We invited public comments on our proposals.

Comment: Several commenters supported the proposal to modify the GROUPER logic for MS–DRGs 061, 062, and 063 to better account for the subset of patients who are treated successfully with tPA at the onset of stroke symptoms. The commenters agreed that this change will encourage appropriate physician documentation for a precerebral occlusion or transient ischemic attack when patients are treated with tPA and that it will more accurately reflect proper payment for stroke care. Commenters also agreed with retitling MS–DRGs 061, 062, 063 and 069. One commenter who supported the proposals also suggested that CMS consider developing new MS–DRGs in the future to specifically distinguish acute ischemic strokes from precerebral occlusions and transient ischemia, with and without thrombolytics, with and without MCC/CC, respectively.

Response: We appreciate the commenters' support. As additional ICD–10 claims data become available, we will continue to welcome input from the public and consider further modifications to the ICD–10 MS–DRGs if warranted.

After consideration of the public comments that we received, we are finalizing our proposal to add the ICD–10–CM diagnosis codes listed earlier in this section that are currently assigned to MS–DRGs 067 and 068 and the ICD–10–CM diagnosis codes currently assigned to MS–DRG 069 to the GROUPER logic for MS–DRGs 061, 062, and 063 when those conditions are sequenced as the principal diagnosis and reported with an ICD–10–PCS procedure code describing use of a thrombolytic agent (for example, tPA). We also are finalizing our proposal to retitle MS–DRGs 061, 062, and 063 as ''Ischemic Stroke, Precerebral Occlusion or Transient Ischemia with Thrombolytic Agent with MCC, with CC and without CC/MCC'', respectively, and to retitle MS–DRG 069 as ''Transient Ischemia without Thrombolytic'' effective October 1, 2017 for the ICD–10 MS–DRGs Version 35.

3. MDC 2 (Diseases and Disorders of the Eye: Swallowing Eye Drops (Tetrahydrozoline)

We received a request to reassign the following ICD–10–CM diagnosis codes that capture swallowing eye drops from MS–DRGs 124 and 125 (Other Disorders of the Eye with and without MCC, respectively) to MS–DRGs 917 and 918 (Poisoning and Toxic Effects of Drugs with and without MCC, respectively). The requestor described a case where a patient was treated following swallowing eye drops, specifically Tetrahydrozoline, which the provider considers to be a poisoning, not a disorder of the eye.

- T49.5X1A (Poisoning by ophthalmological drugs and preparations, accidental (unintentional), initial encounter);
- T49.5X2A (Poisoning by ophthalmological drugs and preparations, intentional self-harm, initial encounter);
- T49.5X3A (Poisoning by ophthalmological drugs and preparations, assault, initial encounter); and
- T49.5X4A (Poisoning by ophthalmological drugs and preparations, undetermined, initial encounter).

As stated in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19824 through 19825), we agree with the requestor that the four diagnosis codes describe a poisoning, not a disorder of the eye. We examined claims data for cases in MS–DRGs 124 and 125 from the December 2016 update of the FY 2016 MedPAR file. Our findings are shown in the table below.

MS–DRG 124 AND 125 CASES

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 124—All cases	874	4.8	$8,826
MS–DRG 124—Cases reporting poisoning by ophthalmological drugs and preparations code	1	2.0	3,007
MS–DRG 125—All cases	3,205	3.3	5,565
MS–DRG 125—Cases reporting poisoning by ophthalmological drugs and preparations code	1	2.0	1,446

As shown in the table above, there were only 2 cases of poisoning by ophthalmological drugs and preparations—1 case in MS–DRG 124 with an average length of stay of 2 days and average costs of $3,007 and 1 case in MS–DRG 125 with an average length of stay of 2 days and average costs of $1,446. The case of poisoning by ophthalmological drugs and preparations in MS–DRG 124 had a shorter average length of stay than the average length of stay for all cases in MS–DRG 124 (2.0 days compared to 4.8 days) and lower average costs than the average costs for all cases in MS–DRG 124 ($3,007 compared to $8,826). The case of poisoning by ophthalmological

drugs and preparations in MS–DRG 125 also had a shorter average length of stay than the average length of stay for all cases in MS–DRG 125 (2.0 days compared to 3.3 days) and lower average costs than the average costs for all cases in MS–DRG 125 ($1,446 compared to $5,565).

We also examined claims data on cases reported in MS–DRGs 917 and 918 from the December 2016 update of the FY 2016 MedPAR file. Our findings are shown in the table below.

MS–DRGs 917 and 918 Cases

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 917— All cases	32,381	4.8	$9,882
MS–DRG 918—All cases	24,061	3.0	5,326

As shown in the table above, the 2 cases of poisoning by ophthalmological drugs and preparations also had shorter average lengths of stay than the average length of stay for all cases in MS–DRGs 917 and 918 (2.0 days compared to 4.8 days in MS–DRG 917 and 2.0 days compared to 3.0 days in MS–DRG 918). The average costs also were lower for the 2 cases of poisoning by ophthalmological drugs and preparations than the average costs for all cases in MS–DRGs 917 and 918 ($3,007 compared to $9,882 for all cases in MS–DRG 917 and $1,446 compared to $5,326 for all cases in MS–DRG 918). Therefore, cases with this type of poisoning had lower average lengths of stay and lower average costs than all other cases assigned to MS–DRGs 124 and 125 and cases in MS–DRGs 917 and 918 where poisonings are assigned.

Because the codes clearly capture a poisoning and not an eye disorder, we stated in the proposed rule that we believe that these codes are more appropriately assigned to MS–DRGs 917 and 918 where other poisonings are assigned. Our clinical advisors also reviewed this issue and agreed that the codes should be moved from MS–DRGs 124 and 125 to MS–DRGs 917 and 918 because they clearly capture a poisoning and not a disorder of the eye. Because MS–DRGs 917 and 918 contain cases with multiple types of poisonings, it is expected that some types of poisoning cases will have longer lengths of stay and greater average costs than other types of poisoning cases. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19824 through 19825), we proposed to reassign the following ICD–10–CM diagnosis codes from MS–DRGs 124 and 125 to MS–DRGs 917 and 918 for FY 2018: T49.5X1A; T49.5X2A; T49.5X3A; and T49.5X4A.

We invited public comments on our proposal.

Comment: Several commenters supported CMS' proposal to reassign four poisoning codes from MS–DRGs 124 and 125 to MS–DRGs 917 and 918. The commenters stated that the proposal was reasonable considering the information provided.

Response: We appreciate the commenters' support for our proposal.

After consideration of the public comments that we received, we are finalizing our proposal to reassign the following ICD–10–CM diagnosis codes from MS–DRGs 124 and 125 to MS–DRGs 917 and 918 for FY 2018: T49.5X1A; T49.5X2A; T49.5X3A; and T49.5X4A.

4. MDC 5 (Diseases and Disorders of the Circulatory System)

a. Percutaneous Cardiovascular Procedures and Insertion of a Radioactive Element

Currently, under ICD–10–PCS, the logic for MS–DRG 246 (Percutaneous Cardiovascular Procedures with Drug-Eluting Stent with MCC or 4+ Vessels or Stents), MS–DRG 247 (Percutaneous Cardiovascular Procedures with Drug-Eluting Stent without MCC), MS–DRG 248 (Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent with MCC or 4+ Vessels or Stents), and MS–DRG 249 (Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent without MCC) includes six procedure codes that describe the insertion of a radioactive element. When any of these six procedure codes are reported without the reporting of a percutaneous cardiovascular procedure code, they are assigned to MS–DRG 264 (Other Circulatory System O.R. Procedures). The six specific procedure codes are shown in the table below.

ICD–10–PCS code	Code description
0WHC01Z	Insertion of radioactive element into mediastinum, open approach.
0WHC31Z	Insertion of radioactive element into mediastinum, percutaneous approach.
0WHC41Z	Insertion of radioactive element into mediastinum, percutaneous endoscopic approach.
0WHD01Z	Insertion of radioactive element into pericardial cavity, open approach.
0WHD31Z	Insertion of radioactive element into pericardial cavity, percutaneous approach.
0WHD41Z	Insertion of radioactive element into pericardial cavity, percutaneous endoscopic approach.

Unlike procedures involving the insertion of stents, none of the procedures described by the procedure codes listed above are performed in conjunction with a percutaneous cardiovascular procedure, and two of the six procedures described by these procedure codes (ICD–10–PCS codes 0WHC01Z and 0WHD01Z) are not performed using a percutaneous approach, but rather describe an open approach to performing the specific procedure. We stated in the proposed rule that our clinical advisors agreed that these procedures should not be used to classify cases within MS–DRGs 246 through 249 because they are not performed in conjunction with a percutaneous cardiovascular procedure. Furthermore, the indications for the insertion of a radioactive element typically involve a diagnosis of cancer, whereas the indications for the insertion of a coronary artery stent typically involve a diagnosis of coronary artery disease.

We conducted an analysis for the six procedures described by these procedure codes by reviewing the claims data for MS–DRGs 246 through 249 from the December 2016 update of the FY 2016 MedPAR file. We did not find any cases where any one of the six

procedure codes listed above was reported. As noted earlier, when any of these six procedure codes are reported without the reporting of a percutaneous cardiovascular procedure code, the case is assigned to MS–DRG 264. Therefore, as we discussed in the proposed rule, our clinical advisors also agreed that it would be more appropriate to remove these six procedure codes from MS–DRGs 246 through 249, but maintain their current assignment in MS–DRG 264. Based on our analysis and the advice from our clinical advisors, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19825 through 19826), for FY 2018, we proposed to remove ICD–10–PCS procedure codes 0WHC01Z, 0WHC31Z, 0WHC41Z, 0WHD01Z, 0WHD31Z, and 0WHD41Z from MS–DRGs 246 through 249, but maintain their current assignment in MS–DRG 264.

We invited public comments on our proposal to remove the six procedure codes listed above from MS–DRGs 246 through 249. We also invited public comments on our proposal to maintain their current assignment in MS–DRG 264.

Comment: Commenters supported the proposal to remove the six procedure codes describing insertion of radioactive element into the mediastinum and insertion of radioactive element into the pericardial cavity from MS–DRGs 246 through 249 and to maintain their assignment in MS–DRG 264.

Response: We appreciate the commenters' support.

Comment: One commenter noted that CMS did not discuss how we identified the listed procedure codes or why CMS believes these procedure codes were assigned to MS–DRGs 246 through 249 erroneously. However, the commenter also agreed with the proposal to remove the six procedure codes describing insertion of radioactive element into the mediastinum and insertion of radioactive element into the pericardial cavity from MS–DRGs 246 through 249 and to maintain their assignment in MS–DRG 264. The commenter acknowledged that eliminating erroneous assignments that may have occurred as a result of the transition to ICD–10 is important and requires ongoing efforts.

Response: We appreciate the commenter's support. In response to the comment regarding how these procedure codes were identified, as discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19825), we recognized the fact that two of the six procedure codes describing insertion of radioactive element (0WHC01Z and 0WHD01Z) are not performed using a percutaneous approach, but rather described an open approach to performing the specific procedure and their assignment was to a group of ''percutaneous'' cardiovascular procedure MS–DRGs. Because the comparable translation of these procedure codes under ICD–9–CM, procedure code 92.27 (Implantation or insertion of radioactive element) did not specify an approach, all comparable ICD–10–PCS translations of the ICD–9–CM code were automatically replicated to the same ICD–10 MS–DRGs during the transition. We agree with the commenter that eliminating erroneous assignments that may have occurred as a result of the transition to ICD–10 is important and requires ongoing efforts.

After consideration of the public comments that we received, we are finalizing our proposal to remove ICD–10–PCS procedure codes 0WHC01Z, 0WHC31Z, 0WHC41Z, 0WHD01Z, 0WHD31Z, and 0WHD41Z from MS–DRGs 246 through 249, and maintain their current assignment in MS–DRG 264 effective October 1, 2017 for ICD–10 MS–DRGs Version 35.

b. Proposed Modification of the Titles for MS–DRG 246 (Percutaneous Cardiovascular Procedures With Drug-Eluting Stent With MCC or 4+ Vessels or Stents) and MS–DRG 248 (Percutaneous Cardiovascular Procedures With Non-Drug-Eluting Stent With MCC or 4+ Vessels or Stents)

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19826), we proposed to revise the titles for MS–DRGs 246 (Percutaneous Cardiovascular Procedures with Drug-Eluting Stent with MCC or 4+ Vessels or Stents) and MS–DRG 248 (Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent with MCC or 4+ Vessels or Stents) to better reflect the ICD–10–PCS terminology of ''arteries'' versus ''vessels'' as used in the procedure code titles within the classification. Specifically, we proposed to revise the title of MS–DRG 246 to ''Percutaneous Cardiovascular Procedures with Drug-Eluting Stent with MCC or 4+ Arteries or Stents''. We proposed to revise the title of MS–DRG 248 to ''Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent with MCC or 4+ Arteries or Stents''. We invited public comments on our proposals.

Comment: Commenters agreed with the proposal to update the titles for MS–DRG 246 and MS–DRG 248 to better reflect the ICD–10–PCS terminology of ''arteries'' versus ''vessels'' as used in the procedure code titles within the classification. One commenter noted that this change adds specificity and makes sense anatomically because percutaneous coronary intervention procedures are performed in arteries, which are a type of vessel.

Response: We appreciate the commenters' support.

After consideration of the public comments that we received, we are finalizing our proposal to revise the titles for MS–DRGs 246 and MS–DRG 248. We are finalizing the title of MS–DRG 246 to ''Percutaneous Cardiovascular Procedures with Drug-Eluting Stent with MCC or 4+ Arteries or Stents'' and the title of MS–DRG 248 to ''Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent with MCC or 4+ Arteries or Stents'' effective October 1, 2017 for ICD–10 MS–DRGs Version 35.

c. Transcatheter Aortic Valve Replacement (TAVR) and Left Atrial Appendage Closure (LAAC)

We received a request to create new MS–DRGs for cases involving transcatheter aortic valve replacement (TAVR) and left atrial appendage closure (LAAC) procedures when performed in combination in the same operative episode. The requestor stated that there are both clinical and financial advantages for the patient when performing concomitant procedures. For example, the requestor indicated that the clinical advantages for the patient may include single exposure to anesthesia and a reduction in overall procedure time, while the financial advantages may include lower cost-sharing. The requestor further believed that a single hospitalization for these concomitant procedures could be cost-effective for various providers and payers.

TAVR is indicated and approved as a treatment option for patients diagnosed with symptomatic aortic stenosis who are not surgical candidates for traditional open surgical techniques. Cases involving TAVR procedures are assigned to MS–DRGs 266 and 267 (Endovascular Cardiac Valve Replacement with MCC and without MCC, respectively), and are identified by the following ICD–10–PCS procedure codes shown in the table below.

ICD–10–PCS code	Code description
02RF37Z	Replacement of aortic valve with autologous tissue substitute, percutaneous approach.
02RF38Z	Replacement of aortic valve with zooplastic tissue, percutaneous approach.
02RF3JZ	Replacement of aortic valve with synthetic substitute, percutaneous approach.
02RF3KZ	Replacement of aortic valve with nonautologous tissue substitute, percutaneous approach.
02RF37H	Replacement of aortic valve with autologous tissue substitute, transapical, percutaneous approach.
02RF38H	Replacement of aortic valve with zooplastic tissue, transapical, percutaneous approach.
02RF3JH	Replacement of aortic valve with synthetic substitute, transapical, percutaneous approach.
02RF3KH	Replacement of aortic valve with nonautologous tissue substitute, transapical, percutaneous approach.

LAAC is indicated and approved as a treatment option for patients diagnosed with atrial fibrillation. Cases involving LAAC procedures are assigned to MS–DRGs 273 and 274 (Percutaneous Intracardiac Procedures with MCC and without MCC, respectively), and are identified by ICD–10–PCS procedure code 02L73DK (Occlusion of left atrial appendage with intraluminal device, percutaneous approach).

The requestor suggested that the structure of the possible new MS–DRGs for TAVR procedures performed in combination with LAAC procedures could be modeled similar to the structure of MS–DRGs 266 and 267. While contemplating creation of the new MS–DRGs, the requestor asked CMS to also consider subdividing the possible new MS–DRGs into two severity levels and title them as follows:

- Suggested MS–DRG 26x (Endovascular Cardiac Valve Replacement with LAAC with MCC); and
- Suggested MS–DRG 26x (Endovascular Cardiac Valve Replacement with LAAC without MCC).

As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19826 through 19827), we analyzed claims data from the December 2016 update of the FY 2016 MedPAR file for MS–DRGs 266 and 267 and identified the cases reporting TAVR procedures with and without an LAAC procedure. As shown in the table below, the data findings show that the total number of cases reported in MS–DRG 266 was 9,949, with an average length of stay of 7.2 days and average costs of $56,762. There were 9,872 cases involving a TAVR procedure, with an average length of stay of 7.2 days and average costs of $56,628. There was only one case identified in MS–DRG 266 where both a TAVR and an LAAC procedure were reported. This case had an average length of stay of 21.0 days and average costs of $60,226. For MS–DRG 267, the total number of cases found was 13,290, with an average length of stay of 3.5 days and average costs of $45,297. There were 13,245 cases involving a TAVR procedure, with an average length of stay of 3.5 days and average costs of $45,302. There were no cases identified in MS–DRG 267 where both a TAVR and an LAAC procedure were reported.

MS–DRGs for TAVR Procedures

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 266—All cases	9,949	7.2	$56,762
MS–DRG 266—Cases with TAVR	9,872	7.2	56,628
MS–DRG 266—Cases TAVR and LAAC	1	21.0	60,226
MS–DRG 267—All cases	13,290	3.5	45,297
MS–DRG 267—Cases with TAVR	13,245	3.5	45,302
MS–DRG 267—Cases TAVR and LAAC	0	0	0

We then analyzed claims data in MS–DRGs 273 and 274 for cases reporting an LAAC procedure. As shown in the table below, the data findings show that the total number of cases reported in MS–DRG 273 was 6,541, with an average length of stay of 7.7 days and average costs of $26,042. There were 179 cases involving an LAAC procedure, with an average length of stay of 3.6 days and average costs of $30,131. For MS–DRG 274, the total number of cases found was 14,441, with an average length of stay of 3.0 days and average costs of $20,267. There were 2,428 cases involving an LAAC procedure, with an average length of stay of 1.2 days and average costs of $26,213.

MS–DRGs for LAAC Procedures

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 273—All cases	6,541	7.7	$26,042
MS–DRG 273—Cases with LAAC	179	3.6	30,131
MS–DRG 274—All cases	14,441	3.0	20,267
MS–DRG 274—Cases with LAAC	2,428	1.2	26,213

We stated in the proposed rule that the analysis of claims data for MS–DRGs 266, 267, 273, and 274 and input from our clinical advisors do not support creating new MS–DRGs for TAVR and LAAC procedures when performed in combination in the same operative episode. We found only one case in MS–DRG 266 where both a TAVR and an LAAC procedure were reported and the claims data for cases reporting an LAAC procedure in MS–DRGs 273 and 274 support their current assignment. Our clinical advisors agreed the current MS–DRG assignments are appropriate for each respective procedure.

Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19827), we

did not propose to create new MS–DRGs for cases involving TAVR and LAAC procedures when performed in combination in the same operative episode. We invited public comments on our proposal to maintain the current MS–DRG structure for TAVR procedures in MS–DRGs 266 and 267, as well as the current MS–DRG structure for LAAC procedures in MS–DRGs 273 and 274.

Comment: Commenters supported the proposal to maintain the current MS–DRG structure for TAVR and LAAC procedures when performed in combination in the same operative episode.

Response: We appreciate the commenters' support.

After consideration of the public comments that we received, we are finalizing our proposal to maintain the current MS–DRG structure for TAVR procedures in MS–DRGs 266 and 267, as well as the current MS–DRG structure for LAAC procedures in MS–DRGs 273 and 274 effective October 1, 2017 for ICD–10 MS–DRGs Version 35.

d. Percutaneous Mitral Valve Replacement Procedures

We received a request to reassign four ICD–10–PCS procedure codes that describe percutaneous mitral valve replacement procedures from MS–DRGs 216 through 221 (Cardiac Valve and Other Major Cardiothoracic Procedures with and without Cardiac Catheterization with MCC, with CC and without CC/MCC, respectively) to MS–DRGs 266 and 267 (Endovascular Cardiac Valve Replacement with MCC and without MCC, respectively). The requestor indicated that there are inconsistencies in the current GROUPER logic for endovascular cardiac valve replacement procedures. Specifically, the requestor stated that the procedure codes that describe both the percutaneous approach and the transapical, percutaneous approach for the aortic and pulmonary valves are included in MS–DRGs 266 and 267. However, for the mitral valve, the GROUPER logic only includes the procedure codes that describe the transapical, percutaneous approach.

The requestor also stated that when MS–DRGs 266 and 267 were created, the intent was to include percutaneous replacement procedures for all cardiac valves. Therefore, the requestor recommended that CMS reassign the four ICD–10–PCS procedure codes shown in the table below that describe mitral valve replacement procedures, performed with the percutaneous approach from MS–DRGs 216 through 221 to MS–DRGs 266 and 267 to more appropriately group these procedures within the MS–DRG structure.

ICD–10–PCS procedure code	Code description
02RG37Z	Replacement of mitral valve with autologous tissue substitute, percutaneous approach.
02RG38Z	Replacement of mitral valve with zooplastic tissue, percutaneous approach.
02RG3JZ	Replacement of mitral valve with synthetic substitute, percutaneous approach.
02RG3KZ	Replacement of mitral valve with nonautologous tissue substitute, percutaneous approach.

We stated in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19827 through 19828) that we agree with the requestor regarding the intent of the creation of MS–DRGs 266 and 267. As discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49890 through 49893), MS–DRGs 266 and 267 were created to uniquely classify the subset of high-risk cases representing patients who undergo a cardiac valve replacement procedure performed by a percutaneous (endovascular) approach. As such, we agree that all cardiac valve replacement procedures should be grouped within the same MS–DRG. In FY 2015, under the ICD–9–CM classification, there was not a specific procedure code for a percutaneous mitral valve replacement procedure. Therefore, when we converted from the ICD–9 based MS–DRGs to the ICD–10 MS–DRGs, there was not a code available from which to replicate. We refer the reader to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49890 through 49893) for a detailed discussion on the initial request to create new MS–DRGs for endovascular cardiac valve replacement procedures, as well as the FY 2016 IPPS/LTCH PPS final rule (80 FR 49354 through 49358) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 56787 through 56790) for a detailed discussion of the conversion to ICD–10 MS–DRGs, including our analysis of claims data and the need to accurately replicate the ICD–9–CM based MS–DRGs.

The requestor also noted that a proposal was discussed at the September 13–14, 2016 ICD–10 Coordination and Maintenance Committee meeting involving the creation of procedure codes that describe percutaneous tricuspid valve replacement procedures and, if finalized, these new procedure codes would also be assigned to MS–DRGs 266 and 267.

As shown in the table below and in Table 6B.–New Procedure Codes, which is associated with the proposed rule and this final rule and available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*, there are eight new procedure codes that describe tricuspid valve replacement procedures performed with percutaneous and transapical types of percutaneous approaches that will be effective October 1, 2017.

ICD–10–PCS procedure code	Code description
02RJ37H	Replacement of tricuspid valve with autologous tissue substitute, transapical, percutaneous Approach.
02RJ37Z	Replacement of tricuspid valve with autologous tissue substitute, percutaneous approach.
02RJ38H	Replacement of tricuspid valve with zooplastic tissue, transapical, percutaneous approach.
02RJ38Z	Replacement of tricuspid valve with zooplastic tissue, percutaneous approach.
02RJ3JH	Replacement of tricuspid valve with synthetic substitute, transapical, percutaneous approach.
02RJ3JZ	Replacement of tricuspid valve with synthetic substitute, percutaneous approach.
02RJ3KH	Replacement of tricuspid valve with nonautologous tissue substitute, transapical, percutaneous approach.
02RJ3KZ	Replacement of tricuspid valve with nonautologous tissue substitute, percutaneous approach.

We stated in the proposed rule that we agree with the requestor and believe that, in addition to the four procedure codes that describe the percutaneous mitral valve replacement procedures listed earlier in this section, the eight codes that describe percutaneous and transapical types of percutaneous tricuspid valve replacement procedures also should be grouped with the other endovascular cardiac valve replacement procedures. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19827 through 19828), we proposed to reassign the four percutaneous mitral valve replacement procedures described by the procedure codes listed in the table above from MS–DRGs 216 through 221 to MS–DRGs 266 and 267. In addition, we proposed to assign the eight new procedure codes (also listed in a separate table above) that describe percutaneous and transapical, percutaneous tricuspid valve replacement procedures to MS–DRGs 266 and 267.

We invited public comments on our proposals.

Comment: Many commenters supported the proposal to reassign the four percutaneous mitral valve replacement procedures from MS–DRGs 216 through 221 to MS–DRGs 266 and 267 and to assign the eight new procedure codes that describe percutaneous and transapical, percutaneous tricuspid valve replacement procedures to MS–DRGs 266 and 267. Commenters noted that these updates will appropriately reflect the clinical characteristics and resource use for this group of endovascular cardiac valve replacement procedures.

Response: We appreciate the commenters' support.

After consideration of the public comments that we received, we are finalizing our proposal to reassign the four percutaneous mitral valve replacement procedures described by the procedure codes listed in the table above from MS–DRGs 216 through 221 to MS–DRGs 266 and 267 and assign the eight new procedure codes (also listed in a separate table above) that describe percutaneous and transapical, percutaneous tricuspid valve replacement procedures to MS–DRGs 266 and 267 effective October 1, 2017 for ICD–10 MS–DRGs Version 35.

e. Percutaneous Tricuspid Valve Repair

We received a request to reassign cases reporting ICD–10–PCS procedure code 02UJ3JZ (Supplement tricuspid valve with synthetic substitute, percutaneous approach) from MS–DRGs 216 through 221 (Cardiac Valve and Other Major Cardiothoracic Procedures with and without Cardiac Catheterization with MCC, with CC and without CC/MCC, respectively) to MS–DRGs 228 and 229 (Other Cardiothoracic Procedures with MCC and without MCC, respectively). According to the requestor, reassigning cases involving these procedures would more appropriately align the cohesiveness with other clinically similar procedures, such as percutaneous mitral valve repair (for example, procedures involving the Mitraclip) described by procedure code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach), which are assigned to MS–DRGs 228 and 229.

The requestor noted that the FORMA Tricuspid Transcatheter Repair System (herein after referred to as the FORMA system) is currently in clinical trials in the United States, Europe, and Canada, but has not received FDA approval/clearance marketing authorization. However, the FORMA system is presently available through a compassionate use program. The FORMA system technology is indicated for use in the treatment of patients diagnosed with tricuspid regurgitation and occupies the regurgitant area of the affected valve, providing a surface for native leaflet coaptation. The requestor stated that the technology offers a viable alternative treatment using traditional tricuspid valve surgery. According to the requestor, the technology consists of a rail and a spacer, and the procedure to insert the device involves fluoroscopic imaging guidance.

As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19828 through 19829), we analyzed claims data from the December 2016 update of the FY 2016 MedPAR file for MS–DRGs 216 through 221 for cases reporting procedure code 02UJ3JZ (Supplement tricuspid valve with synthetic substitute, percutaneous approach). Our findings are shown in the following table.

MS–DRGs for Cardiac Valve and Other Major Cardiothoracic Procedures

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 216—All cases	9,139	14.4	$68,304
MS–DRG 216—Cases with percutaneous tricuspid valve repair	1	5.0	14,954
MS–DRG 217—All cases	3,536	8.9	45,857
MS–DRG 217—Cases with percutaneous tricuspid valve repair	1	3.0	16,234
MS–DRG 218—All cases	498	5.9	41,274
MS–DRG 218—Cases with percutaneous tricuspid valve repair	0	0	0
MS–DRG 219—All cases	16,011	11.1	54,519
MS–DRG 219—Cases with percutaneous tricuspid valve repair	6	9.0	58,075
MS–DRG 220—All cases	18,476	6.8	37,506
MS–DRG 220—Cases with percutaneous tricuspid valve repair	1	5.0	90,155
MS–DRG 221—All cases	3,547	5.0	33,606
MS–DRG 221—Cases with percutaneous tricuspid valve repair	0	0	0

We also analyzed claims data for MS–DRGs 228 and 229. Our findings are shown in the following table below.

MS–DRGs for Other Cardiothoracic Procedures

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 228—All cases	3,466	9.8	$47,435

MS–DRGs FOR OTHER CARDIOTHORACIC PROCEDURES—Continued

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 229—All cases	4,553	4.9	33,347

The claims data show that there were very few cases reported for performing a percutaneous tricuspid valve repair procedure in MS–DRGs 216 through 221. Of the 6 cases found in MS–DRG 219, with average costs of $58,075, the average cost of these cases aligned with the average cost of all cases in the MS–DRG assignment ($54,519). We stated in the proposed rule that the data analysis and our clinical advisors do not support reassigning cases reporting procedure code 02UJ3JZ to MS–DRGs 228 and 229. The current MS–DRG assignment for percutaneous tricuspid valve repair procedures to MS–DRGs 216 through 221 is clinically coherent with the other percutaneous procedures performed on the heart valves that are currently assigned to these MS–DRGs. Percutaneous repair of the aortic, pulmonary and tricuspid valves utilizing various tissue substitutes (autologous, nonautologous, zooplastic, and synthetic) are assigned to MS–DRGs 216 through 221. The exception is the percutaneous mitral valve repair, which, as the requestor pointed out, is assigned to MS–DRGs 228 and 229 as discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56809 through 56813). Our clinical advisors also agreed that the limited number of cases reported in MS–DRGs 216 through 221 does not warrant reassignment.

As a result of our review and the input from our clinical advisors, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19829), we did not propose to reassign cases reporting procedure code 02UJ3JZ from MS–DRGs 216 through 221 to MS–DRGs 228 and 229.

We invited public comments on our proposal to maintain the current MS–DRG assignment for cases reporting procedure code 02UJ3JZ.

Comment: Commenters supported the proposal to maintain the current MS–DRG assignment for ICD–10–PCS procedure code 02UJ3JZ in MS–DRGs 216 through 221. One commenter also noted that, while CMS' analysis demonstrated the current assignment is appropriate, CMS should consider revisiting this procedure in the future in the event it becomes more common and warrants further consideration for reassignment. The commenter believed that there could be value in creating MS–DRGs for endovascular cardiac repair similar to those MS–DRGs for endovascular cardiac valve replacement.

Response: We appreciate the commenters' support. As additional ICD–10 claims data become available, we will continue to welcome input from the public and consider further modifications to the ICD–10 MS–DRGs if warranted.

Comment: One commenter did not agree with the proposal to maintain the current MS–DRG assignment for ICD–10–PCS procedure code 02UJ3JZ in MS–DRGs 216 through 221. The commenter stated that transcatheter tricuspid valve repair procedures are clinically coherent with other percutaneous transcatheter cardiac valve repair procedures. This commenter asserted that the devices utilized in these procedures are currently under clinical investigation and the utilization of these technologies is expected to increase through clinical trials. Therefore, the commenter suggested that these procedures should be assigned to MS–DRGs 228 and 229.

Response: As we noted in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19829), the results of our analysis of the current MS–DRG assignment for percutaneous tricuspid valve repair procedures to MS–DRGs 216 through 221 and the advice of our clinical advisors demonstrate that this procedure is clinically coherent with the other percutaneous procedures performed on the heart valves that are currently assigned to these MS–DRGs because percutaneous repair of the aortic, pulmonary, and tricuspid valves utilizing various tissue substitutes (autologous, nonautologous, zooplastic, and snythetic) are assigned to MS–DRGs 216 through 221. We will continue to consider further modifications to the ICD–10 MS–DRGs as additional ICD–10 claims data become available that support suggested changes.

After consideration of the public comments that we received, we are finalizing our proposal to maintain the current MS–DRG assignment for cases reporting procedure code 02UJ3JZ (Supplement tricuspid valve with synthetic substitute, percutaneous approach) to MS–DRGs 216 through 221 for FY 2018.

5. MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)

a. Total Ankle Replacement (TAR) Procedures

For FY 2018, we again received two requests for the reassignment of total ankle replacement (TAR) procedures to a different MS–DRG. TAR procedures are currently assigned to MS–DRGs 469 and 470 (Major Joint Replacement or Reattachment of Lower Extremity with and without MCC, respectively). This topic was discussed previously in the FY 2015 IPPS/LTCH PPS proposed and final rules (79 FR 28013 through 28015 and 79 FR 49896 through 49899, respectively) and in the FY 2017 IPPS/LTCH PPS proposed and final rules (81 FR 24989 through 24990 and 81 FR 56814 through 56816, respectively). For FY 2015 and FY 2017, we did not change the MS–DRG assignment for TAR procedures. The requestors indicated that TAR procedures are currently assigned to MS–DRGs 469 and 470, to which total hip replacement and total knee replacement procedures also are assigned. The requestors stated that there are significant clinical and cost differences among these procedures, which results in underpayment for TAR procedures. The requestors asked CMS to examine claims data for the following six ICD–10–PCS codes within MS–DRGs 469 and 470:

- 0SRF0J9 (Replacement of right ankle joint with synthetic substitute, cemented, open approach);
- 0SRF0JA (Replacement of right ankle joint with synthetic substitute, uncemented, open approach);
- 0SRF0JZ (Replacement of right ankle joint with synthetic substitute, open approach);
- 0SRG0J9 (Replacement of left ankle joint with synthetic substitute, cemented, open approach);
- 0SRG0JA (Replacement of left ankle joint with synthetic substitute, uncemented, open approach); and
- 0SRG0JZ (Replacement of left ankle joint with synthetic substitute, open approach).

The requestors recommended that, if the claims data show a disparity in costs between TAR procedures and total hip and knee replacement procedures, the TAR procedures be reassigned to a more appropriate MS–DRG.

The requestors also stated that total ankle replacement is a complicated surgery that involves the replacement of the damaged parts of the three bones that comprise the ankle joint, as compared to the two bones in hip and knee replacement procedures. Furthermore, as the smallest weight-bearing large joint in the body, the requestors stated that TAR procedures demand a complexity of implant device design, engineering, and manufacture to exacting functional specifications that is vastly different from that of total hip and knee replacement devices. One of the requestors stated that the ankle region typically has poorer circulation and thinner soft tissue coverage than the hip and knee, leading to a higher risk of wound complications and infection that may be more challenging and expensive to treat. In addition, this requestor stated that the unique anatomical characteristics and function of the ankle joint require a specialized surgical skill set, operative technique, and level of operating room resource utilization that is vastly dissimilar from that of total hip and knee replacement procedures.

As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19829 through 19830), we examined claims data from the December 2016 update of the FY 2016 MedPAR file on reported cases of TAR procedures in MS–DRGs 469 and 470. Our findings are shown in the table below.

TOTAL ANKLE REPLACEMENTS PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 469—All cases	25,778	6.7	$22,139
MS–DRG 469—Cases reporting TAR procedure codes	31	4.6	23,828
MS–DRG 470—All cases	461,553	2.7	14,751
MS–DRG 470—Cases reporting TAR procedure codes	2,114	1.9	20,862

As shown in the table above, for MS–DRG 469, there were a total of 25,778 cases, with an average length of stay of 6.7 days and average costs of $22,139. Of the 25,778 cases in MS–DRG 469, there were 31 cases reporting a TAR procedure, with an average length of stay of 4.6 days and average costs of $23,828. For MS–DRG 470, there were a total of 461,553 cases, with an average length of stay of 2.7 days and average costs of $14,751. Of the 461,553 cases in MS–DRG 470, there were 2,114 cases reporting a TAR procedure, with an average length of stay of 1.9 days and average costs of $20,862. As mentioned earlier, there were only 31 TAR procedure cases in MS–DRG 469, and these cases had average costs of $1,689 higher than the average costs of all cases within MS–DRG 469. The relatively small number of cases may have been impacted by other factors. Several expensive cases could impact the average costs for a very small number of patients. We also note that the average length of stay for the TAR procedure cases was 4.6 days, as compared to 6.7 days for all cases within MS–DRG 469. The 2,114 TAR procedure cases in MS–DRG 470 had average costs that were $6,111 higher than the average costs of all cases in MS–DRG 470 ($20,862 compared to $14,751 for all cases). We stated in the proposed rule that the data support reassigning all of the TAR procedures to MS–DRG 469, even when there is no MCC reported. While the average costs of the TAR procedures in MS–DRG 470 are lower than the average costs for all cases in MS–DRG 469 ($20,862 compared to $22,139), the average costs are much closer to the average costs of TAR procedure cases in MS–DRG 470.

We stated in the proposed rule that our clinical advisors reviewed this clinical issue and the claims data, and agreed that it is clinically appropriate to reassign all of the TAR procedure cases from MS–DRG 470 to MS–DRG 469, even when there is no MCC reported. The claims data support the fact that these cases require more resources than other cases assigned to MS–DRG 470. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19829 through 19830), we proposed to reassign the following TAR procedure codes from MS–DRG 470 to MS–DRG 469, even if there is no MCC reported: 0SRF0J9; 0SRF0JA; 0SRF0JZ; 0SRG0J9; 0SRG0JA; and 0SRG0JZ for FY 2018.

We proposed to change the titles of MS–DRGs 469 and 470 to the following to reflect these proposed MS–DRG reassignments:

- Proposed retitle of MS–DRG 469: ''Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement''; and
- Proposed retitle of MS–DRG 470: ''Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC.''

We invited public comments on our proposals.

Comment: Several commenters supported CMS' recommendation to reassign the following TAR procedure codes from MS DRG 470 to MS DRG 469, even if there is no MCC reported: 0SRF0J9; 0SRF0JA; 0SRF0JZ; 0SRG0J9; 0SRG0JA; and 0SRG0JZ for FY 2018. The commenters also supported the change in MS–DRG titles for MS–DRG 469 and 470 to reflect this MS–DRG update. One commenter stated that claims data supported this recommendation because, as CMS pointed out, the average costs of TAR cases in MS–DRG 470 are much closer to the average costs of all cases in MS–DRG 469 ($20,862 versus $22,139). The commenter also agreed with the CMS clinical advisors that it was clinically appropriate to reassign all TAR procedure cases from MS–DRG 470 to MS–DRG 469, even when there is no MCC reported. The commenter stated that the update will remedy a historical cost-to-payment disparity, and thus enable hospitals to continue offering Primary TAR surgery to Medicare beneficiaries as an economically sustainable, and clinically viable, alternative to ankle fusion when medically appropriate. The commenter commended CMS for its consideration of how to address this MS–DRG issue.

Response: We appreciate the commenters' support.

After consideration of the public comments that we received, we are reassigning the following TAR procedure codes from MS DRG 470 to MS DRG 469, even if there is no MCC reported: 0SRF0J9; 0SRF0JA; 0SRF0JZ; 0SRG0J9; 0SRG0JA; and 0SRG0JZ for FY 2018. We are changing the titles of MS–DRGs 469 and 470 to the following to reflect these MS–DRG reassignments:

- MS–DRG 469: ''Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement''; and
- MS–DRG 470: ''Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC.''

b. Revision of Total Ankle Replacement (TAR) Procedures

We received two requests to modify the MS–DRG assignment for revision of total ankle replacement (TAR) procedures, which the requestors indicated are assigned to MS–DRGs 515, 516, and 517 (Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC, with CC, and without CC/MCC, respectively). This topic was discussed in the FY 2015 IPPS/LTCH PPS proposed and final rules (79 FR 28013 through 28015 and 79 FR 49896 through 49899, respectively) and in the FY 2017 IPPS/LTCH PPS proposed and final rules (81 FR 24992 through 24993 and 81 FR 56819 through 56820, respectively). For FY 2015 and FY 2017, we did not change the MS–DRG assignment for revision of TAR procedures.

The requestors asked that CMS examine the following eight ICD–10–PCS codes which they indicated identify revision of TAR procedures and which are assigned to MS–DRGs 515, 516, and 517. As we discuss later in this section in response to public comments, while the requestors requested that we analyze these eight procedure codes for revisions of TAR procedures in the proposed rule, these procedures are in fact represented by a combination of other codes that capture the root operation removal and replacement of joint devices.

- 0SWF0JZ (Revision of synthetic substitute in right ankle joint, open approach);
- 0SWF3JZ (Revision of synthetic substitute in right ankle joint, percutaneous approach);
- 0SWF4JZ (Revision of synthetic substitute in right ankle joint, percutaneous endoscopic approach);
- 0SWFXJZ (Revision of synthetic substitute in right ankle joint, external approach);
- 0SWG0JZ (Revision of synthetic substitute in left ankle joint, open approach);
- 0SWG3JZ (Revision of synthetic substitute in left ankle joint, percutaneous approach);
- 0SWG4JZ (Revision of synthetic substitute in left ankle joint, percutaneous endoscopic approach); and
- 0SWGXJZ (Revision of synthetic substitute in left ankle joint, external approach).

One requestor stated that these ICD–10–PCS codes more specifically identify the revision of TAR procedures than the prior ICD–9–CM codes. Specifically, ICD–9–CM code 81.59 (Revision of joint replacement of lower extremity, not elsewhere classified) was an unspecified code, which included toe and foot joint revision procedures in addition to revision of TAR procedures. The requestor stated that claims data reporting these ICD–10–PCS codes would allow CMS to better identify revisions of TAR procedures, and determine if the procedures are assigned to the appropriate MS–DRGs.

One requestor suggested the following three options for MS–DRG assignments:

- Assign the ICD–10–PCS ankle revision procedure codes to MS–DRGs 466, 467, and 468 (Revision of Hip or Knee Replacement with MCC, with CC, and without CC/MCC, respectively), and rename MS–DRGs 466, 467, and 468 as ''Revision of Hip, Knee or Ankle with MCC, with CC, and without CC/MCC,'' respectively);
- Assign the ICD–10–PCS ankle revision procedure codes to MS–DRG 469 (Major Joint Replacement or Reattachment of Lower Extremity with MCC) to more appropriately recognize higher hospital procedure costs associated with revision of TAR procedures; or
- Establish a new MS–DRG for the assignment of revision of TAR procedures.

The other requestor asked that CMS consider reassigning revision of TAR procedures to MS–DRGs that better address the cost-to-payment differential, such as MS–DRGs 466, 467, and 468.

As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19830 through 19831), we examined claims data from the December 2016 update of the FY 2016 MedPAR file on cases reporting the eight revision codes listed above as well as cases assigned to MS–DRGs 466, 467, 468, and MS–DRG 469. Our findings are shown in the tables below.

REVISIONS OF JOINT REPLACEMENTS PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 515—All cases	5,038	8.0	$20,562
MS–DRG 515—Cases reporting revision of total ankle replacement procedure codes	0	0	0
MS–DRG 516—All cases	13,276	4.8	13,524
MS–DRG 516—Cases reporting revision of total ankle replacement procedure codes	2	2.5	11,400
MS–DRG 517—All cases	13,330	2.8	10,003
MS–DRG 517—Cases reporting revision of total ankle replacement procedure codes	4	1.5	7,423

CASES IN MS–DRGS 466, 467, 468, AND 469

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 466—All cases	3,886	8.4	$33,720
MS–DRG 467—All cases	19,145	4.2	24,609
MS–DRG 468—All cases	16,529	2.7	20,208
MS–DRG 469—All cases	25,778	6.7	22,139

As shown in the tables above, there were only 6 cases identified with the eight revision codes suggested by the requestor with no cases in MS–DRG 515, two cases in MS–DRG 516, and four cases in MS–DRG 517. We stated in the proposed rule that the limited number of six cases does not justify the creation of a new MS–DRG for the assignment of revision of TAR procedures. Our data analysis demonstrates that the average length of stay for these revision procedures was lower than that for all cases in MS–DRG 516 (2.5 days compared to 4.8 days), and the average costs were lower ($11,400 compared to $13,524). The average length of stay for these revision

procedures also was lower than that for all cases in MS–DRG 517 (1.5 days compared to 2.8 days), and the average costs were lower ($7,423 compared to $10,003). We stated that the data do not support reassigning the cases from MS–DRGs 515, 516, and 517.

Furthermore, we stated that the average length of stay and average costs of cases in MS–DRGs 466, 467, 468, and 469 are significantly higher than those for these revision procedures in MS–DRG 516 and 517. We stated that the average length of stay for all cases in MS–DRGs 466, 467, 468, and 469 is 8.4, 4.2, 2.7, and 6.7 days, respectively, compared to the average length of stay of 2.5 and 1.5 days for cases representing these revision procedures in MS–DRGs 516 and 517, respectively. The average costs for all cases in MS–DRGs 466, 467, 468, and 469 are $33,720, $24,609, $20,208, and $22,139, respectively, compared to the average costs of $11,400 and $7,423 for cases representing these revision procedures in MS–DRGs 516 and 517, respectively. Therefore, we stated that in the proposed rule that the data do not support reassigning the cases to MS–DRGs 466, 467, 468, or 469.

We stated in the proposed rule that our clinical advisors reviewed the clinical issue and the claims data and agreed that the eight revision codes are appropriately assigned to MS–DRGs 515, 516, and 517, along with other procedures that describe revisions of joint replacements of the lower extremities, including the foot and toe. Our clinical advisors did not support reassigning these cases to MS–DRGs 466, 467, 468, or 469, or creating a new MS–DRG. Therefore, based on the findings of our analysis of claims data and the advice of our clinical advisors, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19830 through 19831), we proposed to maintain the current MS–DRG assignment for these revision procedures within MS–DRGs 515, 516, and 517 for FY 2018.

Comment: Commenters supported CMS' proposal to maintain the current MS–DRG assignments for procedures within MS–DRGs 515, 516, and 517 for FY 2018.

Several commenters questioned the reliability of the revision of TAR data presented in the proposed rule. The commenters questioned the codes used in the analysis and stated that revision of TAR procedures are not captured with the Revision of synthetic substitute codes identified in the proposed rule. The commenters stated that the procedures are captured by reporting a combination of codes that capture the removal of a prior device and the replacement of the device with a new device. The commenters stated that the correct root operations for these codes would be Removal and Replacement instead of Revision as stated in the proposed rule. The commenters provided the following codes which reported in combination would identify revision of TAR procedures. The commenters stated that revisions of TAR procedures are performed with an open approach.

Removals

• 0SPG0JZ (Removal of Synthetic Substitute from Left Ankle Joint, Open Approach); and

• 0SPF0JZ (Removal of Synthetic Substitute from Right Ankle Joint, Open Approach)

Replacements

• 0SRF0J9 (Replacement of right ankle joint with synthetic substitute, cemented, open approach);

• 0SRF0JA (Replacement of right ankle joint with synthetic substitute, uncemented, open approach);

• 0SRF0JZ (Replacement of right ankle joint with synthetic substitute, open approach);

• 0SRG0J9 (Replacement of left ankle joint with synthetic substitute, cemented, open approach);

• 0SRG0JA (Replacement of left ankle joint with synthetic substitute, uncemented, open approach); and

• 0SRG0JZ (Replacement of left ankle joint with synthetic substitute, open approach).

The commenters requested that CMS encourage the correct coding of revision of TAR cases through additional educational materials. The commenters requested that CMS review hospital claims data for revision of TAR procedures using the list of Removal and Replacement code combinations provided to identify revision of TAR cases. The commenter stated that an increasing number of claims for revision of TAR procedures will become identifiable in the future as patients and implants naturally age into a need for revision surgery.

Response: We appreciate the commenters' support for our proposal to maintain the current MS–DRG assignment for procedures within MS–DRGs 515, 516, and 517 for FY 2018.

We conducted an analysis of the correct coding of revision of TARs and agree with the commenters that these cases are not captured with ICD–10–PCS codes with the root operation Revision as stated in the proposed rule. The commenters are correct that the revision of TAR cases are correctly coded using a combination of codes with the root operation Removal and Replacement as the commenters suggested. Updates were made to the ICD–10–PCS index on October 1, 2015 to reinforce this direction. The index entry is shown below:

Revision

Correcting a portion of existing device

see Revision of device in Removal of device without replacement

see Removal of device from Replacement of existing device

see Removal of device from

see Root operation to place new device, *e.g.,* Insertion, Replacement, Supplement

We agree that this index entry clearly indicates that the correct root operations for revision of TARs would be Removal and Replacement. The codes with the root operation Revision (included in the Revision of synthetic substitute codes used in our original analysis) would not be used to capture revision of TAR procedures. Cases reporting the combination codes are assigned to MS–DRGs 469 and 470 (Major Joint Replacement or Reattachment of Lower Extremity with and without MCC, respectively).

As requested by the commenters, we identified revision of TAR cases using the correct ICD–10–PCS codes that are captured with the root operation of Removal and Replacement. We examined our claims data for cases within MDC 8 that reported one of the Removal codes with one of the Replacement codes for ankle joint devices. These codes accurately capture revision of TAR cases. The following table shows our findings.

REVISION OF TOTAL ANKLE REPLACEMENT PROCEDURES USING CODE COMBINATIONS

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 469—All cases	25,778	6.7	$22,139
MS–DRG 469—Cases reporting revision of TAR code combinations	0		

REVISION OF TOTAL ANKLE REPLACEMENT PROCEDURES USING CODE COMBINATIONS—Continued

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 470—All cases	461,553	2.7	14,751
MS–DRG 470—Cases reporting revision of TAR code combinations	59	1.7	19,594

Using the updated correct ICD–10–PCS codes, we found that there were 59 revision of TAR procedures in MS–DRG 470 with average costs of $19,594 and average length of stay of 1.7 days compared to average costs of $14,751 and average length of stay of 2.7 days for all cases in MS–DRG 470. There were no revision of TAR procedures in MS–DRG 469. As discussed in section II.5.a. of the preamble of this final rule on Total Ankle Replacements, we are finalizing updates to reassign all of the TAR procedure codes to MS–DRG 469, even if there is no MCC present, for FY 2018. This update will also impact revision of TAR cases because the same total ankle replacement codes are also used to identify revision of TAR procedures. Therefore, the MS–DRG 469 and 470 updates result in all revision of TAR procedures being assigned to MS–DRG 469 even if there is no MCC reported in FY 2018.

Revisions of TARs were assigned to MS–DRGs 515, 516, and 517 under the ICD–9–CM MS–DRGs. However, an error in replication for the ICD–10 MS–DRGs resulted in the revision of TAR procedure cases being assigned to MS–DRGs 469 and 470. This replication error was not noticed until the commenters on the FY 2018 IPPS/LTCH PPS proposed rule pointed out that accurate coding of revision of TARs would result in cases not being assigned to MS–DRGs 515, 516, and 517. Since the implementation of ICD–10 MS–DRGs, revision of TAR procedure cases have not been assigned to MS–DRGs 515, 516, and 517. Therefore, we do not need to modify MS–DRG logic to reassign revision of TAR procedures from MS–DRGs 515, 516, and 517 because correctly coded cases are not assigned there, but instead to MS–DRGs 469 and 470. As noted earlier, under our finalized policy for FY 2018, all revision of TAR procedures will be assigned to MS–DRG 469, even if there is no MCC reported.

We agree with the commenters that it is important to encourage the accurate and consistent use of ICD–10–PCS to capture procedures such as revision of TAR. Therefore, we have asked the American Hospital Association to provide additional information on how to capture revision of TARs in a future issue of Coding Clinic for ICD–10. We encourage any providers that have revision of TAR cases on which they need ICD–10 coding assistance to submit this information and their questions to the American Hospital Association's Central Office on ICD–10 at *https://www.codingclinicadvisor.com/*. We share information included in Coding Clinic for ICD–10 with our contractors.

After consideration of the public comments that we received, we are not finalizing any changes to MS–DRGs 515, 516, and 517 for FY 2018 because, as noted, the revision of TAR procedures are not assigned to these MS–DRGs. Under our finalized policy regarding TAR procedures, as discussed in section II.5.a. of the preamble of this final rule, all TAR procedure cases, as well as revision of TAR procedure cases, will be assigned to MS–DRG 469 for FY 2018, even if there is no MCC present.

c. Magnetic Controlled Growth Rods (MAGEC® System)

We received a request to add six ICD–10–PCS procedure codes that describe the use of magnetically controlled growth rods for the treatment of early onset scoliosis (MAGEC® System) to MS–DRGs 456, 457, and 458 (Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusions with MCC, with CC or without CC/MCC, respectively). The MAGEC® System was discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25040 through 25042) and final rule (81 FR 56888 through 56891) as a new technology add-on payment application. The application was approved for FY 2017 new technology add-on payments, effective with discharges occurring on and after October 1, 2016. The request for new procedure codes to identify the MAGEC® System technology was discussed at the March 9–10, 2016 ICD–10 Coordination and Maintenance Committee meeting. Six new procedure codes were approved, effective October 1, 2016, and were displayed in Table 6B.—New Procedure Codes associated with the FY 2017 IPPS/LTCH PPS final rule (which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2017-IPPS-Final-Rule-Home-Page.html*). These six procedure codes are currently assigned to MS–DRGs 518, 519, and 520 (Back and Neck Procedure Except Spinal Fusion with MCC or Disc Device/Neurostimulator, with CC, or without CC/MCC, respectively) and are shown in the table below.

ICD–10–PCS code	Code description
XNS0032	Reposition of lumbar vertebra using magnetically controlled growth rod(s), open approach, new technology group 2.
XNS0432	Reposition of lumbar vertebra using magnetically controlled growth rod(s), percutaneous endoscopic approach, new technology group 2.
XNS3032	Reposition of cervical vertebra using magnetically controlled growth rod(s), open approach, new technology group 2.
XNS3432	Reposition of cervical vertebra using magnetically controlled growth rod(s), percutaneous endoscopic approach, new technology group 2.
XNS4032	Reposition of thoracic vertebra using magnetically controlled growth rod(s), open approach, new technology group 2.
XNS4432	Reposition of thoracic vertebra using magnetically controlled growth rod(s), percutaneous endoscopic approach, new technology group 2.

According to the requestor, adding these six procedure codes will allow these cases to group to MS–DRGs that more accurately reflect the diagnosis of early onset scoliosis for which the MAGEC® System is indicated. In addition, the requestor stated that because this technology is utilized on a small subset of patients with approximately 2,500 cases per year, adding these procedure codes to MS–DRGs 456, 457, and 458 would have little impact.

We stated in the proposed rule that because these six procedure codes shown in the table above were effective as of October 1, 2016, there are no MedPAR claims data available to analyze. More importantly, we noted that cases are assigned to MS–DRGs 456, 457, and 458 when an actual spinal fusion procedure is performed. We stated that our clinical advisors agree that use of the MAGEC® System's magnetically controlled growth rods technology alone does not constitute a spinal fusion. Therefore, because there were no claims data available at the time of development of the proposed rule and based on the advice of our clinical advisors, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19832), we did not propose to add the six procedure codes to MS–DRGs 456, 457, or 458. We stated that if a spinal fusion procedure is performed along with the procedure to insert the MAGEC® System's magnetically controlled growth rods, it would be appropriate to report that a spinal fusion was performed and the case would be assigned to one of the spinal fusion MS–DRGs.

We invited public comments on our proposal to maintain the current GROUPER logic for cases assigned to MS–DRGs 456, 457, and 458 and not add the six procedure codes describing the use of the MAGEC® System magnetically controlled growth rods. We also invited public comments on our proposal to maintain the assignment of the six procedure codes in MS–DRGs 518, 519, and 520.

Comment: Commenters agreed with CMS' proposal to maintain the assignment of the six procedure codes in MS–DRGs 518, 519, and 520 and to not reassign the six procedure codes describing the use of the MAGEC® System magnetically controlled growth rods to the spinal fusion MS–DRGs 456, 457 and 458.

Response: We appreciate the commenters' support. We also take this time to point out that the three ICD–10–PCS procedure codes describing reposition of the vertebra using magnetically controlled growth rods with a percutaneous endoscopic approach listed below have been deleted as displayed in Table 6D.—Invalid Procedure Codes associated with this FY 2018 IPPS/LTCH PPS final rule (which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) effective October 1, 2017 in the ICD–10 MS–DRGs Version 35.

ICD–10–PCS code	Code description
XNS0432	Reposition of lumbar vertebra using magnetically controlled growth rod(s), percutaneous endoscopic approach, new technology group 2.
XNS3432	Reposition of cervical vertebra using magnetically controlled growth rod(s), percutaneous endoscopic approach, new technology group 2.
XNS4432	Reposition of thoracic vertebra using magnetically controlled growth rod(s), percutaneous endoscopic approach, new technology group 2.

The three ICD–10–PCS procedure codes listed in the table above were discussed in a proposal at the March 7–8, 2017 ICD–10 Coordination and Maintenance Committee meeting. Decisions for proposals presented at that meeting were not finalized at the time of publication of the FY 2018 IPPS/LTCH PPS proposed rule. Additional information relating to the discussion of these codes can be located via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html.* Also included in that discussion was a proposal to add a new approach value to the procedures describing Reposition of the vertebra. As displayed in Table 6B.—New Procedure Codes associated with this FY 2018 IPPS/LTCH PPS final rule (which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*), the following three ICD–10–PCS codes have been created effective October 1, 2017 in the ICD–10 MS–DRGs Version 35 and are assigned to MS–DRGs 518, 519 and 520.

ICD–10–PCS code	Code description
XNS0332	Reposition of lumbar vertebra using magnetically controlled growth rod(s), percutaneous approach, new technology group 2.
XNS3332	Reposition of cervical vertebra using magnetically controlled growth rod(s), percutaneous approach, new technology group 2.
XNS4332	Reposition of thoracic vertebra using magnetically controlled growth rod(s), percutaneous approach, new technology group 2.

After consideration of the public comments that we received, we are finalizing our proposal to maintain the current GROUPER logic for cases assigned to MS–DRGs 456, 457, and 458. We also are finalizing our proposal to maintain the assignment of the three existing ICD–10–PCS procedure codes (describing an open approach) and finalizing assignment of the three new ICD–10–PCS codes (describing a percutaneous approach) for the use of magnetically controlled growth rods in the treatment of early onset scoliosis to MS–DRGs 518, 519, and 520 for FY 2018.

d. Combined Anterior/Posterior Spinal Fusion

It was brought to our attention that 7 of the 10 new ICD–10–PCS procedure codes describing fusion using a nanotextured surface interbody fusion device were not added to the appropriate GROUPER logic list for MS–

DRGs 453, 454, and 455 (Combined Anterior/Posterior Spinal Fusion with MCC, with CC and without CC/MCC, respectively), effective October 1, 2016. The logic for MS–DRGs 453, 454, and 455 is comprised of two lists: An anterior spinal fusion list and a posterior spinal fusion list. Assignment to one of the combined spinal fusion MS–DRGs requires that a code from each list be reported.

The seven new ICD–10–PCS procedure codes currently included in the posterior spinal fusion list for MS–DRGs 453, 454, and 455 are shown in the table below.

ICD–10–PCS code	Code description
XRG6092	Fusion of thoracic vertebral joint using nanotextured surface interbody fusion device, open approach, new technology group 2.
XRG7092	Fusion of 2 to 7 thoracic vertebral joints using nanotextured surface interbody fusion device, open approach, new technology group 2.
XRG8092	Fusion of 8 or more thoracic vertebral joints using nanotextured surface interbody fusion device, open approach, new technology group 2.
XRGA092	Fusion of thoracolumbar vertebral joint using nanotextured surface interbody fusion device, open approach, new technology group 2.
XRGB092	Fusion of lumbar vertebral joint using nanotextured surface interbody fusion device, open approach, new technology group 2.
XRGC092	Fusion of 2 or more lumbar vertebral joints using nanotextured surface interbody fusion device, open approach, new technology group 2.
XRGD092	Fusion of lumbosacral joint using nanotextured surface interbody fusion device, open approach, new technology group 2.

We note that the remaining three new procedure codes are accurately reflected in the anterior spinal fusion list; that is, ICD–10–PCS code XRG1092 (Fusion of cervical vertebral joint using nanotextured surface interbody fusion device, open approach, new technology group 2); ICD–10–PCS code XRG2092 (Fusion of 2 or more cervical vertebral joints using nanotextured surface interbody fusion device, open approach, new technology group 2); and ICD–10–PCS code XRG4092 (Fusion of cervicothoracic vertebral joint using nanotextured surface interbody fusion device, open approach, new technology group 2).

The seven procedure codes currently included in the posterior spinal fusion list describe an anterior spinal fusion by use of the interbody fusion device. In an interbody fusion, the anterior column of the spine is being fused. We stated in the proposed rule that the results of our review of these procedure codes discussed below and the advice of our clinical advisors support moving the seven procedure codes from the posterior spinal fusion list to the anterior spinal fusion list in the GROUPER logic for MS–DRGs 453, 454, and 455. We stated that this will improve clinical accuracy and allow appropriate assignment to these MS–DRGs when both an anterior and posterior spinal fusion is performed.

During our review of the spinal fusion codes using a nanotextured surface interbody fusion device in MS–DRGs 453, 454, and 455, we identified 149 additional procedure codes that should be moved from the posterior spinal fusion list to the anterior spinal fusion list. These codes describe spinal fusion of the anterior column with a posterior approach. As mentioned earlier, the logic for MS–DRGs 453, 454, and 455 is dependent upon a code from the anterior spinal fusion list and a code from the posterior spinal fusion list. Spinal fusion codes involving the anterior column should be included on the anterior spinal fusion list only. In the FY 2018 IPPS/LTCH PPS proposed rule, we proposed to move the 149 ICD–10–PCS procedure codes listed in Table 6P.3a. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) from the posterior spinal fusion list to the anterior spinal fusion list in MS–DRGs 453, 454, and 455.

In addition, we also identified 33 ICD–10–PCS procedure codes in the posterior spinal fusion list in MS–DRGs 453, 454, and 455 that describe an interbody fusion device in the posterior column and, therefore, are not considered clinically valid spinal fusion procedures. These procedure codes are shown in the table below.

ICD–10–PCS code	Code description
0RG00A1	Fusion of occipital-cervical joint with interbody fusion device, posterior approach, posterior column, open approach.
0RG03A1	Fusion of occipital-cervical joint with interbody fusion device, posterior approach, posterior column, percutaneous approach.
0RG04A1	Fusion of occipital-cervical joint with interbody fusion device, posterior approach, posterior column, percutaneous endoscopic approach.
0RG10A1	Fusion of cervical vertebral joint with interbody fusion device, posterior approach, posterior column, open approach.
0RG13A1	Fusion of cervical vertebral joint with interbody fusion device, posterior approach, posterior column, percutaneous approach.
0RG14A1	Fusion of cervical vertebral joint with interbody fusion device, posterior approach, posterior column, percutaneous endoscopic approach.
0RG20A1	Fusion of 2 or more cervical vertebral joints with interbody fusion device, posterior approach, posterior column, open approach.
0RG23A1	Fusion of 2 or more cervical vertebral joints with interbody fusion device, posterior approach, posterior column, percutaneous approach.
0RG24A1	Fusion of 2 or more cervical vertebral joints with interbody fusion device, posterior approach, posterior column, percutaneous endoscopic approach.
0RG40A1	Fusion of cervicothoracic vertebral joint with interbody fusion device, posterior approach, posterior column, open approach.
0RG43A1	Fusion of cervicothoracic vertebral joint with interbody fusion device, posterior approach, posterior column, percutaneous approach.

ICD–10–PCS code	Code description
0RG44A1	Fusion of cervicothoracic vertebral joint with interbody fusion device, posterior approach, posterior column, percutaneous endoscopic approach.
0RG60A1	Fusion of thoracic vertebral joint with interbody fusion device, posterior approach, posterior column, open approach.
0RG63A1	Fusion of thoracic vertebral joint with interbody fusion device, posterior approach, posterior column, percutaneous approach.
0RG64A1	Fusion of thoracic vertebral joint with interbody fusion device, posterior approach, posterior column, percutaneous endoscopic approach.
0RG70A1	Fusion of 2 to 7 thoracic vertebral joints with interbody fusion device, posterior approach, posterior column, open approach.
0RG73A1	Fusion of 2 to 7 thoracic vertebral joints with interbody fusion device, posterior approach, posterior column, percutaneous approach.
0RG74A1	Fusion of 2 to 7 thoracic vertebral joints with interbody fusion device, posterior approach, posterior column, percutaneous endoscopic approach.
0RG80A1	Fusion of 8 or more thoracic vertebral joints with interbody fusion device, posterior approach, posterior column, open approach.
0RG83A1	Fusion of 8 or more thoracic vertebral joints with interbody fusion device, posterior approach, posterior column, percutaneous approach.
0RG84A1	Fusion of 8 or more thoracic vertebral joints with interbody fusion device, posterior approach, posterior column, percutaneous endoscopic approach.
0RGA0A1	Fusion of thoracolumbar vertebral joint with interbody fusion device, posterior approach, posterior column, open approach.
0RGA3A1	Fusion of thoracolumbar vertebral joint with interbody fusion device, posterior approach, posterior column, percutaneous approach.
0RGA4A1	Fusion of thoracolumbar vertebral joint with interbody fusion device, posterior approach, posterior column, percutaneous endoscopic approach.
0SG00A1	Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, posterior column, open approach.
0SG03A1	Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, posterior column, percutaneous approach.
0SG04A1	Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, posterior column, percutaneous endoscopic approach.
0SG10A1	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, posterior approach, posterior column, open approach.
0SG13A1	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, posterior approach, posterior column, percutaneous approach.
0SG14A1	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, posterior approach, posterior column, percutaneous endoscopic approach.
0SG30A1	Fusion of lumbosacral joint with interbody fusion device, posterior approach, posterior column, open approach.
0SG33A1	Fusion of lumbosacral joint with interbody fusion device, posterior approach, posterior column, percutaneous approach.
0SG34A1	Fusion of lumbosacral joint with interbody fusion device, posterior approach, posterior column, percutaneous endoscopic approach.

In the proposed rule, we proposed to delete these 33 procedure codes from MS–DRGs 453, 454, and 455 for FY 2018. We also noted that some of the above listed codes also may be included in the logic for MS–DRGs 456, 457, and 458 (Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusions with MCC, with CC or without CC/MCC, respectively), MS–DRGs 459 and 460 (Spinal Fusion Except Cervical with MCC and without MCC, respectively), and MS–DRGs 471, 472, and 473 (Cervical Spinal Fusion with MCC, with CC and without CC/MCC, respectively). Therefore, we proposed to delete the 33 procedure codes from the logic for those spinal fusion MS–DRGs as well. In addition, we proposed to delete the 33 procedure codes from the ICD–10–PCS classification as shown in Table 6D.—Invalid Procedure Codes associated with the proposed rule (which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*).

In summary, we invited public comments on our proposal to move the seven procedure codes describing spinal fusion using a nanotextured surface interbody fusion device from the posterior spinal fusion list to the anterior spinal fusion list in the GROUPER logic for MS–DRGs 453, 454, and 455. We also invited public comments on our proposal to move the 149 procedure codes describing spinal fusion of the anterior column with a posterior approach from the posterior spinal fusion list to the anterior spinal fusion list in the GROUPER logic for MS–DRGs 453, 454, and 455. In addition, we invited public comments on our proposal to delete the 33 procedure codes describing spinal fusion of the posterior column with an interbody fusion device from MS–DRGs 453, 454, 455, 456, 457, 458, 459, 460, 471, 472, and 473, as well as from the ICD–10–PCS classification.

Comment: Many commenters supported CMS' proposals related to the combined anterior/posterior spinal fusion MS–DRGs, including (1) support to move the seven procedure codes describing spinal fusion using a nanotextured surface interbody fusion device from the posterior spinal fusion list to the anterior spinal fusion list in the GROUPER logic for MS–DRGs 453, 454, and 455; (2) support to move the 149 procedure codes describing spinal fusion of the anterior column with a posterior approach from the posterior spinal fusion list to the anterior spinal fusion list in the GROUPER logic for MS–DRGs 453, 454, and 455; and (3) to delete the 33 procedure codes describing spinal fusion of the posterior column with an interbody fusion device from MS–DRGs 453, 454, 455, 456, 457, 458, 459, 460, 471, 472, and 473, as well as from the ICD–10–PCS classification.

Response: We appreciate the commenters' support.

Comment: One commenter expressed concern with the proposal to move the 149 ICD–10–PCS procedure codes describing spinal fusion of the anterior column with a posterior approach that are currently on the posterior spinal fusion list to the anterior spinal fusion list and indicated that the proposed decrease in payment weights for this set of MS–DRGs would affect providers' ability to continue treating patients necessitating these procedures. The commenter noted that results from an

independent analysis it had conducted demonstrated that reassignment of these procedure codes and the resulting combinations for anterior/posterior spinal fusion are less costly in comparison to other procedure combinations assigned to MS–DRGs 453, 454 and 455. This commenter acknowledged that ICD–10 coded claims data enable CMS to make important clinical refinements to the ICD–10 MS–DRGs. However, the commenter stated, the resource homogeneity of the MS–DRGs may be adversely affected. The commenter also stated that it understood that the greater specificity of ICD–10 codes will naturally lead to changes in the MS–DRG weights and assignments and that these changes should generally lead to improved payment accuracy within the IPPS. However, the commenter pointed out that not all weight fluctuations occurring during the early stages of the ICD–10 transition necessarily reflect improvements in coding and payment. The commenter stated that providers should not be subject to such disruptive fluctuations in their payments in a single year. The commenter recommended applying a cap to the decline in the MS–DRG payment weights relative to the FY 2017 payment weights until the fluctuations in the number of cases and the case weights can be determined and Medicare's utilization reflects hospital adaptation to ICD–10 coding. The commenter stated that applying a cap would allow CMS to move forward with the proposal to move the 149 ICD–10–PCS spinal fusion procedure codes from the posterior spinal fusion list to the anterior spinal fusion list.

Response: We acknowledge the commenter's concerns and appreciate the analysis that was conducted. In response to the recommendation that we implement a cap to the decline in the MS–DRG payment weights relative to the FY 2017 payment weights, we refer readers to section II.G. of the preamble of this FY 2018 IPPS/LTCH PPS final rule for further discussion regarding recalibration of the FY 2018 MS–DRG relative weights, including our response to comments requesting a transition period for substantial reductions in relative weights in order to facilitate payment stability.

We also believe it is important to be able to fully evaluate the MS–DRGs for which all spinal fusion procedures are currently assigned under ICD–10 with additional claims data. Therefore, in response to the public comments received, we are planning to review the ICD–10 logic for the MS–DRGs where procedures involving spinal fusion are currently assigned for FY 2019.

After consideration of the public comments we received, we are finalizing our proposal to: (1) Move the seven procedure codes describing spinal fusion using a nanotextured surface interbody fusion device from the posterior spinal fusion list to the anterior spinal fusion list in the GROUPER logic for MS–DRGs 453, 454, and 455; (2) move the 149 procedure codes describing spinal fusion of the anterior column with a posterior approach from the posterior spinal fusion list to the anterior spinal fusion list in the GROUPER logic for MS–DRGs 453, 454, and 455; and (3) delete the 33 procedure codes describing spinal fusion of the posterior column with an interbody fusion device from MS–DRGs 453, 454, 455, 456, 457, 458, 459, 460, 471, 472, and 473, as well as from the ICD–10–PCS classification for FY 2018.

6. MDC 14 (Pregnancy, Childbirth and the Puerperium)

a. Vaginal Delivery and Complicating Diagnoses

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56854), we noted that the code list as displayed in the ICD–10 MS–DRG Version 33 Definitions Manual for MS–DRG 774 (Vaginal Delivery with Complicating Diagnoses) required further analysis to clarify what constitutes a vaginal delivery to satisfy the ICD–10 MS–DRG logic. We stated our plans to conduct further analysis of the diagnosis code lists in MS–DRG 774 for FY 2018. We stated in the proposed rule that we believe that the Version 34 Definitions Manual and GROUPER logic for MS–DRG 774 continues to require additional analysis to determine how best to classify a vaginal delivery. For example, under MS–DRG 774, the Definitions Manual currently states that three conditions must be met, the first of which is a vaginal delivery. To satisfy this first condition, codes that describe conditions or circumstances from among three lists of codes must be reported. The first list is comprised of ICD–10–CM diagnosis codes that may be reported as a principal diagnosis or a secondary diagnosis. These diagnosis codes describe conditions in which it is assumed that a vaginal delivery has occurred. The second list of codes is a list of ICD–10–PCS procedure codes that also describe circumstances in which it is assumed that a vaginal delivery occurred. The third list of codes identifies diagnoses describing the outcome of the delivery. Therefore, if any code from one of those three lists is reported, the first condition (vaginal delivery) is considered to be met for assignment to MS–DRG 774.

As discussed in the proposed rule, our continued concern with the first list of ICD–10–CM diagnosis codes as currently displayed in the Definitions Manual under the first condition is that not all of the conditions necessarily reflect that a vaginal delivery occurred. Several of the diagnosis codes listed could also reflect that a cesarean delivery occurred. For example, ICD–10–CM diagnosis code O10.02 (Pre-existing essential hypertension complicating childbirth) does not specify that a vaginal delivery took place; yet it is included in the list of conditions that may be reported as a principal diagnosis or a secondary diagnosis in the GROUPER logic for a vaginal delivery. The reporting of this code also could be appropriate for a delivery that occurred by cesarean section.

As noted earlier, the second list of codes for the first condition are comprised of ICD–10–PCS procedure codes. As we stated in the proposed rule, while we agree that the current list of procedure codes in MS–DRG 774 may appropriately describe that a vaginal delivery occurred, we also believe this list could be improved and warrants closer review.

The third list of codes for the first condition in MS–DRG 774 includes conditions describing the outcome of the delivery that would be reported as secondary diagnoses. Similar to concerns with the first list of codes, we believe the conditions do not necessarily reflect that a vaginal delivery occurred because they also can be reported on claims where a cesarean delivery occurred.

For the second condition in MS–DRG 774 to be met, diagnosis codes that are identified as a complicating diagnosis from among two lists may be reported. The first list is comprised of ICD–10–CM diagnosis codes that may be reported as a principal or secondary diagnosis. The second list is comprised of ICD–10–CM diagnosis codes that may be reported as a secondary diagnosis. Currently, there is only one code listed under the secondary diagnosis list. We have concerns with these lists and what is classified as a complicating diagnosis when reviewing the code lists for this and other MS–DRGs that use that logic in MDC 14.

For the third condition in MS–DRG 774 to be met, a limited set of O.R. procedures, including both extensive and nonextensive procedures, are listed. We have concerns with this third condition as being needed to satisfy the logic for a vaginal delivery MS–DRG.

In summary, the MS–DRG logic involving a vaginal delivery under MDC 14 is technically complex as a result of the requirements that must be met to satisfy assignment to the affected MS–DRGs. As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19834), upon review and discussion, our clinical advisors recommended, and we agreed, that we should solicit public comments on further refinement to the following four MS–DRGs related to vaginal delivery: MS–DRG 767 (Vaginal Delivery with Sterilization and/or D&C); MS–DRG 768 (Vaginal Delivery with O.R. Procedure Except Sterilization and/or D&C); MS–DRG 774 (Vaginal Delivery with Complicating Diagnosis); and MS–DRG 775 (Vaginal Delivery without Complicating Diagnosis).

In addition, our clinical advisors agreed that we should solicit public comments on further refinement to the conditions defined as a complicating diagnosis in MS–DRG 774 and MS–DRG 781 (Other Antepartum Diagnoses with Medical Complications).

Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19834), we solicited public comments on which diagnosis or procedure codes, or both, should be considered in the logic to identify a vaginal delivery and which diagnosis codes should be considered in the logic to identify a complicating diagnosis. As MS–DRGs 767, 768, 774, 775, and 781 incorporate one or both aspects (vaginal delivery or complicating diagnosis), we stated that public comments that we receive from this solicitation will be helpful in determining what proposed revisions to the current logic should be made. We indicated that we will review public comments received in response to this solicitation as we continue to evaluate these areas under MDC 14 and, if warranted, we would propose refinements for FY 2019. We requested that all comments be directed to the CMS MS–DRG Classification Change Request Mailbox located at: *MSDRG ClassificationChange@cms.hhs.gov* by November 1, 2017.

Comment: Commenters agreed that the MS–DRG logic for a vaginal delivery under MDC 14 is technically complex. One commenter stated its intention to provide separate comments related to the solicitation in accordance with the November 1, 2017 deadline.

Response: We thank the commenters for their acknowledgment of the complexity with the GROUPER logic for vaginal deliveries under MDC 14 and for their support and consideration of these issues as we continue to consider possible refinement to the logic. We will review the comments received in response to the solicitation as we continue to evaluate this area and, if warranted, we will propose refinements for the FY 2019 rulemaking.

b. MS–DRG 998 (Principal Diagnosis Invalid as Discharge Diagnosis)

The logic for MS–DRG 998 (Principal Diagnosis Invalid as Discharge Diagnosis) currently includes a list of diagnoses that are considered inappropriate for reporting as a principal diagnosis on an inpatient hospital claim. In other words, these conditions would reasonably be expected not to necessitate an inpatient admission. Examples of these diagnosis codes include what are referred to as the ''Supervision of pregnancy'' codes, as well as pregnancy, maternal care and fetal related codes with an ''unspecified trimester''. We refer the reader to the ICD–10 Version 34 Definitions Manual which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2017-IPPS-Final-Rule-Home-Page-Items/FY2017-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending* for the complete list of diagnosis codes in MS–DRG 998 under MDC 14.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56840 through 56841), there was discussion regarding the supervision of ''high-risk'' pregnancy codes, including elderly primigravida and multigravida specifically, with regard to removing them from the Unacceptable principal diagnosis edit code list in the Medicare Code Editor (MCE). After consultation with the staff at the CDC's NCHS, we learned that the FY 2017 ICD–10–CM Official Guidelines for Coding and Reporting were updated to explain appropriate coding for this set of codes. As a result, the codes describing supervision of high-risk pregnancy (and other supervision of pregnancy codes) remained on the Unacceptable principal diagnosis edit code list in the MCE. Therefore, the MCE code edit is consistent with the logic of MS–DRG 998 (Principal Diagnosis Invalid as Discharge Diagnosis) for these supervision of pregnancy codes.

However, as a result of our review and consultation with our clinical advisors regarding the ''unspecified trimester'' codes in MS–DRG 998, as discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19835), we determined that there are more appropriate MS–DRG assignments for this set of codes. Although it may seem unlikely that a patient would be admitted and ultimately discharged or transferred without the caregiver or medical personnel having any further knowledge of the exact trimester, it is conceivable that a situation may present itself. For example, the pregnant patient may be from out of town or unable to communicate effectively. The fact that the specific trimester is not known or documented does not preclude the resources required to care for the patient with the particular diagnosis.

Therefore, as shown in Table 6P.3b. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*), we proposed to remove the 314 ICD–10–CM diagnosis codes identified with ''unspecified trimester'' from MS–DRG 998 and reassign them to the MS–DRGs in which their counterparts (first trimester, second trimester, or third trimester) are currently assigned as specified in Column C. We stated that this would enable more appropriate MS–DRG assignments and payment for these cases. We invited public comments on our proposal.

Comment: Commenters agreed with the proposal to remove the 314 ICD–10–CM diagnosis codes identified with ''unspecified trimester'' from MS–DRG 998 and reassign them to the MS–DRGs in which their counterparts (first trimester, second trimester, or third trimester) are currently assigned. However, one commenter disagreed with the proposal and noted that lack of documentation that specifies the trimester on an inpatient record is representative of poor documentation and should not be acceptable for valid MS–DRG assignment. This commenter believed that the trimester could reasonably be determined or estimated, despite the patient's circumstances, such as being from out of town or unable to communicate effectively.

Response: We appreciate the commenters' support. In response to the commenter who did not support our proposal, we acknowledge that any diagnosis involving the term ''unspecified'' in a code title can appear to be the result of poor documentation. However, there are several instances across the ICD–10 MS–DRG GROUPER logic where an ''unspecified'' principal diagnosis leads to a valid MS–DRG assignment as a result of the resources and/or complexities involved regarding the condition itself. The ''unspecified trimester'' diagnoses involved in the proposal included significant clinical conditions such as eclampsia, preexisting hypertensive heart disease, and cerebral venous thrombosis, to

name a few. The fact that the trimester is not specified does not preclude the significance of these conditions nor the resources involved in caring for the patients with these conditions. Therefore, while we encourage providers to continue to focus efforts on improving their respective facilities medical record documentation practices, we also believe that the MS–DRG assignment should appropriately reflect the resources involved in evaluating and caring for these patients.

After consideration of the public comments we received, we are finalizing our proposal to remove the 314 ICD–10–CM diagnosis codes identified with ''unspecified trimester'' from MS–DRG 998 as shown in Table 6P.3b. associated with this final rule (which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* and reassign them to the MS–DRGs in which their counterparts (first trimester, second trimester, or third trimester) are currently assigned as specified in Column C, in the ICD–10 MS–DRGs Version 35, effective October 1, 2017.

c. MS–DRG 782 (Other Antepartum Diagnoses Without Medical Complications)

The following three ICD–10–CM diagnosis codes are currently on the principal diagnosis list for the MS–DRG 782 (Other Antepartum Diagnoses without Medical Complications) logic.

ICD–10–CM code	Code description
O09.41	Supervision of pregnancy with grand multiparity, first trimester.
O09.42	Supervision of pregnancy with grand multiparity, second trimester.
O09.43	Supervision of pregnancy with grand multiparity, third trimester.

It was brought to our attention that these codes also are included in the MCE Unacceptable principal diagnosis code edit list. As discussed in section II.F.6.b. of the preamble of the FY 2018 IPPS/LTCH PPS proposed rule, the supervision of pregnancy codes are accurately reflected in the MCE code edit list for Unacceptable principal diagnosis. Therefore, we stated that it is not appropriate to include the three above listed codes in MS–DRG 782.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19835), we proposed to remove the three codes describing supervision of pregnancy from MS–DRG 782 and reassign them to MS–DRG 998 (Principal Diagnosis Invalid as Discharge Diagnosis) to reflect a more appropriate MS–DRG assignment. We invited public comments on our proposal.

Comment: Commenters supported the proposal to remove the three codes (ICD–10–CM diagnosis codes O09.41, O09.42 and O09.43) describing supervision of pregnancy and reassign them to a more appropriate MS–DRG assignment.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to remove ICD–10–CM diagnosis codes O09.41, O09.42 and O09.43, which describe supervision of pregnancy, from MS–DRG 782 and reassign them to MS–DRG 998 (Principal Diagnosis Invalid as Discharge Diagnosis) in the ICD–10 MS–DRGs Version 35, effective October 1, 2017.

d. Shock During or Following Labor and Delivery

We received a request to review ICD–10–CM diagnosis code O75.1 (Shock during or following labor and delivery), which is currently assigned to MS–DRG 774 (Vaginal Delivery with Complicating Diagnosis), MS–DRG 767 (Vaginal Delivery with Sterilization and/or D&C), and MS–DRG 768 (Vaginal Delivery with O.R. Procedure Except Sterilization and/or D&C).

The requestor provided an example of a patient that delivered at Hospital A and was transferred to Hospital B for specialized care related to the diagnosis of shock. The claim for Hospital B resulted in assignment to a delivery MS–DRG, despite the fact that a delivery did not occur during that hospitalization. The requestor noted that, by not reporting the diagnosis code for shock, the claim grouped to a postpartum MS–DRG and recommended that we evaluate the issue further.

Our analysis initially involved reviewing the GROUPER logic for MS–DRGs 774, 767 and 768. As discussed in section II.F.14.a. of the preamble of the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19835 through 19836) and this final rule, the GROUPER logic for classification and assignment to MS–DRG 774 requires that three conditions must be met, the first of which is a vaginal delivery. Similar GROUPER logic applies for assignment to MS–DRGs 767 and 768, except that only two conditions must be met, with the first condition being a vaginal delivery. For each of these three MS–DRGs, to satisfy the first condition, one code that describes a condition or circumstance from among the three separate lists of codes must be reported. The first list is comprised of ICD–10–CM diagnosis codes that may be reported as a principal or secondary diagnosis. These diagnosis codes describe conditions in which it is assumed that a vaginal delivery has occurred. Among this first list is ICD–10–CM diagnosis code O75.1, which is included in the GROUPER logic for MS–DRGs 774, 767 and 768 (under the first condition-vaginal delivery). We refer readers to the ICD–10 MS–DRG Version 34 Definitions Manual located via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2017-IPPS-Final-Rule-Home-Page-Items/FY2017-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending* for documentation of the GROUPER logic associated with these MS–DRGs.

In addition, in MS–DRG 774, to satisfy the second condition, diagnosis codes that are identified as a complicating diagnosis from among two lists may be reported. The first list is comprised of ICD–10–CM diagnosis codes that may be reported as a principal or secondary diagnosis. The second list is comprised of ICD–10–CM diagnosis codes that may be reported as a secondary diagnosis. Currently, there is only one code listed under the secondary diagnosis list.

Next, our analysis involved reviewing the GROUPER logic for assignment to post-partum MS–DRG 769 (Postpartum and Post Abortion Diagnoses with Major Procedure) and MS–DRG 776 (Postpartum and Post Abortion Diagnoses without O.R. Procedure). The GROUPER logic for these postpartum

MS–DRGs requires that a principal diagnosis be reported from a list of several conditions, such as those following pregnancy, those complicating the puerperium, conditions that occurred during or following delivery and conditions associated with lactation disorders. For assignment to MS–DRG 769, the GROUPER logic also requires that a major procedure be reported in addition to a principal diagnosis from the list of conditions.

We stated in the proposed rule that as a result of our analysis, we agree with the requestor that ICD–10–CM diagnosis code O75.1 should be added to the GROUPER logic for assignment to the postpartum MS–DRGs. This diagnosis code is consistent with other diagnosis codes structured within the GROUPER logic for assignment to MS–DRGs 769 and 776, and clearly represents a post-partum diagnosis with the terminology ''during or following labor and delivery'' in the title. We stated that we believe that adding this diagnosis code to the postpartum MS–DRGs will enable more appropriate MS–DRG assignment for cases where a delivery did not occur.

Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19835 through 19836), we proposed the following:

- Removing ICD–10–CM diagnosis code O75.1 from the list of principal or secondary diagnosis under the first condition-vaginal delivery GROUPER logic in MS–DRGs 774, 767, and 768;
- Moving ICD–10–CM diagnosis code O75.1 from the list of principal or secondary diagnosis under the second condition-complicating diagnosis for MS–DRG 774 to the secondary diagnosis list only; and
- Adding ICD–10–CM diagnosis code O75.1 to the principal diagnosis list GROUPER logic in MS–DRGs 769 and 776.

We invited public comments on our proposals.

Comment: Many commenters supported all of CMS' proposals involving diagnosis code O75.1 and MS–DRGs 767, 768, 769, 774, and 776.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing the following in the ICD–10 MS–DRGs Version 35, effective October 1, 2017:

- Removing ICD–10–CM diagnosis code O75.1 from the list of principal or secondary diagnosis under the first condition-vaginal delivery GROUPER logic in MS–DRGs 774, 767, and 768;
- Moving ICD–10–CM diagnosis code O75.1 from the list of principal or secondary diagnosis under the second condition-complicating diagnosis for MS–DRG 774 to the secondary diagnosis list only; and
- Adding ICD–10–CM diagnosis code O75.1 to the principal diagnosis list GROUPER logic in MS–DRGs 769 and 776.

7. MDC 15 (Newborns and Other Neonates With Conditions Originating in Perinatal Period): Observation and Evaluation of Newborn

We received a request to add the ICD–10–CM diagnosis codes describing observation and evaluation of newborns for suspected conditions that are ruled out to MS–DRG 795 (Normal Newborn). The 14 diagnosis codes describing observation and evaluation of newborn for suspected conditions ruled out are displayed in the table below.

ICD–10–CM code	Code description
Z05.0	Observation and evaluation of newborn for suspected cardiac condition ruled out.
Z05.1	Observation and evaluation of newborn for suspected infectious condition ruled out.
Z05.2	Observation and evaluation of newborn for suspected neurological condition ruled out.
Z05.3	Observation and evaluation of newborn for suspected respiratory condition ruled out.
Z05.41	Observation and evaluation of newborn for suspected genetic condition ruled out.
Z05.42	Observation and evaluation of newborn for suspected metabolic condition ruled out.
Z05.43	Observation and evaluation of newborn for suspected immunologic condition ruled out.
Z05.5	Observation and evaluation of newborn for suspected gastrointestinal condition ruled out.
Z05.6	Observation and evaluation of newborn for suspected genitourinary condition ruled out.
Z05.71	Observation and evaluation of newborn for suspected skin and subcutaneous tissue condition ruled out.
Z05.72	Observation and evaluation of newborn for suspected musculoskeletal condition ruled out.
Z05.73	Observation and evaluation of newborn for suspected connective tissue condition ruled out.
Z05.8	Observation and evaluation of newborn for other specified suspected condition ruled out.
Z05.9	Observation and evaluation of newborn for unspecified suspected condition ruled out.

The requestor expressed concern that currently when one of these ruled out. codes is added to a newborn encounter with a principal diagnosis described by ICD–10–CM code Z38.00 (Single liveborn infant, delivered vaginally), the case is assigned to MS–DRG 794 (Neonate with Other Significant Problems). The requestor stated that this assignment appears to be in error and that the assignment should instead be to MS–DRG 795 (Normal Newborn).

As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19836), we reviewed Section I.C.16.b. of the 2017 ICD–10–CM Official Guidelines for Coding and Reporting which includes the following instructions for the diagnosis codes listed in the table above:

- Assign a code from category Z05 (Observation and evaluation of newborns and infants for suspected conditions ruled out.) to identify those instances when a healthy newborn is evaluated for a suspected condition that is determined after study not to be present. Do not use a code from category Z05 when the patient has identified signs or symptoms of a suspected problem; in such cases code the sign or symptom.
- A code from category Z05 may also be assigned as a principal or first-listed code for readmissions or encounters when the code from category Z38 code no longer applies. Codes from category Z05 are for use only for healthy newborns and infants for which no condition after study is found to be present.
- A code from category Z05 is to be used as a secondary code after the code from category Z38, Liveborn infants according to place of birth and type of delivery.

We stated in the proposed rule that after review of the guidelines and discussion with our clinical advisors, we agree with the requestor that the assignment of these codes to MS–DRG

794 is not accurate because the assignment incorrectly labels the newborns as having a significant problem when the condition does not truly exist. We stated that we and our clinical advisors also agree that the above list of diagnosis codes should be added to MS–DRG 795. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19836), we proposed to add the 14 diagnosis codes describing observation and evaluation of newborns for suspected conditions that are ruled out listed in the table above to the GROUPER logic for MS–DRG 795. We invited public comments on our proposals.

Comment: Commenters supported the proposal to add the 14 diagnosis codes describing observation and evaluation of newborn for suspected conditions ruled out to the MS–DRG logic for normal newborn.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add the 14 diagnosis codes describing observation and evaluation of newborns for suspected conditions that are ruled out listed in the table above to the GROUPER logic for MS–DRG 795 (Normal newborn) in the ICD–10 MS–DRGs Version 35, effective October 1, 2017.

8. MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs): Complication Codes

We received a request to examine the ICD–10–CM diagnosis codes in the T85.8-series of codes that describe other specified complications of internal prosthetic devices, implants and grafts, not elsewhere classified and their respective MS–DRG assignments. According to the requestor, the 7th character values in this series of codes impact the MS–DRG assignment under MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs) and MDC 23 (Factors Influencing Health Status & Other Contacts with Health Services) that have resulted in inconsistencies (that is, shifts) between the MS–DRG assignments under Version 33 and Version 34 of the ICD–10 MS–DRGs.

Under ICD–10–CM, diagnosis codes in the range of S00 through T88 require a 7th character value of ''A-'' initial encounter, ''D-''subsequent encounter, or ''S-''sequela to identify if the patient is undergoing active treatment for a condition. For complication codes, active treatment refers to treatment for the condition described by the code, even though it may be related to an earlier precipitating problem.

The requestor suggested that the following list of diagnosis codes with the 7th character ''A'' (initial encounter) may have been inadvertently assigned to the GROUPER logic in the list of diagnoses (*Assignment of Diagnosis Codes)* under MDC 23 because when one of these diagnosis codes was reported with an O.R. procedure, the requestor found claims grouping to MS–DRG 939, 940, or 941 (O.R. Procedures with Diagnoses of Other Contact with Health Services with MCC, with CC and without CC/MCC, respectively) that had previously grouped to MDC 21 under Version 33 of the ICD–10 MS–DRGs. The requestor also suggested these codes may have been inadvertently assigned to the GROUPER logic list of principal diagnoses for MS–DRGs 949 and 950 (Aftercare with CC/MCC and without CC/MCC, respectively) under MDC 23 because it found claims that grouped to these MS–DRGs (949 and 950) when one of the following diagnosis codes was reported as a principal diagnosis that had previously grouped to MDC 21 under Version 33 of the ICD–10 MS–DRGs.

ICD–10–CM diagnosis code	Code description
T85.818A	Embolism due to other internal prosthetic devices, implants and grafts, initial encounter.
T85.828A	Fibrosis due to other internal prosthetic devices, implants and grafts, initial encounter.
T85.838A	Hemorrhage due to other internal prosthetic devices, implants and grafts, initial encounter.
T85.848A	Pain due to other internal prosthetic devices, implants and grafts, initial encounter.
T85.858A	Stenosis due to other internal prosthetic devices, implants and grafts, initial encounter.
T85.868A	Thrombosis due to other internal prosthetic devices, implants and grafts, initial encounter.
T85.898A	Other specified complication of other internal prosthetic devices, implants and grafts, initial encounter.

The requestor believed that the above list of diagnosis codes with the 7th character ''A'' (initial encounter) would be more appropriately assigned under MDC 21 to MS–DRGs 919, 920, and 921 (Complications of Treatment with MCC, with CC and without CC/MCC, respectively), according to its review of the 2017 Official Coding Guidelines for use of the 7th character and assignment of other diagnoses of associated complications of care. The requestor also noted that these codes were new, effective October 1, 2016 (FY 2017), and the predecessor codes grouped to MS–DRGs 919, 920, and 921 in MDC 21 under Version 33 of the ICD–10 MS–DRGs in FY 2016.

In addition, the requestor suggested that the following list of diagnosis codes with the 7th character ''D'' (subsequent encounter) may have been inadvertently assigned to the GROUPER logic list of principal diagnoses for MS–DRG 919, 920, or 921 in MDC 21. The requestor noted that these codes were new, effective October 1, 2016 (FY 2017), and the predecessor codes grouped to MS–DRGs 949 and 950 (Aftercare with CC/MCC and without CC/MCC, respectively) in MDC 23 under Version 33 of the ICD–10 MS–DRGs in FY 2016.

ICD–10–CM diagnosis code	Code description
T85.810D	Embolism due to nervous system prosthetic devices, implants and grafts, subsequent encounter.
T85.820D	Fibrosis due to nervous system prosthetic devices, implants and grafts, subsequent encounter.
T85.830D	Hemorrhage due to nervous system prosthetic devices, implants and grafts, subsequent encounter.
T85.840D	Pain due to nervous system prosthetic devices, implants and grafts, subsequent encounter.
T85.850D	Stenosis due to nervous system prosthetic devices, implants and grafts, subsequent encounter.
T85.860D	Thrombosis due to nervous system prosthetic devices, implants and grafts, subsequent encounter.
T85.890D	Other specified complication of nervous system prosthetic devices, implants and grafts, subsequent encounter.

The requestor also suggested that the following list of additional diagnosis codes with the 7th character ''D'' (subsequent encounter) may have been inadvertently assigned to the GROUPER logic list of principal diagnoses for MS–DRGs 922 and 923 (Other Injury, Poisoning and Toxic Effect with MCC and without MCC, respectively) also under MDC 21. The requestor noted these codes were also new, effective October 1, 2016 (FY 2017) and that the predecessor codes grouped to MS–DRGs 949 and 950 in MDC 23 under Version 33 of the ICD–10 MS–DRGs in FY 2016.

ICD–10–CM diagnosis code	Code description
T85.818D	Embolism due to other internal prosthetic devices, implants and grafts, subsequent encounter.
T85.828D	Fibrosis due to other internal prosthetic devices, implants and grafts, subsequent encounter.
T85.838D	Hemorrhage due to other internal prosthetic devices, implants and grafts, subsequent encounter.
T85.848D	Pain due to other internal prosthetic devices, implants and grafts, subsequent encounter.
T85.858D	Stenosis due to other internal prosthetic devices, implants and grafts, subsequent encounter.
T85.868D	Thrombosis due to other internal prosthetic devices, implants and grafts, subsequent encounter.
T85.898D	Other specified complication of other internal prosthetic devices, implants and grafts, subsequent encounter.

The requestor believed that the lists of diagnosis codes above with 7th character ''D'' (subsequent encounter) would be more appropriately assigned to MS–DRGs 949 and 950 under MDC 23, according to its review of the 2017 Official Coding Guidelines for use of the 7th character and assignment of other diagnoses of associated complications of care.

As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19837 through 19839), we ran test cases to determine if we could duplicate the requestor's findings with regard to the shifts in MS–DRG assignment between Version 33 and Version 34 of the ICD–10 MS–DRGs. Results of our review were consistent with the requestor's findings. We found that the T85.8- series of diagnosis codes with the 7th character of ''A'' (initial encounter) and 7th character of ''D'' (subsequent encounter) were inadvertently assigned to the incorrect MDC for Version 34 of the ICD–10 MS–DRGs, which led to inconsistencies (MS–DRG shifts) when compared to Version 33 of the ICD–10 MS–DRGs. Our analysis also included review of all of the diagnosis codes in the T85.8- series and their current MDC and MS–DRG assignments, as well as review of the 2017 Official Coding Guidelines for use of the 7th character and assignment of other diagnoses of associated complications of care. Based on the results of our review, we agreed with the requestor's findings.

In addition, we identified the following list of diagnosis codes with the 7th character ''S'' (sequela) that appear to have been inadvertently assigned to MS–DRGs 949 and 950 in MDC 23 rather than MDC 21 in MS–DRGs 922 and 923 (Other Injury, Poisoning and Toxic Effect with MCC and without MCC, respectively).

ICD–10–CM diagnosis code	Code description
T85.810S	Embolism due to nervous system prosthetic devices, implants and grafts, sequela.
T85.820S	Fibrosis due to nervous system prosthetic devices, implants and grafts, sequela.
T85.830S	Hemorrhage due to nervous system prosthetic devices, implants and grafts, sequela.
T85.840S	Pain due to nervous system prosthetic devices, implants and grafts, sequela.
T85.850S	Stenosis due to nervous system prosthetic devices, implants and grafts, sequela.
T85.860S	Thrombosis due to nervous system prosthetic devices, implants and grafts, sequela.
T85.890S	Other specified complication of nervous system prosthetic devices, implants and grafts, sequela.

In the FY 2018 IPPS/LTCH PPS proposed rule, we invited public comment on our proposals to (1) reassign the ICD–10–CM diagnosis codes with the 7th character ''A'' (initial encounter) from MS–DRGs 949 and 950 in MDC 23 to MS–DRGs 919, 920 and 921 in MDC 21; (2) reassign the ICD–10–CM diagnosis codes with the 7th character ''D'' (subsequent encounter) from MS–DRGs 919, 920, 921, 922, and 923 in MDC 21 to MS–DRGs 949 and 950 in MDC 23; and (3) reassign the ICD–10–CM diagnosis codes with the 7th character ''S'' (sequela) from MS–DRGs 949 and 950 in MDC 23 to MS–DRGs 922 and 923 in MDC 21 for FY 2018. The table below displays the current Version 34 MDC and MS–DRG assignments and the proposed Version 35 MDC and MS–DRG assignments on which we sought public comment for the respective ICD–10–CM diagnosis codes.

ICD–10–CM code	Code description	Current V34 MDC	Current V34 MS–DRG	Proposed V35 MDC	Proposed V35 MS–DRG
T85.810D	Embolism due to nervous system prosthetic devices, implants and grafts, subsequent encounter.	21	919, 920, 921	23	949, 950
T85.810S	Embolism due to nervous system prosthetic devices, implants and grafts, sequela.	23	949, 950	21	922, 923
T85.818A	Embolism due to other internal prosthetic devices, implants and grafts, initial encounter.	23	949, 950	21	919, 920, 921
T85.818D	Embolism due to other internal prosthetic devices, implants and grafts, subsequent encounter.	21	922, 923	23	949, 950
T85.820D	Fibrosis due to nervous system prosthetic devices, implants and grafts, subsequent encounter.	21	919, 920, 921	23	949, 950
T85.820S	Fibrosis due to nervous system prosthetic devices, implants and grafts, sequela.	23	949, 950	21	922, 923

ICD–10–CM code	Code description	Current V34 MDC	Current V34 MS–DRG	Proposed V35 MDC	Proposed V35 MS–DRG
T85.828A	Fibrosis due to other internal prosthetic devices, implants and grafts, initial encounter.	23	949, 950	21	919, 920, 921
T85.828D	Fibrosis due to other internal prosthetic devices, implants and grafts, subsequent encounter.	21	922, 923	23	949, 950
T85.830D	Hemorrhage due to nervous system prosthetic devices, implants and grafts, subsequent encounter.	21	919, 920, 921	23	949, 950
T85.830S	Hemorrhage due to nervous system prosthetic devices, implants and grafts, sequela.	23	949, 950	21	922, 923
T85.838A	Hemorrhage due to other internal prosthetic devices, implants and grafts, initial encounter.	23	949, 950	21	919, 920, 921
T85.838D	Hemorrhage due to other internal prosthetic devices, implants and grafts, subsequent encounter.	21	922, 923	23	949, 950
T85.840D	Pain due to nervous system prosthetic devices, implants and grafts, subsequent encounter.	21	919, 920, 921	23	949, 950
T85.840S	Pain due to nervous system prosthetic devices, implants and grafts, sequela.	23	949, 950	21	922, 923
T85.848A	Pain due to other internal prosthetic devices, implants and grafts, initial encounter.	23	949, 950	21	919, 920, 921
T85.848D	Pain due to other internal prosthetic devices, implants and grafts, subsequent encounter.	21	922, 923	23	949, 950
T85.850D	Stenosis due to nervous system prosthetic devices, implants and grafts, subsequent encounter.	21	919, 920, 921	23	949, 950
T85.850S	Stenosis due to nervous system prosthetic devices, implants and grafts, sequela.	23	949, 950	21	922, 923
T85.858A	Stenosis due to other internal prosthetic devices, implants and grafts, initial encounter.	23	949, 950	21	919, 920, 921
T85.858D	Stenosis due to other internal prosthetic devices, implants and grafts, subsequent encounter.	21	922, 923	23	949, 950
T85.860D	Thrombosis due to nervous system prosthetic devices, implants and grafts, subsequent encounter.	21	919, 920, 921	23	949, 950
T85.860S	Thrombosis due to nervous system prosthetic devices, implants and grafts, sequela.	23	949, 950	21	922, 923
T85.868A	Thrombosis due to other internal prosthetic devices, implants and grafts, initial encounter.	23	949, 950	21	919, 920, 921
T85.868D	Thrombosis due to other internal prosthetic devices, implants and grafts, subsequent encounter.	21	922, 923	23	949, 950
T85.890D	Other specified complication of nervous system prosthetic devices, implants and grafts, subsequent encounter.	21	919, 920, 921	23	949, 950
T85.890S	Other specified complication of nervous system prosthetic devices, implants and grafts, sequela.	23	949, 950	21	922, 923
T85.898A	Other specified complication of other internal prosthetic devices, implants and grafts, initial encounter.	23	949, 950	21	919, 920, 921
T85.898D	Other specified complication of other internal prosthetic devices, implants and grafts, subsequent encounter.	21	922, 923	23	949, 950

Comment: Commenters supported the proposals to (1) reassign the ICD–10–CM diagnosis codes with the 7th character ''A'' (initial encounter) from MS–DRGs 949 and 950 in MDC 23 to MS–DRGs 919, 920 and 921 in MDC 21; (2) reassign the ICD–10–CM diagnosis codes with the 7th character ''D'' (subsequent encounter) from MS–DRGs 919, 920, 921, 922, and 923 in MDC 21 to MS–DRGs 949 and 950 in MDC 23; and (3) reassign the ICD–10–CM diagnosis codes with the 7th character ''S'' (sequela) from MS–DRGs 949 and 950 in MDC 23 to MS–DRGs 922 and 923 in MDC 21 for FY 2018. However, one commenter did not support the reassignment of ICD–10–CM diagnosis codes with the 7th character ''S'' (sequela) from MS–DRGs 949 and 950 in MDC 23 to MS–DRGs 922 and 923 in MDC 21. This commenter agreed that the codes with the 7th character ''S'' should not be assigned to MS–DRGs 949 and 950. However, the commenter disagreed with the proposed reassignment to MS–DRGs 922 and 923 and referenced language from the FY 2017 ICD–10–CM Official Guidelines for Coding and Reporting under Section I.B.10. Sequela (Late Effects) which states: ''A sequela is the residual effect (condition produced) after the acute phase of an illness or injury has terminated. The condition or nature of the sequela is sequenced first. The sequela code is sequenced second.'' According to the commenter, sequela cases are appropriately classified to the MS–DRGs corresponding to the reported residual condition rather than MS–DRGs 922 and 923 or MS–DRGs 949 and 950.

Response: We appreciate the support of the commenters on our proposals. In response to the commenter who did not agree with the reassignment of ICD–10–CM diagnosis codes with the 7th character ''S'' (sequela) from MS–DRGs 949 and 950 in MDC 23 to MS–DRGs 922 and 923 in MDC 21, we note that the proposal for the ICD–10–CM diagnosis codes with the 7th character ''S'' (sequela) is consistent with the assignments under Version 33 of the ICD–10 MS–DRGs from which their respective predecessor codes were derived. For example, under Version 33 of the ICD–10 MS–DRGs, ICD–10–CM diagnosis code T85.81XS (Embolism due to internal prosthetic devices, implants and grafts, not elsewhere

classified, sequela) was assigned to MDC 21 under MS–DRGs 922 and 923. Similar to the inadvertent errors in MDC and MS–DRG assignments that occurred with the ICD–10–CM diagnosis codes involving 7th characters ''A'' (initial encounter) and ''D'' (subsequent encounter) from Version 33 to Version 34 of the ICD–10 MS–DRGs, the ICD–10–CM diagnosis codes involving 7th character ''S'' were also inadvertently assigned to the incorrect MDC and MS–DRGs under Version 34 of the ICD–10 MS–DRGs. Therefore, the proposal is consistent for all the 7th characters. In addition, while the commenter disagreed with our proposed MDC and MS–DRG assignments, the commenter did not offer suggestions on alternative assignments.

After consideration of the public comments we received, we are finalizing our proposals as set forth in the FY 2018 IPPS/LTCH PPS proposed rule for the complication codes discussed above in the ICD–10 MS–DRGs Version 35, effective October 1, 2017.

9. MDC 23 (Factors Influencing Health Status and Other Contacts With Health Services): Updates to MS–DRGs 945 and 946 (Rehabilitation With CC/MCC and Without CC/MCC, Respectively)

In FY 2016, we received requests to modify the MS–DRG assignment for MS–DRGs 945 and 946 (Rehabilitation with CC/MCC and without CC/MCC, respectively). This issue was addressed in the FY 2017 IPPS/LTCH PPS proposed and final rules (81 FR 24998 through 25000 and 81 FR 56826 through 56831). For FY 2017, we did not change the MS–DRG assignments for MS–DRGs 945 and 946.

We did not receive a request to address this issue as part of the FY 2018 IPPS/LTCH PPS proposed rule or suggestions on how to update the MS–DRGs 945 and 946 logic. However, we did refer the FY 2016 requests for a new ICD–10–CM diagnosis code to the Centers for Disease Control and Prevention (CDC) for consideration at a future meeting of the ICD–10 Coordination and Maintenance Committee. CDC has the lead on updating and maintaining ICD–10–CM codes. CDC did not address the issue at the September 13–14, 2016 ICD–10 Coordination and Maintenance Committee meeting. When the topic was not addressed at the September 13–14, 2016 ICD–10 Coordination and Maintenance Committee meeting, we asked CDC to address the code request at the March 7–8, 2017 meeting of the ICD–10 Coordination and Maintenance Committee. The topic was on the agenda for the March 7–8, 2017 ICD–10 Coordination and Maintenance Committee meeting. The deadline for providing comments on proposals considered at this meeting was April 7, 2017. Any new codes approved after this meeting which will be implemented on October 1, 2017 were posted on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/index.html* and on the CDC Web site at: *http://www.cdc.gov/nchs/icd/icd10.html* in June 2017. New codes also are included in Table 6A associated with this FY 2018 IPPS/LTCH PPS final rule (which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*).

As addressed in the FY 2017 IPPS/LTCH PPS final rule, the ICD–9–CM MS–DRGs used ICD–9–CM codes reported as the principal diagnosis that clearly identified an encounter for rehabilitation services, such as diagnosis codes V57.89 (Care involving other specified rehabilitation procedure) and V57.9 (Care involving unspecified rehabilitation procedure), and these codes were not included in ICD–10–CM. Given this lack of ICD–10–CM codes to indicate that the reason for the encounter was for rehabilitation, the ICD–10 MS–DRG logic could not reflect the logic of the ICD–9–CM MS–DRGs. Commenters on the final rule recommended that CDC create new diagnosis codes for these concepts in ICD–10–CM so that the MS–DRG logic could be updated to more closely reflect that of the ICD–9–CM MS–DRGs.

As we stated in the proposed rule, if new ICD–10–CM codes are created for encounter for rehabilitation services, we would address any updates to MS–DRGs 945 and 946 utilizing these new codes in future rulemaking. In the meantime, we welcome other specific recommendations on how to update MS–DRGs 945 and 946. We are sharing the following data on these MS–DRGs from the MedPAR file.

FY 2015 MS–DRGs with ICD–9–CM codes	Number of cases	Average length of stay	Average cost
MS–DRG 945	3,991	10.3	$8,242
MS–DRG 946	1,184	8.0	7,322

FY 2016 MS–DRGs with ICD–10–CM codes	Number of cases	Average length of stay	Average cost
MS–DRG 945	671	10.8	$7,814
MS–DRG 946	157	7.3	7,672

As shown by the tables above, there was a decrease of 3,320 MS–DRG 945 cases (from 3,991 to 671) from FY 2015, when claims were submitted with ICD–9–CM codes, to FY 2016 when ICD–10 codes were submitted. There was a decrease of 1,027 MS–DRG 946 cases (from 1,184 to 157) from FY 2015 to FY 2016. The average length of stay increased 0.5 days (from 10.3 to 10.8 days) for MS–DRG 945 and decreased 0.7 days (from 8.0 to 7.3 days) for MS–DRG 946. The average costs decreased by $428 (from $8,242 to $7,814) for MS–DRG 945 cases and increased by $350 (from $7,322 to $7,672) for MS–DRG 946 cases. The number of cases was significantly lower in FY 2016 compared to FY 2015. However, the difference in average length of stay and average costs did not show large changes.

As discussed in the FY 2018 IPPS/LTCH PPS proposed rule, we also examined possible MS–DRGs where these cases may have been assigned in FY 2016 based on increases in the number of claims. Because there is not a diagnosis code that could be reported as a principal diagnosis, which would indicate if the admissions were for rehabilitation services, we are unable to determine if these were cases admitted for rehabilitation that moved from MS–DRGs 945 and 946 because of the lack of a code for encounter for rehabilitation, or if there was simply a change in the number of cases. The following tables show our findings for MS–DRG 056 (Degenerative Nervous System Disorders with MCC); MS–DRG 057 (Degenerative Nervous System

Disorders without MCC); MS–DRG 079 (Hypertensive Encephalopathy without CC/MCC); MS DRG 083 (Traumatic Stupor & Coma, Coma >1 Hour with CC); MS–DRG 084 (Traumatic Stupor & Coma, Coma >1 Hour without CC/MCC); MS–DRG 092 (Other Disorders of Nervous System with MCC); and MS–DRG 093 (Other Disorders of Nervous System without CC/MCC).

FY 2015 MS–DRGs with ICD–9–CM codes	Number of cases	Average length of stay	Average cost
MS–DRG 056	9,548	7.3	$12,606
MS–DRG 057	25,652	5.1	7,918
MS–DRG 079	618	2.7	5,212
MS–DRG 083	2,516	4.3	9,446
MS–DRG 084	1,955	2.8	6,824
MS–DRG 092	12,643	5.7	11,158
MS–DRG 093	7,928	2.8	5,182

FY 2016 MS–DRGs with ICD–10–CM codes	Number of cases	Average length of stay	Average cost
MS–DRG 056	10,817	7.6	$12,930
MS–DRG 057	28,336	5.3	7,902
MS–DRG 079	1,233	2.7	5,579
MS–DRG 083	4,058	6.2	9,134
MS–DRG 084	3,016	2.7	6,508
MS–DRG 092	19,392	3.9	6,706
MS–DRG 093	8,120	2.7	5,253

As shown by the tables above, some of the MS–DRGs that show the largest increase in number of cases do not show significant changes in the average length of stay or average costs. For instance, MS–DRG 079 cases doubled from FY 2015 to FY 2016 (from 618 to 1,233). However, the average length of stay did not change from 2.7 days and the average costs increased only $367 (from $5,212 to $5,579). MS–DRG 083 cases increased by 1,542 (from 2,516 to 4,058) with a 1.9 day increase in the average length of stay (from 4.3 to 6.2 days); however, the average costs decreased only $312 (from $9,446 to $9,134). There were large changes for MS–DRG 092 with cases increasing by 6,749 (from 12,643 to 19,392), the average length of stay decreasing by 1.8 days (from 5.7 to 3.9) and the average costs decreasing by $4,452 (from $11,158 to $6,706). Once again, it is not possible to determine if any changes are a result of the impact of not having a code for the encounter for rehabilitation services to report as a principal diagnosis, or if other factors such as changes in types of patient admissions were involved.

Given the lack of a diagnosis code to capture the principal diagnosis of encounter for rehabilitation, we stated in the FY 2018 proposed rule that we were unable to update MS–DRG 945 or MS–DRG 946 to better identify those cases in which patients are admitted for rehabilitation services. If the CDC creates a new code, we will consider proposing updates to MS–DRGs 945 and 946 in the future.

We invited public comments on our proposal not to update MS–DRGs 945 and 946 for FY 2018.

Comment: Several commenters acknowledged that CMS' analysis indicates that there was a decrease in the number of cases reported in MS–DRG 945 and 946 from FY 2015 to FY 2016 and there was an increase in average length of stay for MS–DRG 945 and a decrease in average length of stay for MS–DRG 946 from FY 2015 to FY 2016. The commenters stated that, without an ICD–10–CM diagnosis code to capture encounters for rehabilitation therapy, it was not possible to identify any specific shifts in these cases. The commenters stated that they had written to CDC to support the creation of a new diagnosis code to capture these admissions after the topic was presented at the March 7–8, 2017 ICD–10 Coordination and Maintenance Committee meeting. The commenters stated that if CDC creates a new ICD–10–CM code for encounters for rehabilitation therapy, it recommended that CMS propose adding the new code as part of the MS–DRG logic for MS–DRGs 945 and 946 as part of the FY 2019 IPPS/LTCH PPS proposed rule. The commenters stated that if CDC decides not to create a new ICD–10–CM code for encounters for rehabilitation therapy, CMS should consider assembling a technical advisory panel made up of stakeholders, such as rehabilitation providers and other representation, to conduct an evaluation of this issue and recommend options to improve the MS–DRG logic and changes that could be proposed as part of future rulemaking.

Response: We agree with the commenters that without a specific ICD–10–CM code for encounters for rehabilitation therapy, it is not possible to identify any specific shifts in these cases. If the CDC creates a new code effective October 1, 2018, we will evaluate potential updates to the MS–DRGs utilizing this new code as part of the FY 2019 IPPS/LTCH PPS proposed rule. If the CDC decides not to create a new code, we welcome recommendations from the public on how the MS–DRG logic could be updated to better capture patients within MS–DRGs 945 and 946.

After consideration of the public comments that we received, we are finalizing our proposal not to update MS–DRGs 945 and 946 for FY 2018.

10. Changes to the Medicare Code Editor (MCE)

The Medicare Code Editor (MCE) is a software program that detects and reports errors in the coding of Medicare claims data. Patient diagnoses, procedure(s), and demographic information are entered into the Medicare claims processing systems and are subjected to a series of automated screens. The MCE screens are designed to identify cases that require further review before classification into an MS–DRG.

As discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56831 through 56844), we made available the FY 2017 ICD–10 MCE Version 34 manual file and an ICD–9–CM MCE

Version 34.0A manual file (for analysis purposes only). The links to these MCE manual files, along with the links to purchase the mainframe and computer software for the MCE Version 34 (and ICD–10 MS–DRGs) are posted on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* through the FY 2017 IPPS Final Rule Home Page.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19840 through 19846), we addressed the MCE requests we received by the December 7, 2016 deadline. We also discussed the proposals we made based on our internal review and analysis. In addition, as a result of new and modified code updates approved after the annual spring ICD–10 Coordination and Maintenance Committee meeting, we routinely make changes to the MCE. In the past, in both the IPPS proposed and final rules, we have only provided the list of changes to the MCE that were brought to our attention after the prior year's final rule. We historically have not listed the changes we have made to the MCE as a result of the new and modified codes approved after the annual spring ICD–10 Coordination and Maintenance Committee meeting. These changes are approved too late in the rulemaking schedule for inclusion in the proposed rule. Furthermore, although our MCE policies have been described in our proposed and final rules, we have not provided the detail of each new or modified diagnosis and procedure code edit in the final rule. However, we make available the finalized Definitions of Medicare Code Edits (MCE) file. Therefore, we have made available the FY 2018 ICD–10 MCE Version 35 manual file. The link to this MCE manual file, along with the link to the mainframe and computer software for the MCE Version 35 (and ICD–10 MS–DRGs) are posted on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* through the FY 2018 IPPS Final Rule Home Page.

a. Age Conflict Edit

In the MCE, the Age Conflict edit exists to detect inconsistencies between a patient's age and any diagnosis on the patient's record; for example, a 5-year-old patient with benign prostatic hypertrophy or a 78-year-old patient coded with a delivery. In these cases, the diagnosis is clinically and virtually impossible for a patient of the stated age. Therefore, either the diagnosis or the age is presumed to be incorrect. Currently, in the MCE, the following four age diagnosis categories appear under the Age Conflict edit and are listed in the manual and written in the software program:

- Perinatal/Newborn—Age of 0 years only; a subset of diagnoses which will only occur during the perinatal or newborn period of age 0 (for example, tetanus neonatorum, health examination for newborn under 8 days old).
- Pediatric—Age is 0 to 17 years inclusive (for example, Reye's syndrome, routine child health examination).
- Maternity—Age range is 12 to 55 years inclusive (for example, diabetes in pregnancy, antepartum pulmonary complication).
- Adult—Age range is 15 to 124 years inclusive (for example, senile delirium, mature cataract).

We received a request to provide clarification regarding the overlapping age ranges (0 to 17 years and 15 to 124 years) in the Pediatric and Adult categories under the Age Conflict edit. The requestor questioned which diagnosis code would be most appropriate to identify when a general or routine health examination is performed on patients who are within the age range of 15 to 17 years. The specific ICD–10–CM diagnosis codes that the requestor inquired about related to a child or to an adult encounter for a health examination are displayed in the table below.

ICD–10–CM code	Code description
Z00.00	Encounter for general adult medical examination without abnormal findings.
Z00.01	Encounter for general adult medical examination with abnormal findings.
Z00.121	Encounter for routine child health examination with abnormal findings.
Z00.129	Encounter for routine child health examination without abnormal findings.

The age ranges defined within the Age Conflict edits were established with the implementation of the IPPS. The adult age range includes the minimum age of 15 years for those patients who are declared emancipated minors. We note that, historically, we have not provided coding advice in rulemaking with respect to policy. We collaborate with the American Hospital Association (AHA) through the Coding Clinic for ICD–10–CM and ICD–10–PCS to promote proper coding. We recommend that the requestor and other interested parties submit any questions pertaining to correct coding practices for this specific issue to the AHA.

Comment: Some commenters believe that CMS is responsible for addressing questions relating to the pediatric and adult age ranges in the Age Conflict edit. Other commenters stated that, while the Coding Clinic for ICD–10–CM and ICD–10–PCS addresses proper coding, it cannot address issues related to payer-specific edits or definitions.

Response: We believe there is some confusion with regard to the issue presented in the FY 2018 IPPS/LTCH PPS proposed rule pertaining to the Age Conflict edit. We specifically responded to a request that sought clarification regarding the overlapping age ranges (0 to 17 years and 15 to 124 years) in the Pediatric and Adult categories under the Age Conflict edit. We responded that the age ranges defined within the Age Conflict edits were established with the implementation of the IPPS and noted that the adult age range includes the minimum age of 15 years for those patients who are declared emancipated minors. Therefore, we fully responded to the request that we clarify the Age ranges in the MCE. However, in addition to the request regarding the overlapping age ranges in the Age Conflict edit, the requester specifically asked for coding advice. As noted earlier, ''The requester questioned which diagnosis code would be most appropriate to identify when a general or routine health examination is performed on patients who are within the age range of 15 to 17 years.'' We provided the specific ICD–10–CM diagnosis codes that the requestor inquired about related to a child or to an adult encounter for a health examination as displayed in the table above. The statement recommending that the requester and other interested parties submit questions pertaining to correct coding practices for this specific issue to the AHA was with regard to reporting the most appropriate diagnosis code based on the clarification provided regarding the Age Conflict edit. As stated in the FY 2018 IPPS/LTCH PPS proposed rule, we have not provided coding advice in rulemaking with respect to policy. Accordingly, any

questions regarding which diagnosis code would be most appropriate to report when a general or routine health examination is performed on patients who are within the age range of 15 to 17 years would be best addressed by the Coding Clinic.

(1) Perinatal/Newborn Diagnosis Category

Under the ICD–10 MCE, the Perinatal/Newborn Diagnosis category under the Age Conflict edit considers the age of 0 years only; a subset of diagnoses which will only occur during the perinatal or newborn period of age 0 to be inclusive. This includes conditions that have their origin in the fetal or perinatal period (before birth through the first 28 days after birth) even if morbidity occurs later. For that reason, the diagnosis codes on this Age Conflict edit list would be expected to apply to conditions or disorders specific to that age group only.

In the ICD–10–CM classification, there are two diagnosis codes that describe conditions as occurring during infancy and the neonatal period that are currently not on the Perinatal/Newborn Diagnosis category edit code list. We consulted with staff at the Centers for Disease Control's (CDC's) National Center for Health Statistics (NCHS) because NCHS has the lead responsibility for the ICD–10–CM diagnosis codes. The NCHS' staff confirmed that, although diagnosis codes D80.7 (Transient hypogammaglobulinemia of infancy) and diagnosis code E71.511 (Neonatal adrenoleukodystrophy) do occur during infancy and the neonatal period, both conditions can last beyond the 28-day timeframe which is used to define the perinatal/newborn period. These diagnosis codes are not intended to be restricted for assignment to newborn patients. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19841), we proposed to not add these two diagnosis codes to the Perinatal/Newborn Diagnosis category under the Age Conflict edit. We invited public comments on our proposal.

Comment: Commenters agreed that ICD–10–CM diagnosis codes D80.7 and E71.511 should not be added to the Perinatal/Newborn Diagnosis category under the Age Conflict edit.

Response: We appreciate the commenters' support.

After consideration of the public comments that we received, we are finalizing our proposal to not add diagnosis code D80.7 (Transient hypogammaglobulinemia of infancy) and diagnosis code E71.511 (Neonatal adrenoleukodystrophy) to the Perinatal/Newborn Diagnosis category under the Age Conflict edit.

(2) Pediatric Diagnosis Category

Under the ICD–10 MCE, the Pediatric diagnosis category under the Age Conflict edit considers the age range of 0 to 17 years inclusive. For that reason, the diagnosis codes on this Age Conflict edit list would be expected to apply to conditions or disorders specific to that age group only.

The ICD–10–CM diagnosis code list for the Pediatric diagnosis category under the Age Conflict edit currently includes a diagnosis code pertaining to dandruff that is not intended to apply to pediatric patients only. We consulted with staff at the Centers for Disease Control's (CDC's) National Center for Health Statistics (NCHS) because NCHS has the lead responsibility for the ICD–10–CM diagnosis codes. The NCHS' staff confirmed that, although diagnosis code L21.0 (Seborrhea capitis) has an inclusion term of ''Cradle cap,'' the description of the diagnosis code is not intended to be restricted for assignment of pediatric patients. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19841), we proposed to remove diagnosis code L21.0 from the list of diagnosis codes for the Pediatric diagnosis category under the Age Conflict edit. We invited public comments on our proposal.

Comment: Commenters agreed that diagnosis code L21.0 should be removed from the list of diagnosis codes for the Pediatric diagnosis category under the Age Conflict edit.

Response: We appreciate the commenters support.

After consideration of the public comments that we received, we are finalizing our proposal to remove diagnosis code L21.0 (Seborrhea capitis) from the Pediatric diagnosis category under the Age Conflict edit in the ICD–10 MCE Version 35, effective October 1, 2017.

(3) Maternity Diagnoses

Under the ICD–10 MCE, the Maternity diagnosis category under the Age Conflict edit considers the age range of 12 to 55 years inclusive. For that reason, the ICD–10–CM diagnosis codes on this Age Conflict edit list would be expected to apply to conditions or disorders specific to that age group only.

As discussed in section II.F.12. of the preamble of the proposed rule and this final rule, Table 6A.—New Diagnosis Codes lists the new ICD–10–CM diagnosis codes that have been approved to date, which will become effective with discharges occurring on and after October 1, 2017. Included on this list are a number of diagnosis codes associated with pregnancy and maternal care that we believe are appropriate to add to the list of diagnosis codes for the Maternity diagnoses category under the Age Conflict edit. We refer readers to Table 6P.1a. associated with the FY 2018 IPPS/LTCH PPS proposed rule (which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) for a review of the ICD–10–CM diagnosis codes that we proposed to add to the Age Conflict edit list. We invited public comments on our proposal.

Comment: Commenters supported the proposal to add the list of diagnosis codes displayed in Table 6P.1a. associated with the FY 2018 IPPS/LTCH PPS proposed rule to the Maternity diagnoses category under the Age Conflict edit. Commenters recommended that this same list of diagnosis codes also be added to the Diagnoses for Females Only edit.

Response: We appreciate the commenters' support. We agree that the diagnosis codes proposed to be added to the Maternity diagnoses category under the Age Conflict edit are also appropriate to be added to the Diagnoses for Females Only edit code list under the Sex Conflict edit with other diagnosis codes associated with pregnancy and maternal care.

After consideration of the public comments that we received, we are finalizing our proposal to add the list of diagnosis codes displayed in Table 6P.1a. associated with the FY 2018 IPPS/LTCH PPS proposed rule and this final rule (which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) to the Maternity diagnoses category under the Age Conflict edit and we are adding this same list of diagnosis codes to the Diagnoses for Females Only code list under the Sex Conflict edit, effective October 1, 2017.

b. Sex Conflict Edit

In the MCE, the Sex Conflict edit detects inconsistencies between a patient's sex and any diagnosis or procedure on the patient's record; for example, a male patient with cervical cancer (diagnosis) or a female patient with a prostatectomy (procedure). In both instances, the indicated diagnosis or the procedure conflicts with the stated sex of the patient. Therefore, the patient's diagnosis, procedure, or sex is presumed to be incorrect.

(1) Diagnoses for Males Only Edit

We received a request to review the following ICD–10–CM diagnosis codes pertaining to conditions associated with males for possible inclusion on the list of diagnosis codes for the Diagnoses for Males Only edit.

ICD–10–CM code	Code description
B37.42	Candidal balanitis.
N35.011	Post-traumatic bulbous urethral stricture.
N35.012	Post-traumatic membranous urethral stricture.
N35.013	Post-traumatic anterior urethral stricture.
N35.112	Postinfective bulbous urethral stricture, not elsewhere classified.
N35.113	Postinfective membranous urethral stricture, not elsewhere classified.
N35.114	Postinfective anterior urethral stricture, not elsewhere classified.
N99.115	Postprocedural fossa navicularis urethral stricture.

As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19842), we agreed with the requestor that diagnosis code B37.42 describes a condition that is applicable only to males. Balanitis is the inflammation of the glans (rounded head) of the penis. We also agreed that the diagnosis codes listed above that align under subcategory N35.01 (Post-traumatic urethral stricture, male) and subcategory N35.11 (Postinfection urethral stricture, not elsewhere classified, male) are appropriate to add to the list of diagnosis codes for the Diagnoses for Males Only edit because these diagnosis codes include specific terminology that is applicable only to males. Further, we agreed that diagnosis code N99.115 is appropriate to add to the list of diagnosis codes for the Diagnoses for Males Only edit because subcategory N99.11 (Postprocedural urethral stricture, male) includes specific terminology that is applicable to males only as well. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule, we proposed to add the ICD–10–CM diagnosis codes listed in the table above to the list of diagnosis codes for the Diagnoses for Males Only edit.

We also proposed to remove ICD–10–CM diagnosis code Q64.0 (Epispadias) from the list of diagnosis codes for the Diagnoses for Males Only edit because this rare, congenital condition involving the opening of the urethra can occur in both males and females.

In addition, as discussed in section II.F.12. of the preamble of the proposed rule, Table 6A.—New Diagnosis Codes associated with the proposed rule listed the new ICD–10–CM diagnosis codes that had been approved to date, which will become effective with discharges occurring on and after October 1, 2017. Included on this list are a number of diagnosis codes associated with male body parts that we believe are appropriate to add to the list of diagnosis codes for the Diagnoses for Males Only category under the Sex Conflict edit. We refer readers to Table 6P.1b. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) for a review of the ICD–10–CM diagnosis codes that we proposed to add to the list of diagnosis codes for the Diagnoses for Males Only category.

We invited public comments on our proposals.

Comment: Commenters supported the proposal to add the diagnosis codes listed in the table in the proposed rule describing conditions applicable to males to the Diagnoses for Males Only edit. Commenters also supported the addition of new diagnosis codes associated with male body parts as displayed in Table 6P.1b. associated with the proposed rule to the Diagnoses for Males Only edit. In addition, commenters supported the proposal to remove diagnosis code Q64.0 (Epispadias) from the list of diagnosis codes for the Diagnoses for Males Only edit because this condition can occur in both males and females.

Response: We appreciate the commenters' support.

After consideration of the public comments that we received, we are finalizing our proposals to add the eight diagnosis codes displayed in the table above and the new diagnosis codes associated with male body parts as displayed in Table 6P.1b. associated with the proposed rule and this final rule (which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html)* to the Diagnoses for Males Only edit, effective October 1, 2017. We are also finalizing our proposal to remove diagnosis code Q64.0 (Epispadias) from the list of diagnosis codes for the Diagnoses for Males Only edit, effective October 1, 2017.

(2) Diagnoses for Females Only

We received a request to review the following ICD–10–CM diagnosis codes for possible removal from the list of diagnosis codes for the Diagnoses for Females Only edit.

ICD–10–CM code	Code description
F52.6	Dyspareunia not due to a substance or known physiological condition.
J84.81	Lymphangioleiomyomatosis.
R97.1	Elevated cancer antigen 125 [CA 125].

The requestor noted that, in the ICD–10–CM classification, the term ''Dyspareunia'' (painful sexual intercourse) has specified codes for males and females located in the Alphabetic Index to Diseases for Reporting Physiological Dyspareunia. However, the indexing for diagnosis code F52.6 (Dyspareunia not due to a substance or known physiological condition) specifies that it is not due to a physiological condition and the entry is not gender specific. According to the requestor, while the condition is most often associated with female sexual dysfunction, there is a subset of males who also suffer from this condition.

In addition, the requestor stated that diagnosis code J84.81 (Lymphangioleiomyomatosis) describes a rare form of lung disease believed to occur more often in patients with tuberous sclerosis complex (TSC), a disorder due to genetic mutation. Although the condition is described as being exclusive to women, unique cases for men with TSC have also been reported.

Lastly, the requestor indicated that diagnosis code R97.1 (Elevated cancer antigen 125 [CA 125]) describes the tumor marker that commonly identifies ovarian cancer cells in women. However, the requestor stated that high levels have also been demonstrated in men (and women) with lung cancer as well.

As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19842 through 19843), we reviewed ICD–10–CM diagnosis codes F52.6, J84.81, and R97.1, and we agree with the requestor that Dyspareunia, not due to a physiological condition, can also occur in males. We also agree that the condition of Lymphangioleiomyomatosis and Elevated CA 125 levels can be found in males. Therefore, we proposed to remove these three diagnosis codes from the list of diagnosis codes for the Diagnoses for Females Only edit. We invited public comments on our proposals.

In addition, we proposed to add new diagnosis code Z40.03 (Encounter for prophylactic removal of fallopian tube(s)) to the list of diagnosis codes for the Diagnoses for Females Only edit. Currently, diagnosis code Z40.02 (Encounter for prophylactic removal of ovary) is on the edit's code list; therefore, inclusion of new diagnosis code Z40.03 would be consistent. We referred readers to Table 6A.—New Diagnosis Codes associated with the FY 2018 IPPS/LTCH PPS proposed rule (which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) for the list of new ICD–10–CM diagnosis codes that had been finalized to date. We invited public comments on our proposal.

Comment: Commenters supported the proposal to remove diagnosis codes F52.6, J84.81, and R97.1 from the list of diagnosis codes for the Diagnoses for Females Only edit. Commenters also supported the proposal to add new diagnosis code Z40.03 to the list of diagnosis codes for the Diagnoses for Females Only edit.

Response: We appreciate the commenters' support.

After consideration of the public comments that we received, we are finalizing our proposal to remove diagnosis codes F52.6 (Dyspareunia not due to a substance or known physiological condition), J84.81 (Lymphangioleiomyomatosis) and diagnosis code R97.1 (Elevated cancer antigen 125 [CA 125]) from the Diagnoses for Females Only edit, effective October 1, 2017. We are also finalizing our proposal to add new diagnosis code Z40.03 (Encounter for prophylactic removal of fallopian tube(s)) to the list of diagnosis codes for the Diagnoses for Females Only edit, effective Octber 1, 2017.

c. Non-Covered Procedure Edit: Gender Reassignment Surgery

In the MCE, the Non-Covered Procedure edit identifies procedures for which Medicare does not provide payment. Payment is not provided due to specific criteria that are established in the National Coverage Determination (NCD) process. We refer readers to the Web site at: *https://www.cms.gov/Medicare/Coverage/DeterminationProcess/howtorequestanNCD.html* for additional information on this process. In addition, there are procedures that would normally not be paid by Medicare but, due to the presence of certain diagnoses, are paid.

We issued instructions on June 27, 2014, as a one-time notification, Pub. 100–03, Transmittal 169, Change Request 8825, effective May 30, 2014, announcing to MACs the invalidation of National Coverage Determination (NCD) 140.3 for Transsexual Surgery. As a result, MACs determined coverage on a case-by-case basis. The transmittal is available via the Internet on the CMS Web site at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2014-Transmittals-Items/R169NCD.html?DLPage=1&DLEntries=10&DLFilter=Transsexual&DLSort=1&DLSortDir=ascending*.

It was brought to our attention that the ICD–10–PCS procedure codes shown in the table below are currently included on the list of procedure codes for the Non-Covered Procedure edit. As a result, when one of these procedure codes is reported on a claim, the edit for Non-Covered Procedure is triggered and claims are not able to process correctly.

ICD–10–PCS code	Code description
0W4M070	Creation of vagina in male perineum with autologous tissue substitute, open approach.
0W4M0J0	Creation of vagina in male perineum with synthetic substitute, open approach.
0W4M0K0	Creation of vagina in male perineum with nonautologous tissue substitute, open approach.
0W4M0Z0	Creation of vagina in male perineum, open approach.
0W4N071	Creation of penis in female perineum with autologous tissue substitute, open approach.
0W4N0J1	Creation of penis in female perineum with synthetic substitute, open approach.
0W4N0K1	Creation of penis in female perineum with nonautologous tissue substitute, open approach.
0W4N0Z1	Creation of penis in female perineum, open approach.

Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19843), we proposed to remove the ICD–10–PCS procedure codes included in the table above from the list of procedure codes for the Non-Covered Procedure edit to help resolve claims processing issues associated with the reporting of these procedure codes. We invited public comments on our proposal.

Comment: Commenters agreed with the proposal to remove the ICD–10–PCS procedure codes included in the table in the proposed rule from the list of procedure codes under the Non-Covered Procedure edit. One commenter who supported the proposal also requested that CMS review current policies related to breast implant procedures for transgender females. This commenter noted that estrogen therapy by itself does not provide adequate growth tissue. Another commenter stated that these gender reassignment procedures should remain noncovered as they are a form of plastic surgery and, in principle, are not unlike elective abortion procedures.

Response: We appreciate the commenters' support. In response to the commenter who requested that we review current policies related to breast implant procedures for transgender females, we recommend that the commenter contact its local MAC for additional information because there is

no national coverage determination (NCD) for this service. With regard to the commenter who stated that the procedure codes describing gender reassignment surgery listed in the table in the proposed rule should remain noncovered, we note that, as mentioned earlier in this section, NCD 140.3 for Transsexual Surgery was invalidated effective May 30, 2014, and therefore, the MACs determine coverage on a case-by-case basis.

After consideration of the public comments we received, we are finalizing our proposal to remove the ICD–10–PCS procedure codes included in the table above from the list of procedure codes for the Non-Covered Procedure edit to help resolve claims processing issues associated with the reporting of these procedure codes.

d. Unacceptable Principal Diagnosis Edit

In the MCE, there are select codes that describe a circumstance that influences an individual's health status, but does not actually describe a current illness or injury. There also are codes that are not specific manifestations but may be due to an underlying cause. These codes are considered unacceptable as a principal diagnosis. In limited situations, there are a few codes on the MCE Unacceptable Principal Diagnosis edit code list that are considered ''acceptable'' when a specified secondary diagnosis is also coded and reported on the claim.

(1) Bacterial and Viral Infectious Agents (B95 Through B97)

As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19843), we examined ICD–10–CM diagnosis codes in Chapter 1 (Certain Infectious and Parasitic Diseases) of the Classification Manual that fall within the range of three code categories for ''Bacterial and Viral Infectious Agents'' (B95 through B97). The instructional note provided at this section states that these categories are provided for use as supplementary or additional codes to identify the infectious agent(s) in diseases classified elsewhere. We identified 45 ICD–10–CM diagnosis codes within the range of these code categories for ''Bacterial and Viral Infectious Agents'' (B95 through B97) that, as a result of the instructional note, are not appropriate to report as a principal diagnosis. In the FY 2018 IPPS/LTCH PPS proposed rule, we proposed to add the 45 ICD–10–CM diagnosis codes shown in Table 6P.1c. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) to the list of codes for the Unacceptable Principal Diagnosis edit. We invited public comments on our proposal.

Comment: Commenters supported the proposal to add the 45 ICD–10–CM diagnosis codes shown in Table 6P.1c. associated with the proposed rule to the list of codes for the Unacceptable Principal Diagnosis edit.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add the 45 ICD–10–CM diagnosis codes shown in Table 6P.1c. associated with the proposed rule and this final rule (which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) to the list of codes for the Unacceptable Principal Diagnosis edit, effective October 1, 2017.

(2) Mental Disorders Due to Known Physiological Conditions (F01 Through F09)

We examined ICD–10–CM diagnosis codes in Chapter 5 (Mental and Behavioral Disorders) of the Classification Manual that fall within the range of nine code categories for ''Mental Disorders Due to Known Physiological Conditions'' (F01 through F09). The instructional note provided at this section states that this block comprises a range of mental disorders grouped together on the basis of their having in common a demonstrable etiology in cerebral disease, brain injury, or other insult leading to cerebral dysfunction. The dysfunction may be primary, as in diseases, injuries, and insults that affect the brain directly and selectively; or secondary, as in systemic diseases and disorders that attack the brain only as one of the multiple organs or systems of the body that are involved.

We identified 21 ICD–10–CM diagnosis codes that fall within the range of these code categories for ''Mental Disorders Due to Known Physiological Conditions'' (F01 through F09). Of these nine code categories, seven have a ''Code first the underlying physiological condition'' note. For example, at code category F01—Vascular dementia, the note reads, ''Code first the underlying physiological condition or sequelae of cerebrovascular disease.'' We stated in the proposed rule that there are a total of 19 diagnosis codes that fall under these 7 code categories with a ''Code first'' note and, therefore, are not appropriate to report as a principal diagnosis. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19843 through 19844), we proposed to add the 19 ICD–10–CM diagnosis codes shown in Table 6P.1d. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) to the list of codes for the Unacceptable Principal Diagnosis edit. We invited public comments on our proposal.

Comment: Some commenters disagreed with the proposal to add the 19 ICD–10–CM diagnosis codes shown in Table 6P.1d. associated with the proposed rule to the list of codes for the Unacceptable Principal Diagnosis edit. The commenters suggested that CMS consult with the NCHS to determine if any of the codes may appropriately be sequenced as a principal diagnosis in certain circumstances. One commenter noted it had been informed through communications with the NCHS and AHA that, within the ICD–10–CM classification, there are instances where some ''Code first'' notes are intended to be interpreted as ''Code first, if applicable'' or ''Code first, if known,'' although those terms are not explicitly stated in the instructional note. The commenter acknowledged that while some of the diagnosis codes that were proposed to be added to the Unacceptable Principal Diagnosis edit appear straightforward, such as diagnosis code F04 (Amnestic disorder due to known physiological condition), other diagnosis codes are not as clear, such as diagnosis code F01.5 (Vascular dementia) or diagnosis code F07.81 (Postconcussional syndrome).

Response: We appreciate the commenters' review and input regarding the proposal. We consulted with the staff at NCHS and they acknowledged that this group of codes was modified from the original World Health Organization (WHO) version of ICD–10. They indicated that while some code titles do include the language ''due to known physiological condition,'' they are evaluating these ''Code first'' instructional notes further as they perform their annual review of the coding guidelines and consider updates for FY 2018.

After consideration of the public comments that we received and for the reasons described, we are not finalizing our proposal to add the 19 ICD–10–CM diagnosis codes shown in Table 6P.1d. associated with the proposed rule to the list of codes for the Unacceptable Principal Diagnosis edit.

(3) Other Obstetric Conditions, Not Elsewhere Classified (O94 Through O9A)

We examined ICD–10–CM diagnosis codes in Chapter 15 (Pregnancy, Childbirth and the Puerperium) of the Classification Manual that fall within the range of four code categories for ''Other Obstetric Conditions, Not Elsewhere Classified'' (O94 through O9A). The instructional note provided at this section under category O94 states that ''this category is to be used to indicate conditions in O00 through O77, O85 through O94 and O98 through O9A as the cause of late effects. The sequelae include conditions specified as such, or as late effects, which may occur at any time after the puerperium. Code first condition resulting from (sequela) of complication of pregnancy, childbirth, and the puerperium.''

We stated in the proposed rule that we identified one ICD–10–CM diagnosis code within the range of these code categories for ''Other Obstetric Conditions, Not Elsewhere Classified'' (O94 through O9A) that, as a result of the instructional note, is not appropriate to report as a principal diagnosis because that code identifies the cause of the late effect. This ICD–10–CM diagnosis code is O94 (Sequelae of complication of pregnancy, childbirth, and the puerperium). In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19844), we proposed to add ICD–10–CM diagnosis code O94 to the list of codes for the Unacceptable Principal Diagnosis edit. We invited public comments on our proposal.

Comment: Commenters agreed with the proposal to add diagnosis code O94 to the list of codes for the Unacceptable Principal Diagnosis edit.

Response: We appreciate the commenters' support.

After consideration of the public comments that we received, we are finalizing our proposal to add diagnosis code O94 (Sequelae of complication of pregnancy, childbirth, and the puerperium) to the list of codes for the Unacceptable Principal Diagnosis edit, effective October 1, 2017.

(4) Symptoms and Signs Involving Cognition, Perception, Emotional State and Behavior (R40 Through R46)

We examined ICD–10–CM diagnosis codes in Chapter 18 (Symptoms, Signs and Abnormal Findings) of the Classification Manual that fall within the range of code categories for ''Symptoms and Signs Involving Cognition, Perception, Emotional State and Behavior'' (R40 through R46), specifically under code category R40—Somnolence, stupor and coma. At subcategory R40.2—Coma, there is an instructional note, which states ''Code first any associated: Fracture of skull (S02.–); Intracranial injury (S06.–).'' We stated in the proposed rule that we identified 96 ICD–10–CM diagnosis codes under this subcategory that, as a result of the instructional note, are not appropriate to report as a principal diagnosis. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19844), we proposed to add the 96 ICD–10–CM diagnosis codes shown in Table 6P.1e. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) to the list of codes for the Unacceptable Principal Diagnosis edit. We invited public comments on our proposal.

Comment: Commenters agreed with the proposed addition of 95 of the 96 diagnosis codes included in Table 6P.1e. associated with the proposed rule. The commenters specifically disagreed with the proposal to include diagnosis code R40.20 (Unspecified coma) to the Unacceptable Principal Diagnosis edit because the term ''any'' in the instructional note ''Code first any associated: Fracture of skull (S02.–); Intracranial injury (S06.–)'' indicates that if there is not a documented skull fracture or intracranial injury, then diagnosis code R40.20 could appropriately be reported as a Principal Diagnosis.

Response: We appreciate the commenters' support to add 95 of the 96 diagnosis codes included in our proposal as shown in Table 6P.1e. associated with the proposed rule. We agree with the commenters that there could be circumstances in which diagnosis code R40.20 would appropriately be reported as the principal diagnosis in the absence of a documented fracture of skull or intracranial injury.

After consideration of the public comments we received, we are finalizing the addition of 95 of the 96 diagnosis codes shown in Table 6P.1e. associated with the proposed rule (which is available via the Internet on the CMS Web site) to the list of codes for the Unacceptable Principal Diagnosis edit. For the reasons stated, we are not finalizing the proposal to add diagnosis code R40.20 (Unspecified coma) to the Unacceptable Principal Diagnosis edit. Table 6P.1e. associated with this final rule (which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) sets forth the 95 diagnosis codes that we are adding to the list of codes for the Unacceptable Principal Diagnosis edit, consistent with our finalized policy.

(5) General Symptoms and Signs (R50 Through R69)

We examined ICD–10–CM diagnosis codes in Chapter 18 (Symptoms, Signs and Abnormal Findings) of the Classification Manual that fall within the range of code categories for ''General Symptoms and Signs'' (R50 through R69), specifically, at code category R65—Symptoms and signs associated with systemic inflammation and infection. There is an instructional note at subcategory R65.1—Systemic inflammatory response syndrome (SIRS) of non-infectious origin, which states ''Code first underlying condition, such as: Heatstroke (T67.0); Injury and trauma (S00–T88).'' There is also an instructional note at subcategory R65.2—Severe sepsis, which states ''Code first underlying infection, such as:'' and provides a list of examples.

We identified four ICD–10–CM diagnosis codes in these subcategories that, as a result of the instructional notes described above, are not appropriate to report as a principal diagnosis. These four ICD–10–CM codes are shown in the table below.

ICD–10–CM code	Code description
R65.10	Systemic inflammatory response syndrome (SIRS) of non-infectious origin without acute organ dysfunction.
R65.11	Systemic inflammatory response syndrome (SIRS) of non-infectious origin with acute organ dysfunction.
R65.20	Severe sepsis without septic shock.
R65.21	Severe sepsis with septic shock.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19844), we proposed to add the four ICD–10–CM diagnosis codes shown in the table above to the list of codes for the Unacceptable Principal Diagnosis edit. We invited public comments on our proposal.

Comment: Commenters agreed with the proposal to add the four diagnosis codes listed in the table in the proposed rule to the Unacceptable Principal Diagnosis edit. However, another commenter disagreed with adding diagnosis code R65.10 (Systemic inflammatory response syndrome (SIRS) of non-infectious origin without acute organ dysfunction) and diagnosis code R65.11 (Systemic inflammatory response syndrome (SIRS) of non-infectious origin with acute organ dysfunction) to the edit. According to the commenter, if the underlying condition is not known, it would be appropriate to report either one of the two codes (R65.10 and R65.11) as the principal diagnosis.

Response: We appreciate the commenters' support. We disagree with the commenter who asserted that if the underlying condition is not known, it would be appropriate to report either diagnosis code R65.10 or R65.11 as a principal diagnosis. The current FY 2017 ICD–10–CM Official Guidelines for Coding and Reporting at Section 1.C.18.g. states, ''The systemic inflammatory response syndrome (SIRS) can develop as a result of certain non-infectious disease processes, such as trauma, malignant neoplasm, or pancreatitis. When SIRS is documented with a noninfectious condition, and no subsequent infection is documented, the code for the underlying condition, such as an injury, should be assigned, followed by code R65.10, Systemic inflammatory response syndrome (SIRS) of non-infectious origin without acute organ dysfunction, or code R65.11, Systemic inflammatory response syndrome (SIRS) of non-infectious origin with acute organ dysfunction.'' Therefore, the underlying condition (for example, trauma, neoplasm, pancreatitis, amongothers) responsible for causing the systemic inflammatory response syndrome (SIRS) should be readily available in the medical record documentation due to its clinical significance for the care and treatment of the patient.

After consideration of the public comments that we received, we are finalizing our proposal to add the four diagnosis codes shown in the table above from code category R65 (Symptoms and signs associated with systemic inflammation and infection) to the Unacceptable Principal Diagnosis edit code list, effective October 1, 2017.

(6) Poisoning by, Adverse Effects of, and Underdosing of Drugs, Medicaments and Biological Substances (T36 Through T50)

We examined ICD–10–CM diagnosis codes in Chapter 19 (Injury and Poisoning) of the Classification Manual that fall within the range of code categories for ''Poisoning by, Adverse Effects of and Underdosing of Drugs, Medicaments and Biological Substances'' (T36 through T50). The instructional note provided at this section states ''Code first, for adverse effects, the nature of the adverse effect, such as:'' and provides a list of examples. In addition, the FY 2017 ICD–10–CM Official Guidelines for Coding and Reporting at Section I.C.19.e.5.c., state that ''Codes for underdosing should never be assigned as principal or first-listed codes.''

We identified 996 ICD–10–CM diagnosis codes that, as a result of the instructional note for adverse effects and the guideline for reporting diagnosis codes for underdosing, are not appropriate to report as a principal diagnosis. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19844 through 19845), we proposed to add the 996 ICD–10–CM diagnosis codes shown in Table 6P.1f. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) to the list of codes for the Unacceptable Principal Diagnosis edit. We invited public comments on our proposal.

Comment: Commenters supported the proposal to add the 996 ICD–10–CM diagnosis codes shown in Table 6P.1f. associated with the proposed rule describing adverse effects and underdosing to the Unacceptable Principal Diagnosis edit.

Response: We appreciate the commenters' support.

After consideration of the public comments that we received, we are finalizing our proposal to add the 996 ICD–10–CM diagnosis codes shown in Table 6P.1f. associated with the proposed rule and this final rule (which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) to the list of codes for the Unacceptable Principal Diagnosis edit code list, effective October 1, 2017.

(7) Complications of Surgical and Medical Care, Not Elsewhere Classified (T80 Through T88)

We examined ICD–10–CM diagnosis codes in Chapter 19 (Injury and Poisoning) of the Classification Manual that fall within the range of code categories for ''Complications of Surgical and Medical Care, Not Elsewhere Classified'' (T80 through T88), specifically, at code category T81—Complications of procedures, not elsewhere classified. There is an instructional note at subcategory T81.12x—Postprocedural septic shock, which states, ''Code first underlying infection.''

We identified two ICD–10–CM diagnosis codes in this subcategory that, as a result of the instructional note, are not appropriate to report as a principal diagnosis. These two ICD–10–CM codes are shown in the table below.

ICD–10–CM code	Code description
T81.12XD	Postprocedural septic shock, subsequent encounter.
T81.12XS	Postprocedural septic shock, sequela.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19845), we proposed to add the two ICD–10–CM diagnosis codes shown in the table above to the list of codes for the Unacceptable Principal Diagnosis edit. We invited public comments on our proposal.

Comment: Commenters supported the proposal to add the two diagnosis codes shown in the table in the proposed rule to the Unacceptable Principal Diagnosis edit.

Response: We appreciate the commenters' support.

After consideration of the public comments that we received, we are finalizing our proposal to add the two diagnosis codes describing postprocedural septic shock listed in the

proposed rule and above in this final rule to the list of codes for the Unacceptable Principal Diagnosis edit, effective October 1, 2017.

(8) Persons Encountering Health Services for Examinations (Z00 Through Z13)

We examined ICD–10–CM diagnosis codes in Chapter 21 (Factors Influencing Health Status) of the Classification Manual that fall within the range of code categories for ''Persons Encountering Health Services for Examinations'' (Z00 through Z13), specifically, at code category Z00—Encounter for general examination without complaint, suspected or reported diagnosis. The FY 2017 ICD–10–CM Official Guidelines for Coding and Reporting at Section I.C.21.c.16., state that the following ICD–10–CM Z-codes/categories may only be reported as the principal/first-listed diagnosis, except when there are multiple encounters on the same day and the medical records for the encounters are combined:

- Z00 (Encounter for general examination without complaint, suspected or reported diagnosis); except Z00.6 (Encounter for examination for normal comparison and control in clinical research program).

Therefore, we stated in the proposed rule that diagnosis code Z00.6 should not be reported as a principal/first-listed diagnosis. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19845), we proposed to add ICD–10–CM diagnosis code Z00.6 to the list of codes for the Unacceptable Principal Diagnosis edit. We invited public comments on our proposal.

Comment: Commenters did not support the proposal to add diagnosis code Z00.6 to the list of codes for the Unacceptable Principal Diagnosis edit. The commenters stated that, although this diagnosis code is listed as an exception in the FY 2017 ICD–10–CM Official Guidelines for Coding and Reporting, the code is not prohibited from ever being reported as a principal diagnosis, rather, it is not *required* to be reported as a principal diagnosis. According to the commenters, there are circumstances when a control subject in a clinical research program may be admitted to the hospital and diagnosis code Z00.6 would be appropriate to report as the principal diagnosis. One commenter also noted that while Medicare may not be the responsible payer in these circumstances, other payers use the MCE edits, and these edits are frequently programmed in their billing software. Therefore, the commenter believed that including diagnosis code Z00.6 on the edit could cause unintended coding and reporting issues.

Response: We appreciate the commenters' feedback on our proposal. We agree that there could be circumstances where it would be appropriate to report diagnosis code Z00.6 as the principal diagnosis. We have noted previously (72 FR 47152) that we encourage other payers to develop refinements to Medicare's DRG system, which includes the Medicare code edits, consistent with their population's needs. However, we also recognize that tother payers use the MCE edits in their systems.

After consideration of the public comments we received and for the reasons described, we are not finalizing our proposal to add diagnosis code Z00.6 (Encounter for examination for normal comparison and control in clinical research program) to the list of codes for the Unacceptable Principal Diagnosis edit.

To address a separate issue, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19845), we proposed to remove the diagnosis codes under category Z05 (Encounter for observation and examination of newborn for suspected diseases and conditions ruled out) from the list of codes for the Unacceptable Principal Diagnosis edit. The FY 2017 ICD–10–CM Official Guidelines for Coding and Reporting at Section I.C.16.b. state the following:

- Assign a code from category Z05, Observation and evaluation of newborns and infants for suspected conditions ruled out, to identify those instances when a healthy newborn is evaluated for a suspected condition that is determined after study not to be present. Do not use a code from category Z05 when the patient has identified signs or symptoms of a suspected problem; in such cases code the sign or symptom.
- A code from category Z05 may also be assigned as a principal or first-listed code for readmissions or encounters when the code from category Z38 no longer applies. Codes from category Z05 are for use only for healthy newborns and infants for which no condition after study is found to be present.
- A code from category Z05 is to be used as a secondary code after the code from category Z38, Liveborn infants according to place of birth and type of delivery.

Therefore, the ICD–10–CM diagnosis codes under category Z05 are allowed to be reported as a principal diagnosis. We proposed to remove the 14 ICD–10–CM diagnosis codes shown in the table below from the list of codes for the Unacceptable Principal Diagnosis edit.

ICD–10–CM code	Code description
Z05.0	Observation and evaluation of newborn for suspected cardiac condition ruled out.
Z05.1	Observation and evaluation of newborn for suspected infectious condition ruled out.
Z05.2	Observation and evaluation of newborn for suspected neurological condition ruled out.
Z05.3	Observation and evaluation of newborn for suspected respiratory condition ruled out.
Z05.41	Observation and evaluation of newborn for suspected genetic condition ruled out.
Z05.42	Observation and evaluation of newborn for suspected metabolic condition ruled out.
Z05.43	Observation and evaluation of newborn for suspected immunologic condition ruled out.
Z05.5	Observation and evaluation of newborn for suspected gastrointestinal condition ruled out.
Z05.6	Observation and evaluation of newborn for suspected genitourinary condition ruled out.
Z05.71	Observation and evaluation of newborn for suspected skin and subcutaneous tissue condition ruled out.
Z05.72	Observation and evaluation of newborn for suspected musculoskeletal condition ruled out.
Z05.73	Observation and evaluation of newborn for suspected connective tissue condition ruled out.
Z05.8	Observation and evaluation of newborn for other specified suspected condition ruled out.
Z05.9	Observation and evaluation of newborn for unspecified suspected condition ruled out.

We invited public comments on our proposal.

Comment: Commenters agreed with the proposal to remove the 14 ICD–10–CM diagnosis codes describing observation and evaluation of newborn for various suspected conditions that have been ruled out as shown in the

table in the proposed rule from the list of codes for the Unacceptable Principal Diagnosis edit.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to remove the 14 ICD–10–CM diagnosis codes as shown in the table above from the list of codes for the Unacceptable Principal Diagnosis edit, effective October 1, 2017.

(9) Encounters for Other Specific Health Care (Z40 Through Z53)

We examined ICD–10–CM diagnosis codes in Chapter 21 (Factors Influencing Health Status) of the Classification Manual that fall within the range of code categories for ''Encounters for Other Specific Health Care'' (Z40 through Z53), specifically, at code category Z52—Donors of organs and tissues. The FY 2017 ICD–10–CM Official Guidelines for Coding and Reporting at Section I.C.21.c.16. state that the following Z-codes/categories may only be reported as the principal/first-listed diagnosis, except when there are multiple encounters on the same day and the medical records for the encounters are combined:

- Z52 (Donors of organs and tissues); except Z52.9 (Donor of unspecified organ or tissue).

Therefore, we stated in the proposed rule that ICD–10–CM diagnosis code Z52.9 should not be reported as a principal/first-listed diagnosis. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19846), we proposed to add ICD–10–CM diagnosis code Z52.9 to the list of codes for the Unacceptable Principal Diagnosis edit. We invited public comments on our proposal.

Comment: Commenters supported the proposal to add diagnosis code Z52.9 to the list of codes for the Unacceptable Principal Diagnosis edit. Commenters stated that this code is on the list of ''non-specific Z codes'' in the FY 2017 ICD–10–CM Official Guidelines for Coding and Reporting, indicating that this code is so nonspecific that there is little justification for its use in the hospital inpatient setting. However, another commenter disagreed with adding diagnosis code Z52.9 to the list of codes for the Unacceptable Principal Diagnosis edit. Similar to the circumstances with diagnosis code Z00.6 (Encounter for examination for normal comparison and control in clinical research program) discussed earlier in this section, this commenter stated that the FY 2017 ICD–10–CM Official Guidelines for Coding and Reporting does not prohibit diagnosis code Z52.9 from ever being reported as a principal diagnosis; rather, it is not *required* to be reported as a principal diagnosis.

Response: We thank the commenters for their support and feedback. Upon further review, we agree that, consistent with the FY 2017 ICD–10–CM Official Guidelines for Coding and Reporting, the interpretation of the exception for diagnosis code Z52.9 is that it does not prohibit the code from ever being reported as a principal diagnosis; rather, the exception is indicating that the code is not *required* to be reported as a principal diagnosis.

After consideration of the public comments we received and for the reasons described, we are not finalizing our proposal to add ICD–10–CM diagnosis code Z52.9 to the list of codes for the Unacceptable Principal Diagnosis edit.

(10) Persons Encountering Health Services in Other Circumstances (Z69 Through Z76)

We examined ICD–10–CM diagnosis codes in Chapter 21 (Factors Influencing Health Status) of the Classification Manual that fall within the range of code categories for ''Persons Encountering Health Services in Other Circumstances'' (Z69 through Z76), specifically, at subcategory Z71.8—Other specified counseling. Consistent with ICD–10–CM diagnosis codes Z71.81 (Spiritual or religious counseling) and Z71.89 (Other specified counseling), in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19846), we proposed to add new diagnosis code Z71.82 (Exercise counseling) to the list of codes for the Unacceptable Principal Diagnosis edit. We referred readers to Table 6A.—New Diagnosis Codes associated with the proposed rule (which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) for the list of new ICD–10–CM diagnosis codes that had been finalized to date. We invited public comments on our proposal.

Comment: Commenters supported the proposal to add new diagnosis code Z71.82 (Exercise counseling) to the list of codes for the Unacceptable Principal Diagnosis edit.

Response: We appreciate the commenters' support.

After consideration of the public comments that we received, we are finalizing our proposal to add new ICD–10–CM diagnosis code Z71.82 (Exercise counseling) to the list of codes for the Unacceptable Principal Diagnosis edit, effective October 1, 2017.

(11) Persons With Potential Health Hazards Related to Family and Personal History and Certain Conditions Influencing Health Status (Z77 Through Z99)

We examined ICD–10–CM diagnosis codes in Chapter 21 (Factors Influencing Health Status) of the Classification Manual that fall within the range of code categories for ''Persons with Potential Health Hazards Related to Family and Personal History and Certain Conditions Influencing Health Status'' (Z77 through Z99), specifically, at code category Z91.8—Other specified personal risk factors, not elsewhere classified. Consistent with ICD–10–CM diagnosis codes Z91.81 (History of falling), Z91.82 (Personal history of military deployment), and Z91.89 (Other specified personal risk factors, not elsewhere classified), in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19846), we proposed to add new ICD–10–CM diagnosis codes Z91.841 (Risk for dental caries, low), Z91.842 (Risk for dental caries, moderate), Z91.843 (Risk for dental caries, high), and Z91.849 (Unspecified risk for dental caries) to the list of codes for the Unacceptable Principal Diagnosis edit. We referred readers to Table 6A.—New Diagnosis Codes associated with the proposed rule (which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) for the list of new ICD–10–CM diagnosis codes that had been finalized to date. We invited public comments on our proposal.

Comment: Commenters supported the proposal to add new diagnosis codes in subcategory Z91.84, Risk for dental caries, to the list of codes for the Unacceptable Principal Diagnosis edit.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add new ICD–10–CM diagnosis codes Z91.841 (Risk for dental caries, low), Z91.842 (Risk for dental caries, moderate), Z91.843 (Risk for dental caries, high), and Z91.849 (Unspecified risk for dental caries) to the list of codes for the Unacceptable Principal Diagnosis edit, effective October 1, 2017.

e. Future Enhancement

Similar to our discussion in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56843 through 56844), with the implementation of ICD–10, it is clear that there are several new concepts in the classification. Looking ahead to the needs and uses of coded data as the data

continue to evolve from the reporting, collection, processing, coverage, payment and analysis aspects, we believe the need to ensure the accuracy of the coded data becomes increasingly significant.

The purpose of the MCE is to ensure that errors and inconsistencies in the coded data are recognized during Medicare claims processing. As we continue to evaluate the purpose and function of the MCE with respect to ICD–10, we encourage public input for future discussion. As we discussed in the FY 2017 IPPS/LTCH PPS final rule, we recognize a need to further examine the current list of edits and the definitions of those edits. We continue to encourage public comments on whether there are additional concerns with the current edits, including specific edits or language that should be removed or revised, edits that should be combined, or new edits that should be added to assist in detecting errors or inaccuracies in the coded data. Comments should be directed to the MS–DRG Classification Change Mailbox located at *MSDRGClassification Change@cms.hhs.gov* by November 1, 2017 for FY 2019.

11. Changes to Surgical Hierarchies

Some inpatient stays entail multiple surgical procedures, each one of which, occurring by itself, could result in assignment of the case to a different MS–DRG within the MDC to which the principal diagnosis is assigned. Therefore, it is necessary to have a decision rule within the GROUPER by which these cases are assigned to a single MS–DRG. The surgical hierarchy, an ordering of surgical classes from most resource-intensive to least resource-intensive, performs that function. Application of this hierarchy ensures that cases involving multiple surgical procedures are assigned to the MS–DRG associated with the most resource-intensive surgical class.

As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19846), because the relative resource intensity of surgical classes can shift as a function of MS–DRG reclassification and recalibrations, for FY 2018, we reviewed the surgical hierarchy of each MDC, as we have for previous reclassifications and recalibrations, to determine if the ordering of classes coincides with the intensity of resource utilization.

A surgical class can be composed of one or more MS–DRGs. For example, in MDC 11, the surgical class ''kidney transplant'' consists of a single MS–DRG (MS–DRG 652) and the class ''major bladder procedures'' consists of three MS–DRGs (MS–DRGs 653, 654, and 655). Consequently, in many cases, the surgical hierarchy has an impact on more than one MS–DRG. The methodology for determining the most resource-intensive surgical class involves weighting the average resources for each MS–DRG by frequency to determine the weighted average resources for each surgical class. For example, assume surgical class A includes MS–DRGs 001 and 002 and surgical class B includes MS–DRGs 003, 004, and 005. Assume also that the average costs of MS–DRG 001 are higher than that of MS–DRG 003, but the average costs of MS–DRGs 004 and 005 are higher than the average costs of MS–DRG 002. To determine whether surgical class A should be higher or lower than surgical class B in the surgical hierarchy, we would weigh the average costs of each MS–DRG in the class by frequency (that is, by the number of cases in the MS–DRG) to determine average resource consumption for the surgical class. The surgical classes would then be ordered from the class with the highest average resource utilization to that with the lowest, with the exception of ''other O.R. procedures'' as discussed in this rule.

This methodology may occasionally result in assignment of a case involving multiple procedures to the lower-weighted MS–DRG (in the highest, most resource-intensive surgical class) of the available alternatives. However, given that the logic underlying the surgical hierarchy provides that the GROUPER search for the procedure in the most resource-intensive surgical class, in cases involving multiple procedures, this result is sometimes unavoidable.

We note that, notwithstanding the foregoing discussion, there are a few instances when a surgical class with a lower average cost is ordered above a surgical class with a higher average cost. For example, the ''other O.R. procedures'' surgical class is uniformly ordered last in the surgical hierarchy of each MDC in which it occurs, regardless of the fact that the average costs for the MS–DRG or MS–DRGs in that surgical class may be higher than those for other surgical classes in the MDC. The ''other O.R. procedures'' class is a group of procedures that are only infrequently related to the diagnoses in the MDC, but are still occasionally performed on patients with cases assigned to the MDC with these diagnoses. Therefore, assignment to these surgical classes should only occur if no other surgical class more closely related to the diagnoses in the MDC is appropriate.

A second example occurs when the difference between the average costs for two surgical classes is very small. We have found that small differences generally do not warrant reordering of the hierarchy because, as a result of reassigning cases on the basis of the hierarchy change, the average costs are likely to shift such that the higher-ordered surgical class has lower average costs than the class ordered below it.

We received a request to examine a case involving the principal procedure for excision of pituitary gland (ICD–10–PCS code 0GB00ZZ (Excision of pituitary gland, open approach)) with a secondary procedure for harvesting of a fat graft (ICD–10–PCS code 0JB80ZZ (Excision of abdomen subcutaneous tissue and fascia, open approach)) to treat a condition of pituitary adenoma (ICD–10–CM diagnosis code D35.2 (Benign neoplasm of pituitary gland)) and the resulting sella turcica defect. The requestor noted that when the procedure code for harvesting of the fat graft is reported on the claim, the case currently groups to MS–DRGs 622, 623, and 624 (Skin Grafts and Wound Debridement for Endocrine, Nutritional, and Metabolic Disorders with MCC, with CC and without CC/MCC, respectively). However, when the procedure code for harvesting of the fat graft is *not* reported on the claim, the case groups to MS–DRGs 614 and 615 (Adrenal and Pituitary Procedures with CC/MCC and without CC/MCC, respectively), which appears to be a more appropriate assignment. The requester expressed concern regarding the procedure code for harvesting of the fat graft in the secondary position driving the MS–DRG assignment versus the principal procedure of the excision of pituitary gland.

As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19847), we analyzed the codes provided by the requestor in the GROUPER to determine if we could duplicate the requestor's findings. The findings from our analysis were consistent with the requestor's findings. Our clinical advisors reviewed this issue and agreed that it should be the procedure code for excision of the pituitary gland that is used to determine the MS–DRG assignment in this scenario and not the harvesting of the fat graft procedure code.

Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule, we proposed to move MS–DRGs 614 and 615 above MS–DRGs 622, 623, and 624 in the surgical hierarchy to enable more appropriate MS–DRG assignment for these types of cases.

We invited public comments on our proposal.

Comment: Commenters supported the proposal to move MS–DRGs 614 and

615 above MS–DRGs 622, 623, and 624 in the surgical hierarchy. Another commenter expressed concern that the proposal to move MS–DRGs 614 and 615 above MS–DRGs 622, 623, and 624 in the surgical hierarchy was made as the result of a single scenario and recommended that a more thorough analysis be performed to determine the potential impact of such a change prior to modifying existing GROUPER logic.

Response: We appreciate the commenters' support. In response to the commenter who expressed concern that the proposal to move MS–DRGs 614 and 615 above MS–DRGs 622, 623, and 624 in the surgical hierarchy was made as the result of a single scenario and that additional analysis should be performed to determine potential impacts, we are unclear as to what specific impacts the commenter is referring to and what type of analysis the commenter is recommending. However, we did analyze claims from the December 2016 update of the FY 2016 MedPAR file for MS–DRGs 614 and 615, as well as from MS–DRGs 622, 623 and 624, to determine the volume of cases where procedure codes from both sets of MS–DRGs were reported. Our findings are shown in the tables below.

MS–DRGs for Adrenal and Pituitary Procedures

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 614—All cases	1,526	5	$16,957
MS–DRG 615—All cases	1,007	2.4	10,680

MS–DRGs for Skin Grafts and Wound Debridement Procedures

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 622—All cases	1,289	10.7	$23,954
MS–DRG 623—All cases	4,423	6.3	12,522
MS–DRG 624—All cases	454	3.5	9,345

As shown in the tables above, there were a total of 1,526 cases in MS–DRG 614 with an average length of stay of 5 days and average costs of $16,957. There were a total of 1,007 cases in MS–DRG 615 with an average length of stay of 2.4 days and average costs of $10,680. For MS–DRG 622, there were a total of 1,289 cases with an average length of stay of 10.7 days and average costs of $23,954. For MS–DRG 623, there were a total of 4,423 cases with an average length of stay of 6.3 days and average costs of $12,522. For MS–DRG 624, there were a total of 454 cases with an average length of stay of 3.5 days and average costs of $9,345.

We then analyzed claims from the March 2017 update of the FY 2016 MedPAR file to determine the number of cases where a procedure code from MS–DRG 614 or MS–DRG 615 was reported with a procedure code from MS–DRGs 622, 623 or 624 on the same claim. Our findings are shown in the table below.

MS–DRGs for Adrenal, Pituitary, Skin Grafts and Wound Debridement Procedures

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 614 procedures with MS–DRG 622 procedures	46	10.2	$12,977
MS–DRG 614 procedures with MS–DRG 623 procedures	240	4.4	11,540
MS–DRG 615 procedures with MS–DRG 624 procedures	125	2.9	14,494

As shown in the table above, there were a total of 46 cases reporting procedures from MS–DRG 614 and 622 on the same claim with an average length of stay of 10.15 days and average costs of $12,977. There were a total of 240 cases reporting procedures from MS–DRG 614 and MS–DRG 623 on the same claim with an average length of stay of 4.42 days and average costs of $11,540. Lastly, there were a total of 125 cases reporting procedures from MS–DRG 615 and MS–DRG 624 on the same claim with an average length of stay of 2.93 days and average costs of $14,494.

We then examined the redistribution of cases that is anticipated to occur as a result of the proposal to move MS–DRGs 614 and 615 above MS–DRGs 622, 623, and 624 in the surgical hierarchy for Version 35 of the ICD–10 MS–DRGs, by processing the claims data from the March update of the FY 2016 MedPAR file through the ICD–10 MS–DRG GROUPER Version 34 and then processing the same claims data through the ICD–10 MS–DRG GROUPER Version 35 for comparison. The number of cases from this comparison that result in different MS–DRG assignments is the number of the cases that are anticipated to potentially shift or be redistributed. We found that the number of cases moving out of MS–DRG 622 and into MS–DRG 614 is approximately 46 cases, the number of cases moving out of MS–DRG 623 and into MS–DRG 614 is approximately 240 cases and the number of cases moving out of MS–DRG 624 and into MS–DRG 615 is approximately 125 cases. We believe that overall, the impact of this change is limited because the subset of cases that would be reclassified is approximately 6.7 percent of the total cases currently grouping to MS–DRGs 622, 623 and 624. Additionally, as shown above, in the analysis of claims where a procedure code from MS–DRG 614 or MS–DRG 615 was reported with a procedure code from MS–DRGs 622, 623, or 624 on the same claim, the average costs for those cases are consistent with the average costs for all cases in MS DRGs 614 and 615.

For issues pertaining to the surgical hierarchy, as with other MS–DRG

related requests, we encourage commenters to submit requests to examine ICD–10 claims data via the CMS MS–DRG Classification Change Requests Mailbox located at *MSDRG ClassificationChange@cms.hhs.gov* by November 1, 2017 for FY 2019 consideration.

After consideration of the public comments we received, we are finalizing our proposal to move MS–DRGs 614 and 615 above MS–DRGs 622, 623, and 624 in the surgical hierarchy effective October 1, 2017.

12. Changes to the MS–DRG Diagnosis Codes for FY 2018

a. Background of the CC List and the CC Exclusions List

Under the IPPS MS–DRG classification system, we have developed a standard list of diagnoses that are considered CCs. Historically, we developed this list using physician panels that classified each diagnosis code based on whether the diagnosis, when present as a secondary condition, would be considered a substantial complication or comorbidity. A substantial complication or comorbidity was defined as a condition that, because of its presence with a specific principal diagnosis, would cause an increase in the length-of-stay by at least 1 day in at least 75 percent of the patients. However, depending on the principal diagnosis of the patient, some diagnoses on the basic list of complications and comorbidities may be excluded if they are closely related to the principal diagnosis. In FY 2008, we evaluated each diagnosis code to determine its impact on resource use and to determine the most appropriate CC subclassification (non-CC, CC, or MCC) assignment. We refer readers to sections II.D.2. and 3. of the preamble of the FY 2008 IPPS final rule with comment period for a discussion of the refinement of CCs in relation to the MS–DRGs we adopted for FY 2008 (72 FR 47152 through 47171).

b. Additions and Deletions to the Diagnosis Code Severity Levels for FY 2018

We stated in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19847) that the following tables identifying the proposed additions and deletions to the MCC severity levels list and the proposed additions and deletions to the CC severity levels list for FY 2018 are available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

Table 6I.1—Proposed Additions to the MCC List—FY 2018;

Table 6I.2—Proposed Deletions to the MCC List—FY 2018;

Table 6J.1—Proposed Additions to the CC List—FY 2018; and

Table 6J.2—Proposed Deletions to the CC List—FY 2018.

We invited public comments on our proposed severity level designations for the diagnosis codes listed in Table 6I.1. and Table 6J.1. We noted that, for Table 6I.2. and Table 6J.2., the proposed deletions were a result of code expansions. Therefore, the diagnosis codes on these lists are no longer valid codes, effective FY 2018. For example, diagnosis code O00.10 (Tubal pregnancy without intrauterine pregnancy) is a current CC for FY 2017 under Version 34 of the ICD–10 MS–DRGs. Effective FY 2018, under Version 35 of the ICD–10 MS–DRGs, this single code has been expanded into three diagnosis codes to include laterality (left/right) and an unspecified option with the addition of a sixth character. Therefore, diagnosis code O00.10 is included in Table 6J.2. for deletion from the CC list because it is no longer a valid code in FY 2018.

Comment: Commenters agreed with the proposed additions and deletions to the MCC and CC List severity level designations for FY 2018. One commenter suggested that CMS also consider adding existing diagnosis codes from subcategories L97.5 (Non-pressure chronic ulcer of other part of foot) and L98.4 (Non-pressure chronic ulcer of skin, not elsewhere classified) to the CC List. This commenter noted that new diagnosis codes from these subcategories were proposed to be added to the CC List. However, according to the commenter, existing codes from these same subcategories are not currently included in the CC List even though some of them represent a greater severity level than the new codes that were proposed to be added to the CC List.

Response: We appreciate the commenters' support. In response to the commenter who suggested that we consider adding existing diagnosis codes in subcategories L97.5 and L98.4 to the CC list, we were unable to fully evaluate this request for FY 2018 but will consider this recommendation as part of our comprehensive review of the CC and MCC lists. As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19848) and in the sections that follow, we have plans to conduct a comprehensive review of the CC and MCC lists for FY 2019. Therefore, we will be evaluating all of the ICD–10–CM diagnosis codes for this effort.

After consideration of the public comments we received, we are finalizing our proposed additions and deletions to the MCC severity levels list and the proposed additions and deletions to the CC severity levels list for FY 2018. We refer readers to the Tables 6I.1, 6I.2, 6J.1, and 6J.2 associated with this final rule, which are available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

c. Principal Diagnosis Is Its Own CC or MCC

CMS' initial goal in developing the ICD–10 MS–DRGs was to ensure that a patient case was assigned to the same MS–DRG, regardless of whether the patient record was to be coded in ICD–9–CM or ICD–10. When certain ICD–10–CM combination codes are reported as a principal diagnosis, it implies that a CC or MCC is present. This occurs as a result of evaluating the cluster of ICD–9–CM codes that would have been coded on an ICD–9–CM record. If one of the ICD–9–CM codes in the cluster was a CC or an MCC, the single ICD–10–CM combination code used as a principal diagnosis also must imply that the CC or MCC is present.

The ICD–10–CM diagnosis codes to which this logic applies are included in Appendix J of the ICD–10 MS–DRG Version 34 Definitions Manual (which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2017-IPPS-Final-Rule-Home-Page-Items/FY2017-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending*). Appendix J includes two lists: Part 1 is the list of principal diagnosis codes where the ICD–10–CM code is its own MCC. Part 2 is the list of principal diagnosis codes where the ICD–10–CM code is its own CC. Part 1 of Appendix J corresponds to Table 6L.—Principal Diagnosis Is Its Own MCC List, and Part 2 of Appendix J corresponds to Table 6M.—Principal Diagnosis Is Its Own CC List.

We received a request to add the ICD–10–CM diagnosis codes for acute myocardial infarction, decompensated heart failure and specified forms of shock, which are currently designated as a CC or an MCC when reported as a secondary diagnosis, to Table 6L.—Principal Diagnosis Is Its Own MCC List. According to the requestor, the addition of these codes to the list is necessary for bundled payment initiatives and so that facilities that

accept these patients in transfer have resources to care for them.

As we stated in the proposed rule, the purpose of the Principal Diagnosis Is Its Own CC or MCC Lists was to ensure consistent MS–DRG assignment between the ICD–9–CM and ICD–10 MS–DRGs due to the clusters and combination codes. There are a number of other ICD–10–CM combination codes that, due to their prior designation as a CC or an MCC when reported as a secondary diagnosis, are not on either of these lists. Having multiple lists for CC and MCC diagnoses when reported as a principal and/or secondary diagnosis may not provide an accurate representation of resource utilization for the MS–DRGs. As discussed in further detail below, we have plans to conduct a comprehensive review of the CC and MCC lists for FY 2019. We believe the results of that review will help to inform the future of these lists.

Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19848), we did not propose to add the ICD–10–CM diagnosis codes for acute myocardial infarction, decompensated heart failure and specified forms of shock to Table 6L.—Principal Diagnosis Is Its Own MCC List. In addition, we did not propose any changes to Table 6L.—Principal Diagnosis Is Its Own MCC List and Table 6M.—Principal Diagnosis Is Its Own CC List. We invited public comments on our proposal to maintain the existing lists of principal diagnosis codes in Tables 6L. and 6M for FY 2018.

Comment: Commenters supported the proposal to not make changes to Table 6L and Table 6M. One commenter acknowledged that CMS is delaying further modifications to Tables 6L. and 6M. until the severity level (MCC and CC) analysis is performed for FY 2019. However, this commenter requested that the proposed MS–DRG assignments for the new myocardial infarction type 2 diagnosis codes be reviewed for more appropriate assignments.

Response: We appreciate the commenters' support. In response to the commenter's request that we review the proposed MS–DRG assignments for the new myocardial infarction type 2 diagnosis codes for more appropriate assignments, we point out that the codes identifying myocardial infarction type 2 diagnoses were not finalized at the time of publication of the FY 2018 IPPS/LTCH PPS proposed rule and, therefore, were not included in Table 6A.—New Diagnosis Codes that was associated with the proposed rule. As discussed in the section that follows, we have made available the final tables associated with this final rule via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. We refer readers to the final rule Table 6A.—New Diagnosis Codes for the MS–DRG assignments for the acute myocardial infarction type 2 diagnosis codes for FY 2018, which are based on our usual process of assigning new codes to their predecessor code's MS–DRG assignment(s).

After consideration of the public comments we received, we are maintaining the current code lists for Table 6L.—Principal Diagnosis Is Its Own MCC and Table 6M.—Principal Diagnosis Is Its Own CC List for FY 2018.

d. CC Exclusions List for FY 2018

In the September 1, 1987 final notice (52 FR 33143) concerning changes to the DRG classification system, we modified the GROUPER logic so that certain diagnoses included on the standard list of CCs would not be considered valid CCs in combination with a particular principal diagnosis. We created the CC Exclusions List for the following reasons: (1) To preclude coding of CCs for closely related conditions; (2) to preclude duplicative or inconsistent coding from being treated as CCs; and (3) to ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair. As previously indicated, we developed a list of diagnoses, using physician panels, to include those diagnoses that, when present as a secondary condition, would be considered a substantial complication or comorbidity.

In previous years, we made changes to the list of CCs, either by adding new CCs or deleting CCs already on the list.

In the May 19, 1987 proposed notice (52 FR 18877) and the September 1, 1987 final notice (52 FR 33154), we explained that the excluded secondary diagnoses were established using the following five principles:

- Chronic and acute manifestations of the same condition should not be considered CCs for one another;
- Specific and nonspecific (that is, not otherwise specified (NOS)) diagnosis codes for the same condition should not be considered CCs for one another;
- Codes for the same condition that cannot coexist, such as partial/total, unilateral/bilateral, obstructed/unobstructed, and benign/malignant, should not be considered CCs for one another;
- Codes for the same condition in anatomically proximal sites should not be considered CCs for one another; and
- Closely related conditions should not be considered CCs for one another.

The creation of the CC Exclusions List was a major project involving hundreds of codes. We have continued to review the remaining CCs to identify additional exclusions and to remove diagnoses from the master list that have been shown not to meet the definition of a CC. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50541 through 50544) for detailed information regarding revisions that were made to the CC and CC Exclusion Lists under the ICD–9–CM MS–DRGs.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19848), for FY 2018, we proposed changes to the ICD–10 MS–DRGs Version 35 CC Exclusion List. Therefore, we developed Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2018; Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusions List—FY 2018; Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2018; and Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2018. Each of these principal diagnosis codes for which there is a CC exclusion is shown in Table 6G.2. with an asterisk and the conditions that will not count as a CC are provided in an indented column immediately following the affected principal diagnosis. Beginning with discharges on or after October 1 of each year, the indented diagnoses are not recognized by the GROUPER as valid CCs for the asterisked principal diagnoses. Tables 6G. and 6H. associated with the proposed rule are available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

Comment: Commenters supported the proposed modifications to the CC Exclusion List for FY 2018 as displayed in Table 6G.1., Table 6G.2., Table 6H.1., and Table 6H.2. that were associated with the proposed rule and made available via the Internet on the CMS Web site.

Response: We appreciate the commenters' support.

We note that, for this FY 2018 IPPS/LTCH PPS final rule, we have developed Table 6K.—Complete List of CC Exclusions. Table 6K. corresponds to the Part 1 list of Appendix C in the ICD–10 MS–DRG Definitions Manual as described above.

The complete documentation of the ICD–10 MS–DRG Version 35 GROUPER logic, including the CC Exclusion List, is available via the Internet on the CMS Acute Inpatient PPS Web page at: *https://www.cms.gov/Medicare/*

Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.

To identify new, revised and deleted diagnosis and procedure codes, for FY 2018, we developed Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, Table 6C.—Invalid Diagnosis Codes, Table 6D.—Invalid Procedure Codes, Table 6E.—Revised Diagnosis Code Titles, and Table 6F.—Revised Procedure Code Titles for the proposed rule and this final rule.

These tables are not published in the Addendum to the proposed rule or the final rule but are available via the Internet on the CMS Web site at: (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) as described in section VI. of the Addendum to this final rule. As discussed in section II.F.15. of the preamble of this final rule, the code titles are adopted as part of the ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee process. Therefore, although we publish the code titles in the IPPS proposed and final rules, they are not subject to comment in the proposed or final rules. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19849), we invited public comments on the MDC and MS–DRG assignments for the new diagnosis and procedure codes as set forth in Table 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes. In addition, we invited public comments on the proposed severity level designations for the new diagnosis codes as set forth in Table 6A. and the proposed O.R. status for the new procedure codes as set forth in Table 6B.

Comment: One commenter disagreed with the addition of new ICD–10–CM diagnosis code R06.03 (Acute respiratory distress) as displayed in Table 6A.—New Diagnosis Codes associated with the FY 2018 IPPS/LTCH PPS proposed rule, stating that the terminology for this code title is outdated. The commenter stated that physician documentation generally supports either Acute Respiratory Distress Syndrome (ARDS) or Acute Respiratory Failure (ARF). The commenter requested that new diagnosis codes be created to avoid confusion and to support appropriate physician documentation.

Response: As noted earlier and discussed in section II.F.15. of the preamble of this final rule, the code titles are adopted as part of the ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee process. Therefore, although we publish the code titles in the IPPS proposed and final rules, they are not subject to comment in the proposed or final rules. We also note that the condition of ARDS is identified by ICD–10–CM diagnosis code J80 (Acute respiratory distress syndrome) and ARF is identified in ICD–10–CM subcategory J96.0 (Acute respiratory failure). Therefore, it is not necessary to submit a request for new diagnosis codes to the ICD–10 Coordination and Maintenance Committee.

Comment: Several commenters disagreed with the proposed Non-O.R. designations for certain procedure codes displayed in Table 6B.—New Procedure Codes associated with the FY 2018 IPPS/LTCH PPS proposed rule. The commenters recommended that CMS consider revising the designation of these procedure codes from Non-O.R. to O.R. The commenters identified approximately 200 new procedure codes describing the insertion, removal, or revision of ''other device'' in various body parts that they stated require an O.R. setting or are most often performed in the O.R. setting using sterile technique. The commenters further stated that patients undergoing these procedures are placed under general anesthesia and the procedures require significant time and skill.

Response: We reexamined a significant portion of the procedure codes listed in Table 6B.—New Procedure Codes that was associated with the FY 2018 IPPS/LTCH PPS proposed rule that the commenters recommended we consider revising from Non-O.R. to O.R. We note that we were unable to fully reevaluate the complete list for FY 2018, but we plan to conduct a review for FY 2019. Based upon our review, and upon further consideration of whether these procedures would be performed in an O.R. setting, we are revising the designation of the new procedure codes in the following table from non-O.R. to O.R.

ICD–10–PCS code	Code description
00H03YZ	Insertion of Other Device into Brain, Percutaneous Approach.
00H04YZ	Insertion of Other Device into Brain, Percutaneous Endoscopic Approach.
00H63YZ	Insertion of Other Device into Cerebral Ventricle, Percutaneous Approach.
00H64YZ	Insertion of Other Device into Cerebral Ventricle, Percutaneous Endoscopic Approach.
00HU0YZ	Insertion of Other Device into Spinal Canal, Open Approach.
00HV0YZ	Insertion of Other Device into Spinal Cord, Open Approach.
00HV3YZ	Insertion of Other Device into Spinal Cord, Percutaneous Approach.
00HV4YZ	Insertion of Other Device into Spinal Cord, Percutaneous Endoscopic Approach.
02H43YZ	Insertion of Other Device into Coronary Vein, Percutaneous Approach.
02H44YZ	Insertion of Other Device into Coronary Vein, Percutaneous Endoscopic Approach.
02H63YZ	Insertion of Other Device into Right Atrium, Percutaneous Approach.
02H64YZ	Insertion of Other Device into Right Atrium, Percutaneous Endoscopic Approach.
02H73YZ	Insertion of Other Device into Left Atrium, Percutaneous Approach.
02H74YZ	Insertion of Other Device into Left Atrium, Percutaneous Endoscopic Approach.
02HA3YZ	Insertion of Other Device into Heart, Percutaneous Approach.
02HA4YZ	Insertion of Other Device into Heart, Percutaneous Endoscopic Approach.
02HK3YZ	Insertion of Other Device into Right Ventricle, Percutaneous Approach.
02HK4YZ	Insertion of Other Device into Right Ventricle, Percutaneous Endoscopic Approach.
02HL3YZ	Insertion of Other Device into Left Ventricle, Percutaneous Approach.
02HL4YZ	Insertion of Other Device into Left Ventricle, Percutaneous Endoscopic Approach.
02HN3YZ	Insertion of Other Device into Pericardium, Percutaneous Approach.
02HN4YZ	Insertion of Other Device into Pericardium, Percutaneous Endoscopic Approach.
02HP0YZ	Insertion of Other Device into Pulmonary Trunk, Open Approach.
02HP3YZ	Insertion of Other Device into Pulmonary Trunk, Percutaneous Approach.
02HP4YZ	Insertion of Other Device into Pulmonary Trunk, Percutaneous Endoscopic Approach.
02HQ3YZ	Insertion of Other Device into Right Pulmonary Artery, Percutaneous Approach.
02HQ4YZ	Insertion of Other Device into Right Pulmonary Artery, Percutaneous Endoscopic Approach.

ICD–10–PCS code	Code description
02HR3YZ	Insertion of Other Device into Left Pulmonary Artery, Percutaneous Approach.
02HR4YZ	Insertion of Other Device into Left Pulmonary Artery, Percutaneous Endoscopic Approach.
02HS3YZ	Insertion of Other Device into Right Pulmonary Vein, Percutaneous Approach.
02HS4YZ	Insertion of Other Device into Right Pulmonary Vein, Percutaneous Endoscopic Approach.
02HT3YZ	Insertion of Other Device into Left Pulmonary Vein, Percutaneous Approach.
02HT4YZ	Insertion of Other Device into Left Pulmonary Vein, Percutaneous Endoscopic Approach.
02HV3YZ	Insertion of Other Device into Superior Vena Cava, Percutaneous Approach.
02HV4YZ	Insertion of Other Device into Superior Vena Cava, Percutaneous Endoscopic Approach.
02HW0YZ	Insertion of Other Device into Thoracic Aorta, Descending, Open Approach.
02HW3YZ	Insertion of Other Device into Thoracic Aorta, Descending, Percutaneous Approach.
02HW4YZ	Insertion of Other Device into Thoracic Aorta, Descending, Percutaneous Endoscopic Approach.
07HK0YZ	Insertion of Other Device into Thoracic Duct, Open Approach.
07HK4YZ	Insertion of Other Device into Thoracic Duct, Percutaneous Endoscopic Approach.
07HL0YZ	Insertion of Other Device into Cisterna Chyli, Open Approach.
07HL4YZ	Insertion of Other Device into Cisterna Chyli, Percutaneous Endoscopic Approach.
07HM0YZ	Insertion of Other Device into Thymus, Open Approach.
07HM4YZ	Insertion of Other Device into Thymus, Percutaneous Endoscopic Approach.
07HN0YZ	Insertion of Other Device into Lymphatic, Open Approach.
07HP0YZ	Insertion of Other Device into Spleen, Open Approach.
09HY0YZ	Insertion of Other Device into Sinus, Open Approach.
0BH04YZ	Insertion of Other Device into Tracheobronchial Tree, Percutaneous Endoscopic Approach.
0BH14YZ	Insertion of Other Device into Trachea, Percutaneous Endoscopic Approach.
0BHK4YZ	Insertion of Other Device into Right Lung, Percutaneous Endoscopic Approach.
0BHK8YZ	Insertion of Other Device into Right Lung, Via Natural or Artificial Opening Endoscopic.
0BHL4YZ	Insertion of Other Device into Left Lung, Percutaneous Endoscopic Approach.
0BHL8YZ	Insertion of Other Device into Left Lung, Via Natural or Artificial Opening Endoscopic.
0BHQ4YZ	Insertion of Other Device into Pleura, Percutaneous Endoscopic Approach.
0BHQ8YZ	Insertion of Other Device into Pleura, Via Natural or Artificial Opening Endoscopic.
0BHT4YZ	Insertion of Other Device into Diaphragm, Percutaneous Endoscopic Approach.
0BPK4YZ	Removal of Other Device from Right Lung, Percutaneous Endoscopic Approach.
0BPK8YZ	Removal of Other Device from Right Lung, Via Natural or Artificial Opening Endoscopic.
0BPL4YZ	Removal of Other Device from Left Lung, Percutaneous Endoscopic Approach.
0BPL8YZ	Removal of Other Device from Left Lung, Via Natural or Artificial Opening Endoscopic.
0BPQ0YZ	Removal of Other Device from Pleura, Open Approach.
0BPQ4YZ	Removal of Other Device from Pleura, Percutaneous Endoscopic Approach.
0BPQ8YZ	Removal of Other Device from Pleura, Via Natural or Artificial Opening Endoscopic.
0BPT4YZ	Removal of Other Device from Diaphragm, Percutaneous Endoscopic Approach.
0BWK4YZ	Revision of Other Device in Right Lung, Percutaneous Endoscopic Approach.
0BWK8YZ	Revision of Other Device in Right Lung, Via Natural or Artificial Opening Endoscopic.
0BWL4YZ	Revision of Other Device in Left Lung, Percutaneous Endoscopic Approach.
0BWL8YZ	Revision of Other Device in Left Lung, Via Natural or Artificial Opening Endoscopic.
0BWQ4YZ	Revision of Other Device in Pleura, Percutaneous Endoscopic Approach.
0BWQ8YZ	Revision of Other Device in Pleura, Via Natural or Artificial Opening Endoscopic.
0BWT4YZ	Revision of Other Device in Diaphragm, Percutaneous Endoscopic Approach.
0HPT0YZ	Removal of Other Device from Right Breast, Open Approach.
0HPU0YZ	Removal of Other Device from Left Breast, Open Approach.
0HWT0YZ	Revision of Other Device in Right Breast, Open Approach.
0HWU0YZ	Revision of Other Device in Left Breast, Open Approach.
0JHS0YZ	Insertion of Other Device into Head and Neck Subcutaneous Tissue and Fascia, Open Approach.
0JHT0YZ	Insertion of Other Device into Trunk Subcutaneous Tissue and Fascia, Open Approach.
0JHV0YZ	Insertion of Other Device into Upper Extremity Subcutaneous Tissue and Fascia, Open Approach.
0JHW0YZ	Insertion of Other Device into Lower Extremity Subcutaneous Tissue and Fascia, Open Approach.
0TH58YZ	Insertion of Other Device into Kidney, Via Natural or Artificial Opening Endoscopic.
0TH98YZ	Insertion of Other Device into Ureter, Via Natural or Artificial Opening Endoscopic.
0THB8YZ	Insertion of Other Device into Bladder, Via Natural or Artificial Opening Endoscopic.
0TP58YZ	Removal of Other Device from Kidney, Via Natural or Artificial Opening Endoscopic.
0TW98YZ	Revision of Other Device in Ureter, Via Natural or Artificial Opening Endoscopic.
0TWB8YZ	Revision of Other Device in Bladder, Via Natural or Artificial Opening Endoscopic.

After consideration of the public comments that we received, we are finalizing the designation of the procedure codes listed in the table above from non-O.R. to O.R., effective October 1, 2017.

We note that, historically, when new procedure codes were created, they were proposed to be given the same O.R. designation as their predecessor code. However, with the transition from ICD–9 to ICD–10, the determination of when a procedure code should be designated as an O.R. procedure has become a much more complex task. This is, in part, due to the number of various approaches available in the ICD–10–PCS classification. While we have typically evaluated procedures on the basis of whether or not they would be performed in an operating room, we believe that there may be other factors to consider, particularly with the implementation of ICD–10. Therefore, we are soliciting comments on what factors or criteria to consider in determining whether a procedure should be designated as an O.R. procedure in the ICD–10–PCS

classification system. We encourage commenters to submit comments via the CMS MS–DRG Classification Change Requests Mailbox located at *MSDRG ClassificationChange@cms.hhs.gov* by November 1, 2017 for FY 2019 consideration.

We are also making available on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* the following final tables associated with this final rule:

- Table 6A.—New Diagnosis Codes–FY 2018;
- Table 6B.—New Procedure Codes–FY 2018;
- Table 6C.—Invalid Diagnosis Codes–FY 2018;
- Table 6D.—Invalid Procedure Codes–FY 2018;
- Table 6E.—Revised Diagnosis Code Titles–FY 2018;
- Table 6F.—Revised Procedure Code Titles–FY 2018;
- Table 6G.1.—Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2018;
- Table 6G.2.—Principal Diagnosis Order Additions to the CC Exclusions List—FY 2018;
- Table 6H.1.—Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2018;
- Table 6H.2.—Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2018;
- Table 6I.—Complete MCC List—FY 2018;
- Table 6I.1.—Additions to the MCC List–FY 2018;
- Table 6I.2.–Deletions to the MCC List—FY 2018;
- Table 6J.—Complete CC List—FY 2018;
- Table 6J.1.—Additions to the CC List–FY 2018;
- Table 6J.2.—Deletions to the CC List –FY 2018;
- Table 6K.—Complete List of CC Exclusions–FY 2018;
- Table 6L.—Principal Diagnosis Is Its Own MCC List–FY 2018; and
- Table 6M.—Principal Diagnosis Is Its Own CC List–FY 2018.

13. Comprehensive Review of CC List for FY 2019

In the FY 2008 IPPS final rule (72 FR 47153 through 47175), we discussed our efforts to better recognize severity of illness which began with a comprehensive review of the CC list and, ultimately, the implementation of the MS–DRGs. Similar to the analysis that was performed at that time, we are providing the public with notice of our plans to conduct a comprehensive review of the CC and MCC lists for FY 2019.

As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19849), as a result of the time that has elapsed since that review and changes to how inpatient care is currently delivered, we plan to analyze if further refinements to these lists are warranted. For example, over the past several years, there has been a steady increase in the proportion of cases grouping to the MS–DRGs with an MCC severity level than had previously occurred. Our evaluation will assist in determining if the conditions designated as an MCC continue to represent significant increases in resource utilization that support the MCC designation.

We currently utilize a statistical algorithm to determine the impact on resource use of each secondary diagnosis. Each diagnosis for which Medicare data are available is evaluated to determine its impact on resource use and to determine the most appropriate CC subclass (non-CC, CC, or MCC) assignment. In order to make this determination, the average costs for each subset of cases is compared to the expected costs for cases in that subset. The following format is used to evaluate each diagnosis:

Code	Diagnosis	Cnt1	C1	Cnt2	C2	Cnt3	C3

Count (Cnt) is the number of patients in each subset and C1, C2, and C3 are a measure of the impact on resource use of patients in each of the subsets. The C1, C2, and C3 values are a measure of the ratio of average costs for patients with these conditions to the expected average costs across all cases. The C1 value reflects a patient with no other secondary diagnosis or with all other secondary diagnoses that are non-CCs. The C2 value reflects a patient with at least one other secondary diagnosis that is a CC but none that is an MCC. The C3 value reflects a patient with at least one other secondary diagnosis that is an MCC. A value close to 1.0 in the C1 field would suggest that the code produces the same expected value as a non-CC diagnosis. That is, average costs for the case are similar to the expected average costs for that subset and the diagnosis is not expected to increase resource usage. A higher value in the C1 (or C2 and C3) field suggests more resource usage is associated with the diagnosis and an increased likelihood that it is more like a CC or major CC than a non-CC. Thus, a value close to 2.0 suggests the condition is more like a CC than a non-CC but not as significant in resource usage as an MCC. A value close to 3.0 suggests the condition is expected to consume resources more similar to an MCC than a CC or non-CC. For example, a C1 value of 1.8 for a secondary diagnosis means that for the subset of patients who have the secondary diagnosis and have either no other secondary diagnosis present, or all the other secondary diagnoses present are non-CCs, the impact on resource use of the secondary diagnoses is greater than the expected value for a non-CC by an amount equal to 80 percent of the difference between the expected value of a CC and a non-CC (that is, the impact on resource use of the secondary diagnosis is closer to a CC than a non-CC).

We invited public comments regarding other possible ways we can incorporate meaningful indicators of clinical severity.

We did not receive any public comments offering suggestions on alternate ways to incorporate meaningful indicators of clinical severity. Therefore, we expect to continue to utilize this same statistical algorithm to determine the impact on resource use of each secondary diagnosis to conduct our comprehensive review of the CC and MCC lists for FY 2019.

14. Review of Procedure Codes in MS DRGs 981 Through 983; 984 Through 986; and 987 Through 989

Each year, we review cases assigned to MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively); MS–DRGs 984, 985, and 986 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively); and MS–DRGs 987, 988, and 989 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to determine whether it would be appropriate to change the procedures assigned among these MS–DRGs. MS–DRGs 981 through 983, 984 through 986, and 987 through 989 are reserved for those cases in which none of the O.R. procedures performed are related to the principal diagnosis. These MS–DRGs

are intended to capture atypical cases, that is, those cases not occurring with sufficient frequency to represent a distinct, recognizable clinical group.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19849), we stated that under the ICD–10 MS–DRGs Version 34, MS–DRGs 984 through 986 are assigned when one or more of the procedures described by ICD–10–PCS codes in Table 6P.2. that was associated with the FY 2018 proposed rule (which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) are performed and are unrelated to the principal diagnosis. All remaining O.R. procedures are assigned to MS–DRGs 981 through 983 and 987 through 989, with MS–DRGs 987 through 989 assigned to those discharges in which the only procedures performed are nonextensive procedures that are unrelated to the principal diagnosis.

We refer the reader to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56847 through 56848) for a discussion of the movement and redesignation of procedure codes from MS–DRGs 984 through 986 related to the transition of the ICD–10 MS–DRGs.

Our review of MedPAR claims data showed that there are no cases that merited movement or should logically be reassigned from ICD–10 MS–DRGs 984 through 986 to any of the other MDCs for FY 2018. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19849 through 19850), for FY 2018, we did not propose to change the procedures assigned among these MS–DRGs. We invited public comments on our proposal to maintain the current structure of these MS–DRGs.

Comment: Commenters supported the proposal to maintain the current structure of MS–DRGs 984 through 986 and not to reassign or change the procedures assigned among these MS–DRGs to other MDCs.

Response: We appreciate the commenters' support.

After consideration of the public comments that we received, we are finalizing our proposal to maintain the current structure of MS–DRGs 984 through 986 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) and not to reassign or change the procedures assigned among these MS–DRGs to other MDCs for ICD–10 MS–DRGs Version 35, effective October 1, 2017.

a. Moving Procedure Codes From MS–DRGs 981 Through 983 or MS–DRGs 987 Through 989 Into MDCs

We annually conduct a review of procedures producing assignment to MS–DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS–DRGs 987 through 989 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) on the basis of volume, by procedure, to see if it would be appropriate to move procedure codes out of these MS–DRGs into one of the surgical MS–DRGs for the MDC into which the principal diagnosis falls. The data are arrayed in two ways for comparison purposes. We look at a frequency count of each major operative procedure code. We also compare procedures across MDCs by volume of procedure codes within each MDC.

We identify those procedures occurring in conjunction with certain principal diagnoses with sufficient frequency to justify adding them to one of the surgical MS–DRGs for the MDC in which the diagnosis falls. As we indicated in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19850), upon review of the claims data from the December 2016 update of the FY 2016 MedPAR file, we did not find any cases that merited movement or that should logically be assigned to any of the other MDCs. Therefore, for FY 2018, we did not propose to remove any procedures from MS–DRGs 981 through 983 or MS–DRGs 987 through 989 into one of the surgical MS–DRGs for the MDC into which the principal diagnosis is assigned. We invited public comments on our proposal to maintain the current structure of these MS–DRGs.

Comment: Commenters supported the proposal to maintain the current structure of MS–DRGs 981 through 983 and MS–DRGs 987 through 989.

Response: We appreciate the commenters' support.

After consideration of the public comments that we received, we are finalizing our proposal to not remove any procedures from MS–DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS–DRGs 987 through 989 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) into one of the surgical MS–DRGs for the MDC into which the principal diagnosis is assigned for ICD–10 MS–DRGs Version 35, effective October 1, 2017.

b. Reassignment of Procedures Among MS–DRGs 981 Through 983, 984 Through 986, and 987 Through 989

We also review the list of ICD–10–PCS procedures that, when in combination with their principal diagnosis code, result in assignment to MS–DRGs 981 through 983, 984 through 986, or 987 through 989, to ascertain whether any of those procedures should be reassigned from one of those three groups of MS–DRGs to another of the three groups of MS–DRGs based on average costs and the length of stay. We look at the data for trends such as shifts in treatment practice or reporting practice that would make the resulting MS–DRG assignment illogical. If we find these shifts, we would propose to move cases to keep the MS–DRGs clinically similar or to provide payment for the cases in a similar manner. Generally, we move only those procedures for which we have an adequate number of discharges to analyze the data.

Based on the results of our review of the December 2016 update of the FY 2016 MedPAR file, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19850), we proposed to reassign the procedure codes currently assigned to MS–DRGs 984 through 986 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC and without CC/MCC, respectively) to MS–DRGs 987 through 989 (Non-extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC and without CC/MCC, respectively). As shown in the table below, we found a total of 1,001 cases in MS–DRGs 984 through 986 with an average length-of-stay of 7.5 days and average costs of $16,539. In MS–DRGs 987 through 989, we found a total of 17,772 cases, with an average length of stay of 7.5 days and average costs of $16,193.

O.R. PROCEDURES UNRELATED TO PRINCIPAL DIAGNOSIS

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRGs 984, 985 and 986 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively)	1,001	7.5	$16,539
MS–DRGs 987, 988 and 989 (Non-extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively)	17,772	7.5	16,193

The claims data demonstrate that it is no longer necessary to maintain a separate set of MS–DRGs specifically for the prostatic O.R. procedures. The average length of stay of 7.5 days is identical in both sets of MS–DRGs and the average costs are very similar with a difference of only $346. As we discussed in the proposed rule, our clinical advisors reviewed the data and support movement of these 1,001 cases into the nonextensive O.R. procedures MS–DRGs. They noted that treatment practices have shifted since the inception of the prostatic O.R. procedures grouping and the average costs are in alignment.

Therefore, for FY 2018, we proposed to reassign the prostatic O.R. procedure codes from MS–DRGs 984 through 986 to MS–DRGs 987 through 989 and to delete MS–DRGs 984, 985 and 986 because they would no longer be needed as a result of this proposed movement. We invited public comments on our proposals.

Comment: Commenters supported the proposal to reassign the prostatic O.R. procedure codes from MS–DRGs 984 through 986 to MS–DRGs 987 through 989 and to delete MS–DRGs 984, 985 and 986.

Response: We appreciate the commenters' support.

After consideration of the public comments that we received, we are finalizing our proposal to reassign the prostatic O.R. procedure codes from MS–DRGs 984 through 986 to MS–DRGs 987 through 989 (Non-extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC and without CC/MCC, respectively) and to delete MS–DRGs 984, 985 and 986 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC and without CC/MCC, respectively) for ICD–10 MS–DRGs Version 35, effective October 1, 2017.

15. Changes to the ICD–10–CM and ICD–10–PCS Coding Systems

In September 1985, the ICD–9–CM Coordination and Maintenance Committee was formed. This is a Federal interdepartmental committee, co-chaired by the National Center for Health Statistics (NCHS), the Centers for Disease Control and Prevention (CDC), and CMS, charged with maintaining and updating the ICD–9–CM system. The final update to ICD–9–CM codes was made on October 1, 2013. Thereafter, the name of the Committee was changed to the ICD–10 Coordination and Maintenance Committee, effective with the March 19–20, 2014 meeting. The ICD–10 Coordination and Maintenance Committee addresses updates to the ICD–10–CM and ICD–10–PCS coding systems. The Committee is jointly responsible for approving coding changes, and developing errata, addenda, and other modifications to the coding systems to reflect newly developed procedures and technologies and newly identified diseases. The Committee is also responsible for promoting the use of Federal and non-Federal educational programs and other communication techniques with a view toward standardizing coding applications and upgrading the quality of the classification system.

The official list of ICD–9–CM diagnosis and procedure codes by fiscal year can be found on the CMS Web site at: *http://cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/codes.html*. The official list of ICD–10–CM and ICD–10–PCS codes can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/index.html*.

The NCHS has lead responsibility for the ICD–10–CM and ICD–9–CM diagnosis codes included in the Tabular List and Alphabetic Index for Diseases, while CMS has lead responsibility for the ICD–10–PCS and ICD–9–CM procedure codes included in the Tabular List and Alphabetic Index for Procedures.

The Committee encourages participation in the previously mentioned process by health-related organizations. In this regard, the Committee holds public meetings for discussion of educational issues and proposed coding changes. These meetings provide an opportunity for representatives of recognized organizations in the coding field, such as the American Health Information Management Association (AHIMA), the American Hospital Association (AHA), and various physician specialty groups, as well as individual physicians, health information management professionals, and other members of the public, to contribute ideas on coding matters. After considering the opinions expressed at the public meetings and in writing, the Committee formulates recommendations, which then must be approved by the agencies.

The Committee presented proposals for coding changes for implementation in FY 2018 at a public meeting held on September 13–14, 2016, and finalized the coding changes after consideration of comments received at the meetings and in writing by November 13, 2016.

The Committee held its 2017 meeting on March 7–8, 2017. The deadline for submitting comments on these code proposals was April 7, 2017. It was announced at this meeting that any new ICD–10–CM/PCS codes for which there was consensus of public support and for which complete tabular and indexing changes would be made by May 2017 would be included in the October 1, 2017 update to ICD–10–CM/ICD–10–PCS. As discussed in earlier sections of the preamble of the proposed rule and this final rule, there are new, revised, and deleted ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes that are captured in Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, Table 6C.—Invalid Diagnosis Codes, Table 6D.—Invalid Procedure Codes, Table 6E.—Revised Diagnosis Code Titles, and Table 6F.—Revised Procedure Code Titles for the proposed rule and this final rule, which are available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Because of the length of these tables, they are not published in the Addendum to this final rule. Rather, they are available via the Internet as discussed in section VI. of the Addendum to this final rule.

We note that after publication of the FY 2018 IPPS/LTCH PPS proposed rule, we were notified by the CDC of changes to the FY 2018 ICD–10–CM diagnosis codes that were listed in Table 6A.—New Diagnosis Codes and Table 6C.—Invalid Diagnosis Codes that were

associated with the proposed rule. Specifically, ICD–10–CM diagnosis code K61.3 (Ischiorectal abscess) was listed in Table 6C. as an invalid diagnosis, and diagnosis codes K61.31 (Horseshoe abscess) and K61.32 (Ischiorectal abscess, NOS) were listed in Table 6A. as new diagnosis codes. The CDC informed us that they reversed their decision with respect to these codes. Therefore, diagnosis codes K61.31 and K61.32 are not being created for FY 2018 and are not reflected in Table 6A.—New Diagnosis Codes associated with this FY 2018 IPPS/LTCH PPS final rule. In addition, diagnosis code K61.3 is no longer reflected in Table 6C. associated with this final rule as an invalid diagnosis. Diagnosis code K61.3 will continue to be a valid code for FY 2018 in the ICD–10–CM classification.

The CDC also informed us of changes to diagnosis code K61.5 (Supralevator abscess). This diagnosis code was listed as a new diagnosis code in Table 6A.—New Diagnosis Codes that was associated with the proposed rule. However, this decision was also reversed. Therefore, diagnosis code K61.5 is not reflected in Table 6A. associated with this FY 2018 IPPS/LTCH PPS final rule and will not be reflected in the ICD–10–CM classification.

We also note that after publication of the FY 2018 IPPS/LTCH PPS proposed rule, the CDC revised the title for diagnosis code O00.212 from ''Left ovarian pregnancy without intrauterine pregnancy'' to ''Left ovarian pregnancy *with* intrauterine pregnancy''. The description of the code title changed from ''without'' to ''with'' for this diagnosis code. This change will not be reflected in Table 6E.—Revised Diagnosis Code Titles because it is a new diagnosis code effective FY 2018. Rather, the corrected code title description will appear in Table 6A.—New Diagnosis Codes associated with this FY 2018 IPPS/LTCH PPS final rule. Furthermore, the CDC issued an ICD–10–CM Errata on June 27, 2017 regarding this code title change for diagnosis code O00.212. The Errata document is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Coding/ICD10/2018-ICD-10-CM-and-GEMs.html*.

Live Webcast recordings of the discussions of procedure codes at the Committee's September 13–14, 2016 meeting and March 7–8, 2017 meeting can be obtained from the CMS Web site at: *http://cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html?redirect/icd9ProviderDiagnosticCodes/03_meetings.asp*. The minutes of the discussions of diagnosis codes at the September 13–14, 2016 meeting and March 7–8, 2017 meeting can be found at: *http://www.cdc.gov/nchs/icd/icd10cm_maintenance.html*. These Web sites also provide detailed information about the Committee, including information on requesting a new code, attending a Committee meeting, and timeline requirements and meeting dates.

We encourage commenters to address suggestions on coding issues involving diagnosis codes to: Donna Pickett, Co-Chairperson, ICD–10 Coordination and Maintenance Committee, NCHS, Room 2402, 3311 Toledo Road, Hyattsville, MD 20782. Comments may be sent by Email to: *nchsicd10cm@cdc.gov*.

Questions and comments concerning the procedure codes should be addressed to: Patricia Brooks, Co-Chairperson, ICD–10 Coordination and Maintenance Committee, CMS, Center for Medicare Management, Hospital and Ambulatory Policy Group, Division of Acute Care, C4–08–06, 7500 Security Boulevard, Baltimore, MD 21244–1850. Comments may be sent by Email to: *ICDProcedureCodeRequest@cms.hhs.gov*.

In the September 7, 2001 final rule implementing the IPPS new technology add-on payments (66 FR 46906), we indicated we would attempt to include proposals for procedure codes that would describe new technology discussed and approved at the Spring meeting as part of the code revisions effective the following October.

Section 503(a) of Public Law 108–173 included a requirement for updating diagnosis and procedure codes twice a year instead of a single update on October 1 of each year. This requirement was included as part of the amendments to the Act relating to recognition of new technology under the IPPS. Section 503(a) amended section 1886(d)(5)(K) of the Act by adding a clause (vii) which states that the Secretary shall provide for the addition of new diagnosis and procedure codes on April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) until the fiscal year that begins after such date. This requirement improves the recognition of new technologies under the IPPS system by providing information on these new technologies at an earlier date. Data will be available 6 months earlier than would be possible with updates occurring only once a year on October 1.

While section 1886(d)(5)(K)(vii) of the Act states that the addition of new diagnosis and procedure codes on April 1 of each year shall not require the Secretary to adjust the payment, or DRG classification, under section 1886(d) of the Act until the fiscal year that begins after such date, we have to update the DRG software and other systems in order to recognize and accept the new codes. We also publicize the code changes and the need for a mid-year systems update by providers to identify the new codes. Hospitals also have to obtain the new code books and encoder updates, and make other system changes in order to identify and report the new codes.

The ICD–10 (previously the ICD–9–CM) Coordination and Maintenance Committee holds its meetings in the spring and fall in order to update the codes and the applicable payment and reporting systems by October 1 of each year. Items are placed on the agenda for the Committee meeting if the request is received at least 2 months prior to the meeting. This requirement allows time for staff to review and research the coding issues and prepare material for discussion at the meeting. It also allows time for the topic to be publicized in meeting announcements in the **Federal Register** as well as on the CMS Web site. Final decisions on code title revisions are currently made by March 1 so that these titles can be included in the IPPS proposed rule. A complete addendum describing details of all diagnosis and procedure coding changes, both tabular and index, is published on the CMS and NCHS Web sites in June of each year. Publishers of coding books and software use this information to modify their products that are used by health care providers. This 5-month time period has proved to be necessary for hospitals and other providers to update their systems.

A discussion of this timeline and the need for changes are included in the December 4–5, 2005 ICD–9–CM Coordination and Maintenance Committee Meeting minutes. The public agreed that there was a need to hold the fall meetings earlier, in September or October, in order to meet the new implementation dates. The public provided comment that additional time would be needed to update hospital systems and obtain new code books and coding software. There was considerable concern expressed about the impact this April update would have on providers.

In the FY 2005 IPPS final rule, we implemented section 1886(d)(5)(K)(vii) of the Act, as added by section 503(a) of Public Law 108–173, by developing a mechanism for approving, in time for the April update, diagnosis and procedure code revisions needed to describe new technologies and medical services for purposes of the new technology add-on payment process. We

also established the following process for making these determinations. Topics considered during the Fall ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee meeting are considered for an April 1 update if a strong and convincing case is made by the requester at the Committee's public meeting. The request must identify the reason why a new code is needed in April for purposes of the new technology process. The participants at the meeting and those reviewing the Committee meeting summary report are provided the opportunity to comment on this expedited request. All other topics are considered for the October 1 update. Participants at the Committee meeting are encouraged to comment on all such requests. There were no requests approved for an expedited April l, 2017 implementation of a code at the September 13–14, 2016 Committee meeting. Therefore, there were no new codes implemented on April 1, 2017.

ICD–9–CM addendum and code title information is published on the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html?redirect/icd9ProviderDiagnosticCodes/01overview.asp#TopofPage*. ICD–10–CM and ICD–10–PCS addendum and code title information is published on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/index.html*. Information on ICD–10–CM diagnosis codes, along with the Official ICD–10–CM Coding Guidelines, can also be found on the CDC Web site at: *http://www.cdc.gov/nchs/icd/icd10.htm*. Information on new, revised, and deleted ICD–10–CM/ICD–10–PCS codes is also provided to the AHA for publication in the *Coding Clinic for ICD–10*. AHA also distributes information to publishers and software vendors.

CMS also sends copies of all ICD–10–CM and ICD–10–PCS coding changes to its Medicare contractors for use in updating their systems and providing education to providers.

The code titles are adopted as part of the ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee process. Therefore, although we publish the code titles in the IPPS proposed and final rules, they are not subject to comment in the proposed or final rules.

The following chart shows the number of ICD–10–CM and ICD–10–PCS codes and code changes since FY 2016 when ICD–10 was implemented.

TOTAL NUMBER OF CODES AND CHANGES IN TOTAL NUMBER OF CODES PER FISCAL YEAR ICD–10–CM AND ICD–10–PCS CODES

Fiscal year	Number	Change
FY 2016		
ICD–10–CM	69,823	
ICD–10–PCS	71,974	
FY 2017		
ICD–10–CM	71,486	+1,663
ICD–10–PCS	75,789	+3,815
FY 2018		
ICD–10–CM	71,704	+218
ICD–10–PCS	78,705	+2,916

As mentioned previously, the public is provided the opportunity to comment on any requests for new diagnosis or procedure codes discussed at the ICD–10 Coordination and Maintenance Committee meeting.

At the September 12–13, 2016 and March 7–8, 2017 Committee meetings, we discussed any requests we had received for new ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes that were to be implemented on October 1, 2017. We invited public comments on any code requests discussed at the September 12–13, 2016 and March 7–8, 2017 Committee meetings for implementation as part of the October 1, 2017 update. The deadline for commenting on code proposals discussed at the September 12–13, 2016 Committee meeting was November 13, 2016. The deadline for commenting on code proposals discussed at the March 7–8, 2017 Committee meeting was April 7, 2017.

Comment: One commenter stated that coding updates interfere with consistent clinical vocabulary maintenance. The commenter pointed to ICD–10–PCS code updates for FY 2018 which involve the addition of specificity beyond what was included in the 2017 version of ICD–10–PCS. The commenter stated that a core principle of clinical vocabulary maintenance is that the meaning of a code should not change over time. The commenter acknowledged that deadline for submitting comments on code proposals for the FY 2018 ICD–10–PCS had passed. The commenter stated that clinical vocabulary maintenance should be a primary consideration of the ICD–10 Coordination and Maintenance Committee before any further coding updates are proposed. The commenter looked forward to working with the ICD–10 Coordination and Maintenance Committee meeting on future code updates.

Response: CMS and CDC welcome the participation of the public at the ICD–10 Coordination and Maintenance Committee meetings. CMS and CDC encourage comments on any ICD–10–CM and ICD–10–PCS code updates presented at the meetings. The ICD–10–CM and ICD–10–PCS coding systems are not clinical vocabularies. The coding systems do not attempt to clarify or standardize how physicians describe clinical conditions or procedures. The ICD–10–CM and ICD–10–PCS coding systems are clinical classification systems. Classification systems arrange and organize like or related clinical conditions and procedures. The coding systems assign codes to capture diagnoses and procedures as documented by physicians. This can involve multiple diagnosis and procedure terms being captured in a single code. It is recognized that not all physicians use consistent terminology for identifying a condition or procedure. The coding systems recognize this fact and develop codes which capture this group of similar terms into a single code. The coding systems should not be viewed as a means to standardize medical terminology.

In response to public requests for updates to ICD–10–CM and ICD–10–PCS, the ICD–10 Coordination and Maintenance Committee presents the requested code updates and then solicits comments prior to making those updates. The ICD–9–CM and ICD–10 coding systems have been updated through the Coordination and Maintenance Committee since 1985, making updates to the coding systems that capture advances in medicine and changes in medical practices. The Committee will continue to meet to allow the public to provide comments on any requests to update the ICD–10–CM and ICD–10–PCS coding systems.

Comment: One commenter stated that it was a strong supporter of the conversion from ICD–9–CM to ICD–10–CM, including the creation of the new Section ''X'' codes to identify new medical services and technologies, because the newer, more robust coding system will allow for recognition of more technologies, procedures, and variations in patients' conditions on Medicare claims, which in turn will support greater specificity in MS–DRGs. However, the commenter asked that CMS provide additional information about how the ''X'' codes will be used and applied.

Response: We encourage the public to participate in the ICD–10 Coordination and Maintenance Committee meetings to offer comments on code updates. Any new codes that are finalized prior to the IPPS/LTCH PPS proposed rules, including ICD–10–PCS ''X'' codes, are included in the Table 6 series in the

IPPS/LTCH PPS proposed rule along with their proposed MS–DRG classifications. The public is offered the opportunity to comment on those MS–DRG classifications. Any new codes that are finalized after the IPPS/LTCH PPS proposed rule are included in the IPPS/LTCH PPS final rule along with their MS–DRG classifications. We refer the commenter to section II.H. of the preamble of this final rule for additional discussion of the section ''X'' codes.

16. Replaced Devices Offered Without Cost or With a Credit

a. Background

In the FY 2008 IPPS final rule with comment period (72 FR 47246 through 47251), we discussed the topic of Medicare payment for devices that are replaced without cost or where credit for a replaced device is furnished to the hospital. We implemented a policy to reduce a hospital's IPPS payment for certain MS–DRGs where the implantation of a device that has been recalled determined the base MS–DRG assignment. At that time, we specified that we will reduce a hospital's IPPS payment for those MS–DRGs where the hospital received a credit for a replaced device equal to 50 percent or more of the cost of the device.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51556 through 51557), we clarified this policy to state that the policy applies if the hospital received a credit equal to 50 percent or more of the cost of the replacement device and issued instructions to hospitals accordingly.

b. Changes for FY 2018

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19852 through 19853), for FY 2018, we did not propose to add any MS–DRGs to the policy for replaced devices offered without cost or with a credit. We proposed to continue to include the existing MS–DRGs currently subject to the policy as displayed in a table in the proposed rule.

In the proposed rule, we solicited public comments on our proposal to continue to include the existing MS–DRGs currently subject to the policy for replaced devices offered without cost or with credit and to not add any additional MS–DRGs to the policy. We noted that, as discussed in section II.F.2.b. and in section II.F.5.a. of the preamble of the proposed rule, we proposed to revise the titles for MS–DRG 023 and MS–DRGs 469 and 470. We referred readers to those discussions of the specific proposed MS–DRG titles. We did not receive any public comments opposing our proposal to continue to include the existing MS–DRGs currently subject to the policy and to not add any additional MS–DRGs. Therefore, we are finalizing the list of MS–DRGs displayed in the table in the proposed rule and below, with conforming changes to the finalized titles for MS–DRGs 023, 469, and 470, that will be subject to the replaced devices offered without cost or with a credit policy, effective October 1, 2017. As we indicated in the proposed rule, we also will issue this final list of MS–DRGs subject to the payment policy for devices provided at no cost or with a credit for FY 2018 to providers through guidance and instructions in the form of a Change Request (CR).

MDC	MS–DRG	MS–DRG title
Pre-MDC	001	Heart Transplant or Implant of Heart Assist System with MCC.
Pre-MDC	002	Heart Transplant or Implant of Heart Assist System without MCC.
1	023	Craniotomy with Major Device Implant or Acute CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator.
1	024	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC.
1	025	Craniotomy & Endovascular Intracranial Procedures with MCC.
1	026	Craniotomy & Endovascular Intracranial Procedures with CC.
1	027	Craniotomy & Endovascular Intracranial Procedures without CC/MCC.
1	040	Peripheral, Cranial Nerve & Other Nervous System Procedures with MCC.
1	041	Peripheral, Cranial Nerve & Other Nervous System Procedures with CC or Peripheral Neurostimulator.
1	042	Peripheral, Cranial Nerve & Other Nervous System Procedures without CC/MCC.
3	129	Major Head & Neck Procedures with CC/MCC or Major Device.
3	130	Major Head & Neck Procedures without CC/MCC.
5	215	Other Heart Assist System Implant.
5	216	Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheterization with MCC.
5	217	Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheterization with CC.
5	218	Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheterization without CC/MCC.
5	219	Cardiac Valve & Other Major Cardiothoracic Procedure without Cardiac Catheterization with MCC.
5	220	Cardiac Valve & Other Major Cardiothoracic Procedure without Cardiac Catheterization with CC.
5	221	Cardiac Valve & Other Major Cardiothoracic Procedure without Cardiac Catheterization without CC/MCC.
5	222	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/Heart Failure/Shock with MCC.
5	223	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/Heart Failure/Shock without MCC.
5	224	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/Heart Failure/Shock with MCC.
5	225	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/Heart Failure/Shock without MCC.
5	226	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC.
5	227	Cardiac Defibrillator Implant without Cardiac Catheterization without MCC.
5	242	Permanent Cardiac Pacemaker Implant with MCC.
5	243	Permanent Cardiac Pacemaker Implant with CC.
5	244	Permanent Cardiac Pacemaker Implant without CC/MCC.
5	245	AICD Generator Procedures.
5	258	Cardiac Pacemaker Device Replacement with MCC.
5	259	Cardiac Pacemaker Device Replacement without MCC.
5	260	Cardiac Pacemaker Revision Except Device Replacement with MCC.
5	261	Cardiac Pacemaker Revision Except Device Replacement with CC.
5	262	Cardiac Pacemaker Revision Except Device Replacement without CC/MCC.
5	265	AICD Lead Procedures.
5	266	Endovascular Cardiac Valve Replacement with MCC.
5	267	Endovascular Cardiac Valve Replacement without MCC.

MDC	MS–DRG	MS–DRG title
5	268	Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC.
5	269	Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC.
5	270	Other Major Cardiovascular Procedures with MCC.
5	271	Other Major Cardiovascular Procedures with CC.
5	272	Other Major Cardiovascular Procedures without CC/MCC.
8	461	Bilateral or Multiple Major Joint Procedures Of Lower Extremity with MCC.
8	462	Bilateral or Multiple Major Joint Procedures of Lower Extremity without MCC.
8	466	Revision of Hip or Knee Replacement with MCC.
8	467	Revision of Hip or Knee Replacement with CC.
8	468	Revision of Hip or Knee Replacement without CC/MCC.
8	469	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement.
8	470	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC.

17. Other Policy Changes: Other Operating Room (O.R.) and Non-O.R. Issues

a. O.R. Procedures to Non-O.R. Procedures

As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19853), we have continued our efforts to address the recommendations for consideration that we received in response to some of the proposals set forth in the FY 2017 IPPS/LTCH PPS proposed rule pertaining to changing the designation of ICD–10–PCS procedure codes from O.R. procedures to non-O.R. procedures. As we stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56871), we received requests and recommendations for over 800 procedure codes that we were not able to fully evaluate and finalize for FY 2017. We discuss these requests and recommendations below.

As discussed in the proposed rule, we also are addressing separate requests that we received regarding changing the designation of specific ICD–10–PCS procedure codes. For each group summarized below, the detailed lists of procedure codes are shown in Tables 6P.4a. through 6P.4p. (ICD–10–CM and ICD–10–PCS Code Designations, MCE and MS–DRG Changes—FY 2018) associated with the FY 2018 proposed rule and this final rule (which are available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*).

Comment: Some commenters expressed concern with the proposed changes from O.R. procedures to non-O.R. procedures for such a large number of procedure codes without having more detailed analysis of the impact to specific MS–DRGs. The commenters stated that many of the proposed changes for FY 2018 go beyond last year's changes when the changes from O.R. procedures to non-O.R. procedures were done for purposes of replicating the logic of the ICD–9 MS–DRGs.

Response: We acknowledge the concerns of the commenters regarding the volume of proposed changes for procedures to be redesignated from O.R. to non-O.R. As we stated in the FY 2018 IPPS/LTCH PPS proposed rule, we continued our efforts to address the recommendations that we received in response to some of the proposals set forth in the FY 2017 IPPS/LTCH PPS proposed rule pertaining to changing the designation of ICD–10–PCS procedure codes from O.R. procedures to non-O.R. procedures. We noted that those recommendations were for over 800 procedure codes that we were not able to fully evaluate and finalize for FY 2017. Therefore, we discussed the proposed changes for FY 2018.

The commenters are correct that the proposed changes for FY 2018 go beyond the FY 2017 proposed (and finalized) MS–DRG updates to change the designation of procedure codes from O.R. to non-O.R. that were done for purposes of replicating the logic of the ICD–9 MS–DRGs. We stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56790) that some of the issues evaluated for the FY 2017 MS–DRGs update continued to relate to the need for the ICD–10 MS–DRGs to accurately replicate the logic of the ICD–9–CM based version of the MS–DRGs. We noted that replication was important because both the logic for the MS–DRGs and the data source used to calculate and develop the relative payment weights were based on the same MedPAR claims data. We further noted that the logic for the proposed and final FY 2017 ICD–10 MS–DRGs was based upon the FY 2015 ICD–9–CM MedPAR claims data, which was also the data source used to calculate and develop the FY 2017 relative payment weights. However, for FY 2018 and future fiscal years, we are no longer replicating the ICD–9 MS–DRGs. As discussed in the FY 2018 IPPS/LTCH PPS proposed rule and this final rule, we are using ICD–10 coded claims data for the first time to propose changes to the ICD–10 MS–DRG classifications and to compute the relative weights. Therefore, our proposals and final policies for FY 2018 are based solely on the ICD–10 claims data from the FY 2016 MedPAR file.

As such, procedures that were designated as O.R. under ICD–9 will not necessarily be appropriate to designate as O.R. under ICD–10. Conversely, procedures that were not designated as O.R. under ICD–9 may be appropriate to designate as O.R. under ICD–10. As discussed elsewhere in this final rule, with the transition from ICD–9 to ICD–10, the determination of when a procedure code should be designated as an O.R. procedure has become a much more complex task. This is, in part, due to the number of various approaches available in the ICD–10–PCS classification, as well as changes in medical practice. While we have typically evaluated procedures on the basis of whether or not they would be performed in an operating room, we believe that there may be other factors to consider with regard to resource utilization, particularly with the implementation of ICD–10. Therefore, we are soliciting comments on what factors or criteria to consider in determining whether a procedure is designated as an O.R. procedure in the ICD–10–PCS classification system for FY 2019 consideration. Commenters should submit their recommendations to the following email address: *MSDRGClassificationChange@cms.hhs.gov* by November 1, 2017.

(1) Percutaneous/Diagnostic Drainage

One commenter identified 135 ICD–10–PCS procedure codes describing procedures involving percutaneous diagnostic and therapeutic drainage of central nervous system, vascular and other body sites that generally would not require the resources of an operating room and can be performed at the bedside. The list includes procedure codes that describe procedures

involving drainage with or without placement of a drainage device. We stated in the proposed rule that we agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19853), we proposed that the 135 ICD–10–PCS procedure codes listed in Table 6P.4a. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of the 135 procedure codes describing percutaneous diagnostic and therapeutic drainage of central nervous system, vascular and other body sites. However, one commenter disagreed with reclassifying procedure codes 009330Z (Drainage of Epidural Space with Drainage Device, Percutaneous Approach) and 00933ZZ (Drainage of Epidural Space, Percutaneous Approach) to non-O.R. procedures. According to the commenter, these two codes are assigned for percutaneous burr hole drainage of acute traumatic and nontraumatic intracranial epidural hematomas, and for drainage of intracranial epidural abscesses. The commenter noted that, although percutaneous burr hole drainages are performed through smaller openings in the skull than open burr hole drainages, they require drilling through the skull under sterile technique and anesthesia for pain control. The commenter also noted that similar procedure codes such as 009430Z (Drainage of Subdural Space with Drainage Device, Percutaneous Approach) and 00943ZZ (Drainage of Subdural Space, Percutaneous Approach) are currently classified as O.R. procedures.

Response: We appreciate the commenters' support. In response to the commenter who disagreed with reclassifying procedure codes 009330Z and 00933ZZ to non-O.R. procedures, upon further review and consideration, for the reasons the commenter pointed out and consistent with the current designation of procedure codes 009430Z and 00943ZZ, which are classified as O.R. procedures, we believe it is appropriate to maintain the current O.R. designation of procedure codes 009330Z and 00933ZZ.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of 133 ICD–10–PCS procedure codes listed in Table 6P.4a. associated with this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* from O.R. procedures to non-O.R. procedures, effective October 1, 2017. We also are finalizing the designation of procedure codes 009330Z and 00933ZZ to remain O.R. procedures for FY 2018. We note that, as shown in Table 6F.—Revised Procedure Code Titles associated with this final rule, the titles for procedure codes 009330Z, 00933ZZ, 009430Z and 00943ZZ are revised to include the term ''intracranial.'' Effective October 1, 2017, the title of ICD–10–PCS procedure code 009330Z is revised to read ''Drainage of Intracranial Epidural Space with Drainage Device, Percutaneous Approach''; the title of ICD–10–PCS procedure code 00933ZZ is revised to read ''Drainage of Intracranial Epidural Space, Percutaneous Approach''; the title of ICD–10–PCS procedure code 009430Z is revised to read ''Drainage of Intracranial Subdural Space with Drainage Device, Percutaneous Approach''; and the title of ICD–10–PCS procedure code 00943ZZ is revised to read ''Drainage of Intracranial Subdural Space, Percutaneous Approach''.

(2) Percutaneous Insertion of Intraluminal or Monitoring Device

One commenter identified 28 ICD–10–PCS procedure codes describing procedures involving the percutaneous insertion of intraluminal and monitoring devices into central nervous system and other cardiovascular body parts that generally would not require the resources of an operating room and can be performed at the bedside. We stated in the proposed rule that we agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19853), we proposed that the 28 ICD–10–PCS procedure codes listed in Table 6P.4b. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of the 28 procedure codes describing percutaneous insertion of intraluminal or monitoring devices into central nervous system and other cardiovascular body parts. However, one commenter disagreed with changing the designation for 15 of the 28 listed procedure codes. The commenter disagreed with changing the designation for ICD–10–PCS procedure codes 00H032Z (Insertion of Monitoring Device into Brain, Percutaneous Approach) and 00H632Z (Insertion of Monitoring Device into Cerebral Ventricle, Percutaneous Approach). According to the commenter, these two codes are assigned for inserting a monitoring device into the brain or cerebral ventricle by a percutaneous burr hole which is most often performed in the O.R. setting under sterile technique and requires anesthesia for pain control. In addition, the commenter disagreed with changing the designation for the following 13 ICD–10–PCS procedure codes. The commenter stated that these intravascular procedures are performed in specialized vascular suites and involve insertion of a filter into the vena cava for prevention of pulmonary emboli or the insertion of vascular stents for conditions such as stenosis and other types of intraluminal devices into the great vessels and are significant procedures that warrant an O.R. designation.

ICD–10–PCS code	Code description
02H43DZ	Insertion of intraluminal device into coronary vein, percutaneous approach.
02H63DZ	Insertion of intraluminal device into right atrium, percutaneous approach.
02H73DZ	Insertion of intraluminal device into left atrium, percutaneous approach.
02HK3DZ	Insertion of intraluminal device into right ventricle, percutaneous approach.
02HL3DZ	Insertion of intraluminal device into left ventricle, percutaneous approach.
02HP3DZ	Insertion of intraluminal device into pulmonary trunk, percutaneous approach.
02HQ3DZ	Insertion of intraluminal device into right pulmonary artery, percutaneous approach.
02HR3DZ	Insertion of intraluminal device into left pulmonary artery, percutaneous approach.
02HS3DZ	Insertion of intraluminal device into right pulmonary vein, percutaneous approach.
02HT3DZ	Insertion of intraluminal device into left pulmonary vein, percutaneous approach.
02HV3DZ	Insertion of intraluminal device into superior vena cava, percutaneous approach.

ICD–10–PCS code	Code description
02HW3DZ	Insertion of intraluminal device into thoracic aorta, percutaneous approach.
06H03DZ	Insertion of intraluminal device into inferior vena cava, percutaneous approach.

Response: We appreciate the commenters' support. In response to the commenter who disagreed with changing the designation for 15 of the 28 procedure codes, upon further review and consideration, we agree that the status of the above list of procedure codes, in addition to the two procedure codes discussed earlier in this section (00H032Z and 00H632Z) should be maintained as O.R. procedures due to the indications for which these procedures may be performed and the risks involved.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of 13 ICD–10–PCS procedure codes listed in Table 6P.4b. associated with this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) from O.R. procedures to non-O.R. procedures, effective October 1, 2017. We also are finalizing maintaining the designation of ICD–10–PCS procedure codes 00H032Z (Insertion of Monitoring Device into Brain, Percutaneous Approach) and 00H632Z (Insertion of Monitoring Device into Cerebral Ventricle, Percutaneous Approach) and the list of procedure codes shown in the table above as O.R. procedures, effective October 1, 2017.

(3) Percutaneous Removal of Drainage, Infusion, Intraluminal or Monitoring Device

One commenter identified 22 ICD–10–PCS procedure codes that describe procedures involving the percutaneous removal of drainage, infusion, intraluminal and monitoring devices from central nervous system and other vascular body parts that generally would not require the resources of an operating room and can be performed at the bedside. We agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19854), we proposed that the 22 ICD–10–PCS procedure codes listed in Table 6P.4c. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of 22 ICD–10–PCS procedure codes describing the percutaneous removal of drainage, infusion, intraluminal and monitoring devices from central nervous system and other vascular body parts.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the 22 ICD–10–PCS procedure codes listed in Table 6P.4c. associated with the proposed rule and this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* from O.R. procedures to non-O.R. procedures, effective October 1, 2017.

(4) External Removal of Cardiac or Neurostimulator Lead

One commenter identified four ICD–10–PCS procedure codes that describe procedures involving the external removal of cardiac leads from the heart and neurostimulator leads from central nervous system body parts that generally would not require the resources of an operating room and can be performed at the bedside. These four ICD–10–PCS codes are shown in the table below.

ICD–10–PCS code	Code description
00P6XMZ	Removal of neurostimulator lead from cerebral ventricle, external approach.
00PEXMZ	Removal of neurostimulator lead from cranial nerve, external approach.
01PYXMZ	Removal of neurostimulator lead from peripheral nerve, external approach.
02PAXMZ	Removal of cardiac lead from heart, external approach.

We agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19854), we proposed that the four ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of four ICD–10–PCS procedure codes that describe the external removal of cardiac leads from the heart and neurostimulator leads from central nervous system body parts.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the four ICD–10–PCS procedure codes shown in the table above from O.R. procedures to non-O.R. procedures, effective October 1, 2017.

(5) Percutaneous Revision of Drainage, Infusion, Intraluminal or Monitoring Device

One commenter identified 28 ICD–10–PCS procedure codes that describe procedures involving the percutaneous revision of drainage, infusion, intraluminal and monitoring devices for vascular and heart and great vessel body parts that generally would not require the resources of an operating room and can be performed at the bedside. We agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19854), we proposed that the 28 ICD–10–PCS procedure codes listed in Table 6P.4d. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of 28 ICD–10–PCS procedure codes that describe the percutaneous revision of drainage, infusion, intraluminal and monitoring devices for vascular and heart and great vessel body parts.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation for the 28 ICD–10–PCS procedure codes listed in Table 6P.4d. associated with the proposed rule and this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) from O.R. procedures to non-O.R. procedures, effective October 1, 2017.

(6) Percutaneous Destruction

One commenter identified two ICD–10–PCS procedure codes that describe procedures involving the percutaneous destruction of retina body parts that generally would not require the resources of an operating room and can be performed at the bedside. These two ICD–10–PCS codes are shown in the table below.

ICD–10–PCS code	Code description
085E3ZZ	Destruction of right retina, percutaneous approach.
085F3ZZ	Destruction of left retina, percutaneous approach.

We agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19854), we proposed that the two ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of two ICD–10–PCS procedure codes that describe the percutaneous destruction of retina body parts.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the two ICD–10–PCS procedure codes shown in the table above from O.R. procedures to non-O.R. procedures, effective October 1, 2017.

(7) External/Diagnostic Drainage

One commenter identified 20 ICD–10–PCS procedure codes that describe procedures involving external drainage for structures of the eye that generally would not require the resources of an operating room and can be performed at the bedside. We agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19854), we proposed that the 20 ICD–10–PCS procedure codes listed in Table 6P.4e. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of 20 ICD–10–PCS procedure codes that describe external drainage for structures of the eye.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation for the 20 ICD–10–PCS procedure codes listed in Table 6P.4e. associated with the proposed rule and this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) from O.R. procedures to non-O.R. procedures, effective October 1, 2017.

(8) External Extirpation

One commenter identified four ICD–10–PCS procedure codes that describe procedures involving external extirpation of matter from eye structures that generally would not require the resources of an operating room and can be performed at the bedside. These four ICD–10–PCS codes are shown in the table below.

ICD–10–PCS code	Code description
08C0XZZ	Extirpation of matter from right eye, external approach.
08C1XZZ	Extirpation of matter from left eye, external approach.
08CSXZZ	Extirpation of matter from right conjunctiva, external approach.
08CTXZZ	Extirpation of matter from left conjunctiva, external approach.

We agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19854 through 19855), we proposed that the four ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of the four ICD–10–PCS procedure codes shown in the table above that describe procedures involving external extirpation of matter from eye structures.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the four ICD–10–PCS procedure codes shown in the table above from O.R. procedures to non-O.R. procedures, effective October 1, 2017.

(9) External Removal of Radioactive Element or Synthetic Substitute

One commenter identified three ICD–10–PCS procedure codes that describe procedures involving the external removal of radioactive or synthetic substitutes from the eye that generally would not require the resources of an operating room and can be performed at the bedside. These three ICD–10–PCS codes are shown in the table below.

ICD–10–PCS code	Code description
08P0X1Z	Removal of radioactive element from right eye, external approach.
08P0XJZ	Removal of synthetic substitute from right eye, external approach.
08P1XJZ	Removal of synthetic substitute from left eye, external approach.

We agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19855), we proposed that the three ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of the three ICD–10–PCS procedure codes shown in the table above that describe the external removal of radioactive or synthetic substitutes from the eye.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the three ICD–10–PCS procedure codes shown in the table above from O.R. procedures to non-O.R. procedures, effective October 1, 2017.

(10) Endoscopic/Transorifice Diagnostic Drainage

One commenter identified eight ICD–10–PCS procedure codes that describe procedures involving endoscopic/transorifice (via natural or artificial opening) drainage of ear structures that generally would not require the resources of an operating room and can be performed at the bedside. These eight ICD–10–PCS codes are shown in the table below.

ICD–10–PCS code	Code description
09977ZX	Drainage of right tympanic membrane, via natural or artificial opening, diagnostic.
09978ZX	Drainage of right tympanic membrane, via natural or artificial opening endoscopic, diagnostic.
09987ZX	Drainage of left tympanic membrane, via natural or artificial opening, diagnostic.
09988ZX	Drainage of left tympanic membrane, via natural or artificial opening endoscopic, diagnostic.
099F7ZX	Drainage of right eustachian tube, via natural or artificial opening, diagnostic.
099F8ZX	Drainage of right eustachian tube, via natural or artificial opening endoscopic, diagnostic.
099G7ZX	Drainage of left eustachian tube, via natural or artificial opening, diagnostic.
099G8ZX	Drainage of left eustachian tube, via natural or artificial opening endoscopic, diagnostic.

We stated in the proposed rule that we agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19855), we proposed that the eight ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of the eight ICD–10–PCS procedure codes shown in the table above that describe drainage of ear structures.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the eight ICD–10–PCS procedure codes shown in the table above from O.R. procedures to non-O.R. procedures, effective October 1, 2017.

(11) External Release

One commenter identified four ICD–10–PCS procedure codes that describe procedures involving the external release of ear structures that generally would not require the resources of an operating room and can be performed at the bedside. These four ICD–10–PCS codes are shown in the table below.

ICD–10–PCS code	Code description
09N0XZZ	Release right external ear, external approach.
09N1XZZ	Release left external ear, external approach.
09N3XZZ	Release right external auditory canal, external approach.
09N4XZZ	Release left external auditory canal, external approach.

We agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19855), we proposed that the four ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of the four ICD–10–PCS procedure codes shown in the table above that describe external release of ear structures.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the four ICD–10–PCS procedure codes shown in the table above from O.R. procedures to non-O.R. procedures, effective October 1, 2017.

(12) External Repair

One commenter identified three ICD–10–PCS procedure codes that describe procedures involving the external repair of body parts that generally would not require the resources of an operating room and can be performed at the bedside. These three ICD–10–PCS codes are shown in the table below.

ICD–10–PCS code	Code description
09QKXZZ	Repair nose, external approach.
0CQ4XZZ	Repair buccal mucosa, external approach.
0CQ7XZZ	Repair tongue, external approach.

We agreed with the commenter. Therefore, in the FY 2019 IPPS/LTCH PPS proposed rule (82 FR 19855), we proposed that the three ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of the three ICD–10–PCS procedure codes shown in the table above that describe

external repair of body parts of various structures.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the three ICD–10–PCS procedure codes shown in the table above from O.R. procedures to non-O.R. procedures, effective October 1, 2017.

(13) Endoscopic/Transorifice Destruction

One commenter identified eight ICD–10–PCS procedure codes that describe procedures involving the endoscopic/transorifice destruction of respiratory system body parts that generally would not require the resources of an operating room and can be performed at the bedside. These eight ICD–10–PCS codes are shown in the table below.

ICD–10–PCS code	Code description
0B538ZZ	Destruction of right main bronchus, via natural or artificial opening endoscopic.
0B548ZZ	Destruction of right upper lobe bronchus, via natural or artificial opening endoscopic.
0B558ZZ	Destruction of right middle lobe bronchus, via natural or artificial opening endoscopic.
0B568ZZ	Destruction of right lower lobe bronchus, via natural or artificial opening endoscopic.
0B578ZZ	Destruction of left main bronchus, via natural or artificial opening endoscopic.
0B588ZZ	Destruction of left upper lobe bronchus, via natural or artificial opening endoscopic.
0B598ZZ	Destruction of lingula bronchus, via natural or artificial opening endoscopic.
0B5B8ZZ	Destruction of left lower lobe bronchus, via natural or artificial opening endoscopic.

We stated in the proposed rule that we agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19855 through 19856), we proposed that the eight ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Some commenters agreed with the proposal to change the designation of the eight ICD–10–PCS procedure codes that describe procedures involving the endoscopic/transorifice destruction of respiratory system body parts from O.R. procedures to non-O.R. procedures. However, other commenters disagreed with the proposal. These commenters believed that these procedures do, in fact, require the resources of an operating room and stated that the suggestion that these procedures can be performed at the bedside is clinically inaccurate and misrepresents the nature of these procedures. According to the commenters, the only instances in which these procedures would be performed at the bedside would be if the patient was in the intensive care unit and in emergent need of care. Otherwise, the commenters indicated that providing these services at the patient's bedside would not be appropriate. Commenters also noted that the patients who undergo the above procedures typically have poor respiratory function that requires treatment within an O.R. setting for clinical and safety purposes. In addition, the commenters reported that the administration of anesthesia during these procedures is critically important. The commenters conducted an in-depth analysis to determine the impact of the proposed change and noted that the resource utilization associated with the inpatient claims reporting these procedures more closely aligns with surgical MS–DRGs versus medical MS–DRGs.

Response: We appreciate the commenters' support. In response to the commenters who disagreed with changing the designation of the eight ICD–10–PCS procedure codes that describe the endoscopic/transorifice destruction of respiratory system body parts, we appreciate the thorough review and analysis conducted in response to our solicitation for comments on the proposal. Upon further review and consideration, we agree that these procedures warrant an O.R. setting and assignment to surgical MS–DRGs.

After consideration of the public comments we received, we are not finalizing our proposal to change the designation of the eight ICD–10–PCS procedure codes shown in the table above from O.R. procedures to non-O.R. procedures. The eight procedure codes shown in the table above will maintain their O.R. designation for FY 2018.

(14) Endoscopic/Transorifice Drainage

One commenter identified 40 ICD–10–PCS procedure codes that describe procedures involving endoscopic/transorifice (via natural or artificial opening) drainage of respiratory system body parts that generally would not require the resources of an operating room and can be performed at the bedside. We agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19856), we proposed that the 40 ICD–10–PCS procedure codes listed in Table 6P.4f. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of the 40 ICD–10–PCS procedure codes that describe endoscopic/transorifice (via natural or artificial opening) drainage of respiratory system body parts.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the 40 ICD–10–PCS procedure codes listed in Table 6P.4f. associated with the proposed rule and this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) from O.R. procedures to non-O.R. procedures, effective October 1, 2017.

(15) Endoscopic/Transorifice Extirpation

One commenter identified nine ICD–10–PCS procedure codes that describe procedures involving endoscopic/transorifice extirpation of matter from respiratory system body parts that generally would not require the resources of an operating room and can be performed at the bedside. These nine ICD–10–PCS codes are shown in the table below.

ICD–10–PCS code	Code description
0BCC8ZZ	Extirpation of matter from right upper lung lobe, via natural or artificial opening endoscopic.

ICD–10–PCS code	Code description
0BCD8ZZ	Extirpation of matter from right middle lung lobe, via natural or artificial opening endoscopic.
0BCF8ZZ	Extirpation of matter from right lower lung lobe, via natural or artificial opening endoscopic.
0BCG8ZZ	Extirpation of matter from left upper lung lobe, via natural or artificial opening endoscopic.
0BCH8ZZ	Extirpation of matter from lung lingula, via natural or artificial opening endoscopic.
0BCJ8ZZ	Extirpation of matter from left lower lung lobe, via natural or artificial opening endoscopic.
0BCK8ZZ	Extirpation of matter from right lung, via natural or artificial opening endoscopic.
0BCL8ZZ	Extirpation of matter from left lung, via natural or artificial opening endoscopic.
0BCM8ZZ	Extirpation of matter from bilateral lungs, via natural or artificial opening endoscopic.

We stated in the proposed rule that we agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19856), we proposed that the nine ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of the nine ICD–10–PCS procedure codes that describe endoscopic/transorifice extirpation of matter from respiratory system body parts. However, one commenter disagreed with the proposal. According to the commenter, the codes describe endoscopic procedures performed on the lung and are more invasive in comparison to endobronchial procedures and they require specialized equipment. The commenter also noted that time, skill, and duration of sedation are increased for endoscopic lung procedures versus procedures performed on the bronchus (endobronchial).

Response: We appreciate the commenters' support. In response to the commenter who disagreed with our proposal, upon further review and consideration, we agree that these procedure codes warrant an O.R. setting.

After consideration of the public comments we received, we are not finalizing our proposal to designate the nine ICD–10–PCS procedure codes shown in the table above as non-O.R. procedures. These procedure codes will remain designated as O.R. procedures for FY 2018.

(16) Endoscopic/Transorifice Fragmentation

One commenter identified 16 ICD–10–PCS procedure codes that describe procedures involving endoscopic/transorifice fragmentation of respiratory system body parts that generally would not require the resources of an operating room and can be performed at the bedside. These 16 ICD–10–PCS codes are shown in the table below.

ICD–10–PCS code	Code description
0BF37ZZ	Fragmentation in right main bronchus, via natural or artificial opening.
0BF38ZZ	Fragmentation in right main bronchus, via natural or artificial opening endoscopic.
0BF47ZZ	Fragmentation in right upper lobe bronchus, via natural or artificial opening.
0BF48ZZ	Fragmentation in right upper lobe bronchus, via natural or artificial opening endoscopic.
0BF57ZZ	Fragmentation in right middle lobe bronchus, via natural or artificial opening.
0BF58ZZ	Fragmentation in right middle lobe bronchus, via natural or artificial opening endoscopic.
0BF67ZZ	Fragmentation in right lower lobe bronchus, via natural or artificial opening.
0BF68ZZ	Fragmentation in right lower lobe bronchus, via natural or artificial opening endoscopic.
0BF77ZZ	Fragmentation in left main bronchus, via natural or artificial opening.
0BF78ZZ	Fragmentation in left main bronchus, via natural or artificial opening endoscopic.
0BF87ZZ	Fragmentation in left upper lobe bronchus, via natural or artificial opening.
0BF88ZZ	Fragmentation in left upper lobe bronchus, via natural or artificial opening endoscopic.
0BF97ZZ	Fragmentation in lingula bronchus, via natural or artificial opening.
0BF98ZZ	Fragmentation in lingula bronchus, via natural or artificial opening endoscopic.
0BFB7ZZ	Fragmentation in left lower lobe bronchus, via natural or artificial opening.
0BFB8ZZ	Fragmentation in left lower lobe bronchus, via natural or artificial opening endoscopic.

We agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19856 through 19857), we proposed that the 16 ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of the16 ICD–10–PCS procedure codes that describe endoscopic/transorifice fragmentation of respiratory system body parts.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the 16 ICD–10–PCS procedure codes shown in the table above from O.R. procedures to non-O.R. procedures, effective October 1, 2017.

(17) Endoscopic/Transorifice Insertion of Intraluminal Device

One commenter identified two ICD–10–PCS procedure codes that describe procedures involving an endoscopic/transorifice (via natural or artificial opening) insertion of intraluminal devices into respiratory system body parts that generally would not require the resources of an operating room and can be performed at the bedside. These two ICD–10–PCS codes are shown in the table below.

ICD–10–PCS code	Code description
0BH17DZ	Insertion of intraluminal device into trachea, via natural or artificial opening.
0BH18DZ	Insertion of intraluminal device into trachea, via natural or artificial opening endoscopic.

We agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19857), we proposed that the two ICD–10–PCS procedure codes shown in the table above be designated non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of the two ICD–10–PCS procedure codes that describe an endoscopic/transorifice (via natural or artificial opening) insertion of intraluminal devices into respiratory system body parts.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the two ICD–10–PCS procedure codes shown in the table above from O.R. procedures to non-O.R. procedures, effective October 1, 2017.

(18) Endoscopic/Transorifice Removal of Radioactive Element

One commenter identified two ICD–10–PCS procedure codes that describe procedures involving the endoscopic/transorifice removal of radioactive elements from respiratory system body parts that generally would not require the resources of an operating room and can be performed at the bedside. These two ICD–10–PCS codes are shown in the table below.

ICD–10–PCS code	Code description
0BPK71Z	Removal of radioactive element from right lung, via natural or artificial opening.
0BPK81Z	Removal of radioactive element from right lung, via natural or artificial opening endoscopic.

We agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19857), we proposed that the two ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of the two ICD–10–PCS procedure codes that describe procedures involving the endoscopic/transorifice removal of radioactive elements from respiratory system body parts. However, one commenter disagreed with the proposal and asserted that endoscopic procedures performed on the lung are more invasive than endobronchial procedures.

Response: We appreciate the commenters' support. In response to the commenter who disagreed with our proposal, we recognize that endoscopic procedures performed on the lung may be considered more invasive than endobronchial procedures. However, according to the American Cancer Society, in most cases, anesthesia is not needed when the applicator and/or radioactive implant is removed, as it is usually done in the hospital room.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of ICD–10–PCS procedure codes 0BPK71Z and 0BPK81Z from O.R. procedures to non-O.R. procedures, effective October 1, 2017.

(19) Endoscopic/Transorifice Revision of Drainage, Infusion, Intraluminal or Monitoring Device

One commenter identified 18 ICD–10–PCS procedure codes that describe procedures involving the revision of drainage, infusion, intraluminal, or monitoring devices from respiratory system body parts that generally would not require the resources of an operating room and can be performed at the bedside. We agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19857), we proposed that the 18 ICD–10–PCS procedure codes listed in Table 6P.4g. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of the 18 ICD–10–PCS procedure codes that describe procedures involving the revision of drainage, infusion, intraluminal, or monitoring devices from respiratory system body parts. However, one commenter disagreed with the proposal and recommended that CMS maintain an O.R. designation of 12 of the 18 proposed codes. The commenter stated that, although it is uncertain how often a device within the lung would be revised versus removed and replaced, endoscopic procedures performed on the lung are more invasive than endobronchial procedures.

Response: We appreciate the commenters' support. In response to the commenter who disagreed with 12 of the 18 procedure codes in our proposal, we still believe our proposal is appropriate, given that there are a wide range of procedures that may be performed and are described as a revision of a drainage, infusion, intraluminal, or monitoring device in the lung and generally do not require the resources of an operating room.

After consideration of the public comments we received, we are finalizing our proposal to designate the 18 ICD–10–PCS procedure codes listed in Table 6P.4g. associated with the proposed rule and this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) as non-O.R. procedures, effective October 1, 2017.

(20) Endoscopic/Transorifice Excision

One commenter identified one ICD–10–PCS procedure code that describes the procedure involving endoscopic/transorifice (via natural or artificial opening) excision of the digestive system body parts that generally would not require the resources of an operating room and can be performed at the bedside. This code is 0DBQ8ZZ (Excision of anus, via natural or artificial opening endoscopic). We agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19857), we proposed that ICD–10–PCS procedure code 0DBQ8ZZ be designated as a non-O.R. procedure. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of ICD–10–PCS procedure code 0DBQ8ZZ.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of ICD–10–PCS procedure code 0DBQ8ZZ (Excision of anus, via natural or artificial opening endoscopic) from an O.R. procedure to a non-O.R. procedure, effective October 1, 2017.

(21) Endoscopic/Transorifice Insertion

One commenter identified two ICD–10–PCS procedure codes that describe procedures involving the endoscopic/transorifice (via natural or artificial opening) insertion of intraluminal device into the stomach that generally would not require the resources of an operating room and can be performed at

the bedside. These two ICD–10–PCS codes are shown in the table below.

ICD–10–PCS code	Code description
0DH67DZ	Insertion of intraluminal device into stomach, via natural or artificial opening.
0DH68DZ	Insertion of intraluminal device into stomach, via natural or artificial opening endoscopic.

We agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19857), we proposed that the two ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of the two ICD–10–PCS procedure codes that describe the endoscopic/transorifice (via natural or artificial opening) insertion of intraluminal device into the stomach.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the two ICD–10–PCS procedure codes shown in the table above from O.R. procedures to non-O.R. procedures, effective October 1, 2017.

(22) Endoscopic/Transorifice Removal

One commenter identified six ICD–10–PCS procedure codes that describe procedures involving endoscopic/transorifice (via natural or artificial opening) removal of feeding devices that generally would not require the resources of an operating room and can be performed at the bedside. These six ICD–10–PCS codes are shown in the table below.

ICD–10–PCS code	Code description
0DP07UZ	Removal of feeding device from upper intestinal tract, via natural or artificial opening.
0DP08UZ	Removal of feeding device from upper intestinal tract, via natural or artificial opening endoscopic.
0DP67UZ	Removal of feeding device from stomach, via natural or artificial opening.
0DP68UZ	Removal of feeding device from stomach, via natural or artificial opening endoscopic.
0DPD7UZ	Removal of feeding device from lower intestinal tract, via natural or artificial opening.
0DPD8UZ	Removal of feeding device from lower intestinal tract, via natural or artificial opening endoscopic.

We agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19857 through 19858), we proposed that the six ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of the six ICD–10–PCS procedure codes that describe the endoscopic/transorifice (via natural or artificial opening) removal of feeding devices.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the six ICD–10–PCS procedure codes shown in the table above from O.R. procedures to non-O.R. procedures, effective October 1, 2017.

(23) External Reposition

One commenter identified two ICD–10–PCS procedure codes that describe procedures involving external reposition of gastrointestinal body parts that generally would not require the resources of an operating room and can be performed at the bedside. These two ICD–10–PCS codes are shown in the table below.

ICD–10–PCS code	Code description
0DS5XZZ	Reposition esophagus, external approach.
0DSQXZZ	Reposition anus, external approach.

We agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19858), we proposed that the two ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of the two ICD–10–PCS procedure codes that describe the external reposition of gastrointestinal body parts.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the two ICD–10–PCS procedure codes shown in the table above from O.R. procedures to non-O.R. procedures, effective October 1, 2017.

(24) Endoscopic/Transorifice Drainage

One commenter identified eight ICD–10–PCS procedure codes that describe procedures involving endoscopic/transorifice (via natural or artificial opening) drainage of hepatobiliary system and pancreatic body parts that generally would not require the resources of an operating room and can be performed at the bedside. These eight ICD–10–PCS codes are shown in the table below.

ICD–10–PCS code	Code description
0F9580Z	Drainage of right hepatic duct with drainage device, via natural or artificial opening endoscopic.
0F958ZZ	Drainage of right hepatic duct, via natural or artificial opening endoscopic.
0F9680Z	Drainage of left hepatic duct with drainage device, via natural or artificial opening endoscopic.
0F968ZZ	Drainage of left hepatic duct, via natural or artificial opening endoscopic.
0F9880Z	Drainage of cystic duct with drainage device, via natural or artificial opening endoscopic.
0F988ZZ	Drainage of cystic duct, via natural or artificial opening endoscopic.
0F9D8ZZ	Drainage of pancreatic duct, via natural or artificial opening endoscopic.
0F9F8ZZ	Drainage of accessory pancreatic duct, via natural or artificial opening endoscopic.

We agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19858), we proposed that the eight ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of the eight ICD–10–PCS procedure codes that describe endoscopic/transorifice (via natural or artificial opening) drainage of hepatobiliary system and pancreatic body parts.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the eight ICD–10–PCS procedure codes shown in the table above from O.R. procedures to non-O.R. procedures, effective October 1, 2017.

(25) Endoscopic/Transorifice Fragmentation

One commenter identified two ICD–10–PCS procedure codes that describe procedures involving endoscopic/transorifice (via natural or artificial opening) fragmentation of hepatobiliary system and pancreatic body parts that generally would not require the resources of an operating room and can be performed at the bedside. These two ICD–10–PCS codes are shown in the table below.

ICD–10–PCS code	Code description
0FFD8ZZ	Fragmentation in pancreatic duct, via natural or artificial opening endoscopic.
0FFF8ZZ	Fragmentation in accessory pancreatic duct, via natural or artificial opening endoscopic.

We agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19858), we proposed that the two ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of the two ICD–10–PCS procedure codes that describe endoscopic/transorifice (via natural or artificial opening) fragmentation of hepatobiliary system and pancreatic body parts.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the two ICD–10–PCS procedure codes shown in the table above from O.R. procedures to non-O.R. procedures, effective October 1, 2017.

(26) Percutaneous Alteration

One commenter identified three ICD–10–PCS procedure codes that describe procedures involving percutaneous alteration of the breast that generally would not require the resources of an operating room and can be performed at the bedside. These three ICD–10–PCS codes are shown in the table below.

ICD–10–PCS code	Code description
0H0T3JZ	Alteration of right breast with synthetic substitute, percutaneous approach.
0H0U3JZ	Alteration of left breast with synthetic substitute, percutaneous approach.
0H0V3JZ	Alteration of bilateral breast with synthetic substitute, percutaneous approach.

We agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19858 through 19859), we proposed that the three ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of the three ICD–10–PCS procedure codes that describe percutaneous alteration of the breast.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the three ICD–10–PCS procedure codes shown in the table above from O.R. procedures to non-O.R. procedures, effective October 1, 2017.

(27) External Division and Excision of Skin

One commenter identified 41 ICD–10–PCS procedure codes that describe procedures involving external division and excision of the skin for body parts that generally would not require the resources of an operating room and can be performed at the bedside. We agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19859), we proposed that the 41 ICD–10–PCS procedure codes listed in Table 6P.4h. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/*

AcuteInpatientPPS/index.html) be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of the 41 ICD–10–PCS procedure codes that describe external division and excision of the skin for body parts.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the 41 ICD–10–PCS procedure codes listed in Table 6P.4h. associated with the proposed rule and this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) from O.R. procedures to non-O.R. procedures, effective October 1, 2017.

(28) External Excision of Breast

One commenter identified six ICD–10–PCS procedure codes that describe procedures involving external excision of the breast that they believed would generally not require the resources of an operating room and can be performed at the bedside. These six ICD–10–PCS codes are shown in the table below.

ICD–10–PCS code	Code description
0HBTXZZ	Excision of right breast, external approach.
0HBUXZZ	Excision of left breast, external approach.
0HBVXZZ	Excision of bilateral breast, external approach.
0HBWXZZ	Excision of right nipple, external approach.
0HBXXZZ	Excision of left nipple, external approach.
0HBYXZZ	Excision of supernumerary breast, external approach.

We disagreed with the commenter because these procedure codes describe various types of surgery performed on the breast or nipple (for example, partial mastectomy) that would typically involve the use of general anesthesia. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19859), we proposed that the six ICD–10–PCS procedure codes shown in the table above remain designated as O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to maintain the current designation of the six ICD–10–PCS procedure codes that describe external excision of the breast. However, one commenter disagreed specifically with the example of a partial mastectomy utilizing an external approach. The commenter stated that the breast itself includes glandular and ductal tissue, although it is assigned with skin to Section 0H in the Medical and Surgical section of the ICD–10–PCS classification. Therefore, according to the commenter, by definition, a partial mastectomy, which involves excision of glandular/ductal tissue, cannot be performed by an external approach because glandular tissue cannot be removed through direct action upon the skin or mucous membrane.

Response: We appreciate the commenters' support. In response to the commenter who noted the example of a partial mastectomy that cannot be performed by an external approach, we agree that the example may not have been an appropriate illustration of an external approach according to the ICD–10–PCS definitions. A more appropriate example would be an excision of lesion of breast for the external approach. As the commenter pointed out, the breast itself includes glandular and ductal tissue, although it is assigned with skin to Chapter 0H. Because the code title description does not specifically include the term ''skin,'' it can lead to confusion. We believe this area in the classification may benefit from further review to determine if modifications are warranted, in which case any proposals would be presented at a future ICD–10 Coordination and Maintenance Committee meeting.

After consideration of the public comments we received, we are finalizing our proposal to maintain the six ICD–10–PCS procedure codes shown in the table above as O.R. procedures for FY 2018.

(29) Percutaneous Supplement

One commenter identified three ICD–10–PCS procedure codes that describe procedures involving percutaneous supplement of the breast with synthetic substitute that generally would not require the resources of an operating room and can be performed at the bedside. These three ICD–10–PCS codes are shown in the table below.

ICD–10–PCS code	Code description
0HUT3JZ	Supplement right breast with synthetic substitute, percutaneous approach.
0HUU3JZ	Supplement left breast with synthetic substitute, percutaneous approach.
0HUV3JZ	Supplement bilateral breast with synthetic substitute, percutaneous approach.

We agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19859), we proposed that the three ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of the three ICD–10–PCS procedure codes that describe percutaneous supplement of the breast with synthetic substitute.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the three ICD–10–PCS procedure codes shown in the table above from O.R. procedures to non-O.R. procedures, effective October 1, 2017.

(30) Open Drainage

One commenter identified 25 ICD–10–PCS procedure codes that describe procedures involving open drainage of subcutaneous tissue and fascia body parts that generally would not require the resources of an operating room and can be performed at the bedside. The list includes procedure codes for drainage with or without placement of a drainage device. We stated in the

proposed rule that we agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19859), we proposed that the 25 ICD–10–PCS procedure codes listed in Table 6P.4i. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of the 25 ICD–10–PCS procedure codes that describe procedures involving open drainage of subcutaneous tissue and fascia body parts. However, one commenter disagreed with changing the designation for 22 of the 25 procedure codes in the proposal from O.R. to non-O.R. This commenter agreed with the proposal to change the designation for 3 of the 25 procedure codes because these codes specifically describe the objective of placing a drainage device. The commenter noted that the other procedures described by the 22 procedure codes are performed on deeper subcutaneous tissue and fascia, are more invasive, and are most often performed in the O.R. setting under general anesthesia. According to the commenter, these codes are assigned when the primary objective of the procedure is to incise through the skin into the subcutaneous tissue and/or fascia in order to drain and clean out an abscess or hematoma (fluid collection). The commenter also noted that CMS disagreed with the recommendation to reclassify open extraction of subcutaneous tissue and fascia to non-O.R. procedures as discussed with regard to Table 6P.4k associated with the FY 2018 IPPS/LTCH PPS proposed rule and for the same reasons, the commenter believed that open drainage of subcutaneous tissue and fascia should not be changed from an O.R. procedure to a non-O.R. procedure.

Response: We appreciate the commenters' support. In response to the commenter who noted that the procedures described by the 22 procedure codes are performed on deeper subcutaneous tissue and fascia, are more invasive, and are most often performed in the O.R. setting under general anesthesia, upon further review and consideration, we agree that it is appropriate to maintain the designation of the procedure codes as O.R. procedures.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the following three ICD–10–PCS procedure codes that were listed in Table 6P.4i. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) from O.R. procedures to non-O.R. procedures, effective October 1, 2017.

ICD–10–PCS code	Code description
0J9100Z	Drainage of Face Subcutaneous Tissue and Fascia with Drainage Device, Open Approach.
0J9J00Z	Drainage of Right Hand Subcutaneous Tissue and Fascia with Drainage Device, Open Approach.
0J9K00Z	Drainage of Left Hand Subcutaneous Tissue and Fascia with Drainage Device, Open Approach.

We are not finalizing our proposal to change the designation for the remaining 22 ICD–10–PCS procedure codes that were listed in Table 6P.4i. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) from O.R. procedures to non-O.R. procedures. Rather, these codes will maintain their O.R. designation for FY 2018.

(31) Percutaneous Drainage

One commenter identified two ICD–10–PCS procedure codes that describe procedures involving percutaneous drainage of subcutaneous tissue and fascia body parts that generally would not require the resources of an operating room and can be performed at the bedside. These two ICD–10–PCS codes are shown in the table below.

ICD–10–PCS code	Code description
0J9J3ZZ	Drainage of right hand subcutaneous tissue and fascia, percutaneous approach.
0J9K3ZZ	Drainage of left hand subcutaneous tissue and fascia, percutaneous approach.

We agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19859), we proposed that the two ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of the two ICD–10–PCS procedure codes that describe percutaneous drainage of subcutaneous tissue and fascia body parts.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the two ICD–10–PCS procedure codes shown in the table above from O.R. procedures to non-O.R. procedures, effective October 1, 2017.

(32) Percutaneous Extraction

One commenter identified 22 ICD–10–PCS procedure codes that describe procedures involving percutaneous extraction of subcutaneous tissue and fascia body parts that generally would not require the resources of an operating room and can be performed at the bedside. We agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19859 through 19860), we proposed that the 22 ICD–10–PCS procedure codes listed in Table 6P.4j. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of the 22 ICD–10–PCS procedure codes that describe percutaneous extraction of

subcutaneous tissue and fascia body parts.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the 22 ICD–10–PCS procedure codes listed in Table 6P.4j. associated with the proposed rule and this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) from O.R. procedures to non-O.R. procedures, effective October 1, 2017.

(33) Open Extraction

One commenter identified 22 ICD–10–PCS procedure codes that describe procedures involving open extraction of subcutaneous tissue and fascia body parts that the commenter believed would generally not require the resources of an operating room and can be performed at the bedside. We stated in the proposed rule that we disagreed with the commenter because these codes describe procedures that utilize an open approach and are being performed on the skin and subcutaneous tissue. Depending on the medical reason for the open extraction, the procedures may require an O.R. setting. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19860), we proposed that the 22 ICD–10–PCS procedure codes listed in Table 6P.4k. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) remain designated as O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to maintain the designation of the 22 ICD–10–PCS procedure codes that describe open extraction of subcutaneous tissue and fascia body parts.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to maintain the 22 ICD–10–PCS procedure codes listed in Table 6P.4k. associated with the proposed rule and this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) as O.R. procedures for FY 2018.

(34) Percutaneous and Open Repair

One commenter identified 44 ICD–10–PCS procedure codes that describe procedures involving percutaneous and open repair of subcutaneous tissue and fascia body parts that generally would not require the resources of an operating room and can be performed at the bedside. We stated in the proposed rule that we agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19860), we proposed that the 44 ICD–10–PCS procedure codes listed in Table 6P.4l. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of 44 ICD–10–PCS procedure codes that describe percutaneous and open repair of subcutaneous tissue and fascia body parts from O.R. to non-O.R. However, one commenter disagreed with changing the designation of 22 of the 44 procedure codes. The commenter stated that open repair of deeper subcutaneous tissue and fascia is much more invasive and often performed in the O.R. setting under general anesthesia. The commenter noted that patients who are admitted to the inpatient setting following trauma often have multiple traumatic injuries whereby extensive wound lacerations often require the O.R. setting for complex repair and debridement under anesthesia.

Response: We appreciate the commenters' support. In response to the commenter who disagreed with the proposal to change the designation of 22 of the 44 procedure codes, we agree that open repair of deeper subcutaneous tissue and fascia is much more invasive and may be performed in the O.R. setting under general anesthesia.

After consideration of the public comments we received, we are finalizing our proposal to change the designation for 22 procedure codes that describe percutaneous repair of subcutaneous tissue and fascia body parts listed in Table 6P.4l. associated with this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) from O.R. procedures to non-O.R. procedures, effective October 1, 2017. We are not finalizing our proposal to change the designation for the other 22 procedure codes that describe open repair of subcutaneous tissue and fascia body parts from O.R. procedures to non-O.R. procedures. Rather, they will maintain their O.R. designation for FY 2018.

(35) External Release

One commenter identified 28 ICD–10–PCS procedure codes that describe procedures involving external release of bursa and ligament body parts that generally would not require the resources of an operating room and can be performed at the bedside. We agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19860), we proposed that the 28 ICD–10–PCS procedure codes listed in Table 6P.4m. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of the 28 ICD–10–PCS procedure codes that describe procedures involving external release of bursa and ligament body parts.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the 28 ICD–10–PCS procedure codes listed in Table 6P.4m. associated with the proposed rule and this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) from O.R. procedures to non-O.R. procedures, effective October 1, 2017.

(36) External Repair

One commenter identified 135 ICD–10–PCS procedure codes that describe procedures involving external repair of various bones and joints. We stated in the proposed rule that we believed that these procedures generally would not be performed in the operating room. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19860), we proposed that the 135 ICD–10–PCS procedure codes listed in Table 6P.4n. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of the 135 ICD–10–PCS procedure codes that describe external repair of various bones and joints.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the 135 ICD–10–PCS procedure codes listed in Table 6P.4n. associated with the proposed rule and this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) from O.R. procedures to non-O.R. procedures, effective October 1, 2017.

(37) External Reposition

One commenter identified 14 ICD–10–PCS procedure codes that describe procedures involving external reposition of various bones. These 14 ICD–10–PCS codes are shown in the table below.

ICD–10–PCS code	Code description
0NS0XZZ	Reposition skull, external approach.
0NS1XZZ	Reposition right frontal bone, external approach.
0NS2XZZ	Reposition left frontal bone, external approach.
0NS3XZZ	Reposition right parietal bone, external approach.
0NS4XZZ	Reposition left parietal bone, external approach.
0NS5XZZ	Reposition right temporal bone, external approach.
0NS6XZZ	Reposition left temporal bone, external approach.
0NS7XZZ	Reposition right occipital bone, external approach.
0NS8XZZ	Reposition left occipital bone, external approach.
0PS3XZZ	Reposition cervical vertebra, external approach.
0PS4XZZ	Reposition thoracic vertebra, external approach.
0QS0XZZ	Reposition lumbar vertebra, external approach.
0QS1XZZ	Reposition sacrum, external approach.
0QSSXZZ	Reposition coccyx, external approach.

We stated in the proposed rule that we believed that these procedures generally would not be performed in the operating room. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19860), we proposed that the 14 ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of the 14 ICD–10–PCS procedure codes that describe procedures involving external reposition of various bones.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the 14 ICD–10–PCS procedure codes shown in the table above from O.R. procedures to non-O.R. procedures, effective October 1, 2017. We note that, effective October 1, 2017, the code titles for procedure code 0NS1XZZ (Reposition right frontal bone, external approach) and procedure code 0NS7XZZ (Reposition right occipital bone, external approach) have been revised as reflected in Table 6F.—Revised Procedure Code Titles, and procedure codes 0NS2XZZ (Reposition left frontal bone, external approach) and 0NS8XZZ (Reposition left occipital bone, external approach) have been deleted as reflected in Table 6D.—Invalid Procedure Codes associated with this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*).

(38) Endoscopic/Transorifice Dilation

One commenter identified eight ICD–10–PCS procedure codes that describe procedures involving endoscopic/transorifice (via natural or artificial opening) dilation of urinary system body parts that generally would not require the resources of an operating room and can be performed at the bedside. These eight ICD–10–PCS codes are shown in the table below.

ICD–10–PCS code	Code description
0T767ZZ	Dilation of right ureter, via natural or artificial opening.
0T768ZZ	Dilation of right ureter, via natural or artificial opening endoscopic.
0T777ZZ	Dilation of left ureter, via natural or artificial opening.
0T778ZZ	Dilation of left ureter, via natural or artificial opening endoscopic.
0T7B7DZ	Dilation of bladder with intraluminal device, via natural or artificial opening.
0T7B7ZZ	Dilation of bladder, via natural or artificial opening.
0T7B8DZ	Dilation of bladder with intraluminal device, via natural or artificial opening endoscopic.
0T7B8ZZ	Dilation of bladder, via natural or artificial opening endoscopic.

We stated in the proposed rule that we agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19860 through 19861), we proposed that the eight ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of the eight ICD–10–PCS procedure codes that describe procedures involving endoscopic/transorifice (via natural or artificial opening) dilation of urinary system body parts. However, one commenter disagreed with changing the designation for four of the eight procedure codes. These four codes are shown in the table below:

ICD–10–PCS code	Code description
0T768ZZ	Dilation of right ureter, via natural or artificial opening endoscopic.
0T778ZZ	Dilation of left ureter, via natural or artificial opening endoscopic.
0T7B8DZ	Dilation of bladder with intraluminal device, via natural or artificial opening endoscopic.
0T7B8ZZ	Dilation of bladder, via natural or artificial opening endoscopic.

According to the commenter, these four endoscopic procedures typically require the use of the operating room or a dedicated suite with specialized equipment and anesthesia.

Response: We appreciate the commenters' support. In response to the commenter who disagreed with changing the designation for four of the eight procedure codes that are displayed above, upon further review and consideration, we agree that these four procedures are appropriate to designate as O.R. procedures for the reasons provided by the commenter.

After consideration of the public comments we received, we are finalizing our proposal to change the designation for four ICD–10–PCS procedure codes describing a transorifice (via natural or artificial opening) approach for dilation of urinary system body parts from O.R. procedures to non-O.R. procedures as shown in the table below, effective October 1, 2017.

ICD–10–PCS code	Code description
0T767ZZ	Dilation of right ureter, via natural or artificial opening.
0T777ZZ	Dilation of left ureter, via natural or artificial opening.
0T7B7DZ	Dilation of bladder with intraluminal device, via natural or artificial opening.
0T7B7ZZ	Dilation of bladder, via natural or artificial opening.

We are not finalizing our proposal to change the designation of four procedure codes (0T768ZZ, 0T778ZZ, 0T7B8DZ, and 0T7B8ZZ) that describe endoscopic dilation of urinary system body parts from O.R. procedures to non-O.R. procedures. Rather, they will maintain their O.R designation for FY 2018.

(39) Endoscopic/Transorifice Excision

One commenter identified three ICD–10–PCS procedure codes that describe procedures involving endoscopic/transorifice (via natural or artificial opening) excision of urinary system body parts that the commenter believed would generally not require the resources of an operating room and can be performed at the bedside. These three ICD–10–PCS codes are shown in the table below.

ICD–10–PCS code	Code description
0TBD7ZZ	Excision of urethra, via natural or artificial opening.
0TBD8ZZ	Excision of urethra, via natural or artificial opening endoscopic.
0TBDXZZ	Excision of urethra, external approach.

We disagreed with the commenter because, depending on the medical reason for the excision, the procedures may require an O.R. setting. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19861), we proposed that the three ICD–10–PCS procedure codes shown in the table above remain designated as O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to maintain the designation for three ICD–10–PCS procedure codes that describe an endoscopic/transorifice (via natural or artificial opening) excision of urinary system body parts.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal for the three ICD–10–PCS procedure codes shown in the table above to maintain the O.R. designation for FY 2018.

(40) External/Transorifice Repair

One commenter identified three ICD–10–PCS procedure codes that describe procedures involving external and transorifice (via natural or artificial opening) repair of the vagina body part that generally would not require the resources of an operating room and can be performed at the bedside. These three ICD–10–PCS codes are shown in the table below.

ICD–10–PCS code	Code description
0UQG7ZZ	Repair vagina, via natural or artificial opening.
0UQGXZZ	Repair vagina, external approach.
0UQMXZZ	Repair vulva, external approach.

We agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19861), we proposed that these three ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation for three ICD–10–PCS procedure codes that describe external and transorifice (via natural or artificial opening) repair of the vagina body part.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal for the three ICD–10–PCS procedure codes shown in the table above to change the designation from O.R. procedures to non-O.R. procedures, effective October 1, 2017.

(41) Percutaneous Transfusion

One commenter identified 20 ICD–10–PCS procedure codes that describe procedures involving percutaneous transfusion of bone marrow and stem cells that generally would not require the resources of an operating room and can be performed at the bedside. We agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19861), we proposed that the 20 ICD–10–PCS procedure codes listed in Table 6P.4o. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Numerous commenters expressed concern with the proposal that involved 20 ICD–10–PCS procedure codes describing percutaneous transfusion of bone marrow and stem cells. The commenters agreed that, clinically, the proposal to designate these procedures as non-O.R. is appropriate. However, the commenters objected to the notion that these procedures would be reassigned to medical MS–DRGs with lower payment rates as a result of the proposal. The commenters urged CMS to maintain the current Pre-MDC logic for patients undergoing bone marrow transplants and to maintain their respective MS–DRG assignments to MS–DRG 014 (Allogeneic Bone Marrow Transplant); MS–DRG 016 (Autologous Bone Marrow Transplant with CC/MCC and MS–DRG 017 (Autologous Bone Marrow Transplant without CC/MCC).

Response: We acknowledge the concerns of the commenters. We agree that it is important to maintain the current Pre-MDC logic for these procedures while also appropriately designating them as non-O.R. procedures.

After consideration of the public comments we received, we are finalizing our proposal to change the designation for the 20 ICD 10–PCS procedure codes listed in Table 6P.4o. associated with the proposed rule and this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) from O.R. procedures to non-O.R. procedures, effective October 1, 2017, and maintaining their assignment to the Pre-MDC MS–DRGs 014, 016, and 017 for FY 2018.

(42) External/Percutaneous/Transorifice Introduction

One commenter identified 51 ICD–10–PCS procedure codes that describe procedures involving external, percutaneous and transorifice (via natural or artificial opening) introduction of substances that generally would not require the resources of an operating room and can be performed at the bedside. We agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19861), we proposed that the 51 ICD–10–PCS procedure codes listed in Table 6P.4p. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of the 51 ICD–10–PCS procedure codes that describe procedures involving external, percutaneous and transorifice (via natural or artificial opening) introduction of substances.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the 51 ICD–10–PCS procedure codes listed in Table 6P.4p. associated with the proposed rule and this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) from O.R. procedures to non-O.R. procedures, effective October 1, 2017.

(43) Percutaneous/Diagnostic and Endoscopic/Transorifice Irrigation, Measurement and Monitoring

One commenter identified 15 ICD–10–PCS procedure codes that describe procedures involving percutaneous/diagnostic and endoscopic/transorifice (via natural or artificial opening) irrigation, measurement and monitoring of structures, pressures and flow that generally would not require the resources of an operating room and can be performed at the bedside. These 15 ICD–10–PCS codes are shown in the table below.

ICD–10–PCS code	Code description
3E1N38X	Irrigation of male reproductive using irrigating substance, percutaneous approach, diagnostic.
3E1N38Z	Irrigation of male reproductive using irrigating substance, percutaneous approach.
3E1N78X	Irrigation of male reproductive using irrigating substance, via natural or artificial opening, diagnostic.
3E1N78Z	Irrigation of male reproductive using irrigating substance, via natural or artificial opening.
3E1N88X	Irrigation of male reproductive using irrigating substance, via natural or artificial opening endoscopic, diagnostic.
3E1N88Z	Irrigation of male reproductive using irrigating substance, via natural or artificial opening endoscopic.
4A0635Z	Measurement of lymphatic flow, percutaneous approach.
4A063BZ	Measurement of lymphatic pressure, percutaneous approach.
4A0C35Z	Measurement of biliary flow, percutaneous approach.
4A0C3BZ	Measurement of biliary pressure, percutaneous approach.
4A0C75Z	Measurement of biliary flow, via natural or artificial opening.
4A0C7BZ	Measurement of biliary pressure, via natural or artificial opening.
4A0C85Z	Measurement of biliary flow, via natural or artificial opening endoscopic.
4A1635Z	Monitoring of lymphatic flow, percutaneous approach.
4A163BZ	Monitoring of lymphatic pressure, percutaneous approach.

We agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19861 through 19862), we proposed that the 15 ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of the 15 ICD–10–PCS procedure codes that describe procedures involving percutaneous/diagnostic and endoscopic/transorifice (via natural or artificial opening) irrigation, measurement and monitoring of structures, pressures and flow.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the 15 ICD–10–PCS procedure codes shown in the table above from O.R. procedures to non-O.R. procedures, effective October 1, 2017.

(44) Imaging

One commenter identified six ICD–10–PCS procedure codes that describe procedures involving imaging with contrast of hepatobiliary system body parts that generally would not require the resources of an operating room and can be performed at the bedside. These six ICD–10–PCS codes are shown in the table below.

ICD–10–PCS code	Code description
BF030ZZ	Plain radiography of gallbladder and bile ducts using high osmolar contrast.
BF031ZZ	Plain radiography of gallbladder and bile ducts using low osmolar contrast.
BF03YZZ	Plain radiography of gallbladder and bile ducts using other contrast.
BF0C0ZZ	Plain radiography of hepatobiliary system, all using high osmolar contrast.
BF0C1ZZ	Plain radiography of hepatobiliary system, all using low osmolar contrast.
BF0CYZZ	Plain radiography of hepatobiliary system, all using other contrast.

We agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19862), we proposed that the six ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of the six ICD–10–PCS procedure codes that describe imaging with contrast of hepatobiliary system body parts.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the six ICD–10–PCS procedure codes shown in the table above from O.R. procedures to non-O.R. procedures, effective October 1, 2017.

(45) Prosthetics

One commenter identified five ICD–10–PCS procedure codes that describe procedures involving the fitting and use of prosthetics and assistive devices that would not require the resources of an operating room. These five ICD–10–PCS codes are shown in the table below.

ICD–10–PCS code	Code description
F0DZ8ZZ	Prosthesis device fitting.
F0DZ9EZ	Assistive, adaptive, supportive or protective devices device fitting using orthosis.
F0DZ9FZ	Assistive, adaptive, supportive or protective devices device fitting using assistive, adaptive, supportive or protective equipment.
F0DZ9UZ	Assistive, adaptive, supportive or protective devices device fitting using prosthesis.
F0DZ9ZZ	Assistive, adaptive, supportive or protective devices device fitting.

We agreed with the commenter. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19862), we proposed that the five ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of the five ICD–10–PCS procedure codes that describe the fitting and use of prosthetics and assistive devices.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the five ICD–10–PCS procedure codes shown in the table above from O.R. procedures to non-O.R. procedures, effective October 1, 2017.

b. Revision of Neurostimulator Generator

We received a request to review three ICD–10–PCS procedure codes that describe procedures for revision of a neurostimulator generator that are currently designated as O.R. procedures and assigned to MS–DRGs 252, 253 and 254 (Other Vascular Procedures with MCC, with CC and without CC/MCC, respectively). The three codes are 0JWT0MZ (Revision of stimulator generator in trunk subcutaneous tissue and fascia, open approach), 0JWT3MZ (Revision of stimulator generator in trunk subcutaneous tissue and fascia, percutaneous approach), and 0JWTXMZ (Revision of stimulator generator in trunk subcutaneous tissue and fascia, external approach).

The requester expressed concern with the MS–DRG assignments and noted that although these codes are used to report revision of a carotid sinus stimulator pulse generator and appropriately assigned to MS–DRGs 252, 253 and 254 in MDC 5 (Diseases and Disorders of the Circulatory System), they also are very frequently used for the revision of the more common (for example, gastric, intracranial, sacral and spinal) neurostimulator generators that would generally not require the resources of an operating room.

The requestor also stated that the indication for revision of a neurostimulator generator is typically due to a complication, which would be reflected in a complication code such as ICD–10–CM diagnosis code T85.734A (Infection and inflammatory reaction

due to implanted electronic neurostimulator, generator, initial encounter) or T85.890A (Other specified complication of nervous system prosthetic devices, implants and grafts, initial encounter). Because both of these diagnosis codes are assigned to MDC 1 (Diseases and Disorders of the Nervous System), when either code is reported in combination with one of the three procedure codes that describe revision of neurostimulator generator codes (currently assigned to MDC 5 (Diseases and Disorders of the Circulatory System)), the resulting MS–DRG assignment is to MS–DRGs 981, 982 and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC and without CC/MCC, respectively).

The requestor presented the following three options for consideration.

• Reclassify the ICD–10–PCS procedure codes from O.R. Procedures to non-O.R. procedures that affect MS–DRG assignment only in MDC 5. The requestor stated that, under this option, the procedure codes would continue to appropriately group to MDC 5 when representing cases involving carotid sinus stimulators and the other types of neurostimulator cases would appropriately group to medical MS–DRGs.

• Add the ICD–10–PCS procedure codes to MDC 1, such as to MS–DRGs 040, 041 and 042 (Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC, with CC or Peripheral Neurostimulator and without CC/MCC, respectively) under MDC 1. The requestor stated that this option would resolve the inconsistency between a revision of a carotid sinus stimulator generator being classified as an O.R. procedure, while the other comparable procedures involving a revision of a regular neurostimulator generator are not. The requestor also stated that this option would preclude cases being assigned to MS–DRGs 981 through 983.

• Stop classifying the ICD–10–PCS procedure codes as O.R. procedures entirely. The requestor stated that, under this option, all cases would then group to medical MS–DRGs, regardless of the type of neurostimulator generator.

As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19862 through 19863), we analyzed claims data for the three revision of neurostimulator generator procedure codes from the December 2016 update of the FY 2016 MedPAR file and identified cases under MDC 1 in MS–DRGs 025, 026, and 027 (Craniotomy and Endovascular Intracranial Procedures with MCC, with CC and without CC/MCC, respectively); MS–DRGs 029 and 030 (Spinal Procedures with CC or Neurostimulators and Spinal Procedures without CC/MCC, respectively); and MS–DRGs 041 and 042 (Peripheral, Cranial Nerve and Other Nervous System Procedures with CC or Peripheral Neurostimulator and without CC/MCC, respectively). We also identified cases in MS–DRGs 982 and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with CC and without CC/MCC, respectively). Lastly, we identified cases under MDC 5 in MS–DRGs 252, 253 and 254 (Other Vascular Procedures with MCC, with CC and without CC/MCC, respectively). Our findings are shown in the table below.

MS–DRGs for Revision of Neurostimulator Generator

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 025—All cases	18,442	9.1	$29,984
MS–DRG 025—Cases with revision of neurostimulator generator	1	12.0	73,716
MS–DRG 026—All cases	8,415	5.6	21,557
MS–DRG 026—Cases with revision of neurostimulator generator	1	6.0	4,537
MS–DRG 027—All cases	10,089	2.9	17,320
MS–DRG 027—Cases with revision of neurostimulator generator	4	1.8	13,906
MS–DRG 029—All cases	3,192	5.9	23,145
MS–DRG 029—Cases with revision of neurostimulator generator	6	3.5	32,799
MS–DRG 030—All cases	1,933	2.9	14,901
MS–DRG 030—Cases with revision of neurostimulator generator	11	2.2	18,294
MS–DRG 041—All cases	5,154	5.5	16,633
MS–DRG 041—Cases with revision of neurostimulator generator	1	1.0	14,145
MS–DRG 042—All cases	2,099	3.2	13,725
MS–DRG 042—Cases with revision of neurostimulator generator	2	2.0	28,587
MS–DRG 982—All cases	15,216	6.6	17,341
MS–DRG 982—Cases with revision of neurostimulator generator	11	3.0	15,336
MS–DRG 983—All cases	3,508	3.2	11,627
MS–DRG 983—Cases with revision of neurostimulator generator	9	4.2	19,951
MS–DRG 252—All cases	33,817	7.6	23,384
MS–DRG 252—Cases with revision of neurostimulator generator	1	7.0	18,740
MS–DRG 253—All cases	27,456	5.5	18,519
MS–DRG 253—Cases with revision of neurostimulator generator	7	2.4	19,078
MS–DRG 254—All cases	13,036	2.9	13,253
MS–DRG 254—Cases with revision of neurostimulator generator	3	3.0	11,981

As shown in the table above, the overall volume of cases reporting revision of neurostimulator generator is low, with a total of only 57 cases found across all of the MS–DRGs reviewed. The average length of stay for these cases reporting revision of neurostimulator generators is, in most cases, consistent with the average length of stay for all cases in the respective MS–DRG, with the majority having an average length of stay below the average length of stay of all cases in the respective MS–DRG. Finally, the average costs for cases reporting revision of neurostimulator generator reflect a wide range, with a low of $4,537 in MS–DRG 026 to a high of $73,716 in MS–DRG 025. It is clear that, for MS–DRG 025 where the average costs of all cases were $29,984 and the average costs of the one case reporting revision of a neurostimulator generator was $73,716, this is an atypical case. It is also clear from the data that there were other procedures reported on the claims where a procedure code for a revision of a neurostimulator generator was assigned due to the various MS–DRG assignments.

We stated in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19862 and 19863) that after review of the claims data and discussion with our clinical advisors, we agreed with and supported the requestor's first option—to reclassify the three ICD–10–PCS procedure codes for revision of neurostimulator generators from O.R. procedures to non-O.R. procedures that affect the assignment for MS–DRGs 252, 253 and 254 to account for the subset of patients undergoing revision of a carotid sinus neurostimulator generator specifically. In cases where one of the more common (for example, gastric, intracranial, sacral and spinal) neurostimulator generators are undergoing revision, in the absence of another O.R. procedure, these cases would group to a medical MS–DRG. We invited public comments on our proposal.

Comment: Commenters supported the proposal to reclassify the procedures described by ICD–10–PCS procedure codes 0JWT0MZ, 0JWT3MZ, and 0JWTXMZ from O.R. procedures to non-O.R. procedures that affect the assignment for MS–DRGs 252, 253 and 254. One commenter agreed with reclassifying procedures described by ICD–10–PCS procedure codes 0JWT3MZ and 0JWTXMZ from O.R. procedures to non-O.R. procedures. However, this commenter disagreed with reclassifying the procedure described by procedure code 0JWT0MZ and stated that the procedure utilizes an open approach and may require an O.R. setting. The commenter suggested that the procedure code should be retained as an O.R. designation to group to surgical MS–DRGs.

Response: We appreciate the commenters' support. In response to the commenter who disagreed with reclassifying the procedure described by procedure code 0JWT0MZ from an O.R. procedure to a non-O.R. procedure, we note that, as discussed earlier, the three ICD–10–PCS procedure codes would be classified as non-O.R. procedures that affect MS–DRGs 252, 253, and 254 for revision of carotid sinus neurostimulator generators. We also noted that the volume of cases reporting revision of neurostimulator generator is low, with a total of only 57 cases found across all of the MS–DRGs reviewed. The initial requestor pointed out that these three procedure codes are very frequently used for the revision of the more common (for example, gastric, intracranial, sacral, and spinal) neurostimulator generators that would generally not require the resources of an operating room. Therefore, we believe it is appropriate to classify the three procedure codes as non-O.R. procedures affecting MS–DRGs 252, 253, and 254 specifically.

After consideration of the public comments we received, we are finalizing our proposal to reclassify the procedures described by ICD–10–PCS procedure codes 0JWT0MZ (Revision of stimulator generator in trunk subcutaneous tissue and fascia, open approach), 0JWT3MZ (Revision of stimulator generator in trunk subcutaneous tissue and fascia, percutaneous approach), and 0JWTXMZ (Revision of stimulator generator in trunk subcutaneous tissue and fascia, external approach) from O.R. procedures to non-O.R. procedures that affect the assignment for MS–DRGs 252, 253, and 254 to account for the subset of patients undergoing revision of a carotid sinus neurostimulator generator, effective October 1, 2017.

c. External Repair of Hymen

We received a request to examine ICD–10–PCS procedure code 0UQKXZZ (Repair Hymen, External Approach). This procedure code is currently designated as an O.R. procedure in MS–DRGs 746 and 747 (Vagina, Cervix and Vulva Procedures with CC/MCC and without CC/MCC, respectively) under MDC 13. The requestor provided examples and expressed concern that procedure code 0UQKXZZ was assigned to MS–DRG 987 (Non-Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC) when reported on a maternal delivery claim. The requestor noted that when a similar code was reported with an external approach (for example, procedure code 0UQMXZZ (Repair vulva, external approach)), the case was appropriately assigned to MS–DRG 774 (Vaginal Delivery with Complicating Diagnosis). The requestor stated that the physician documentation was simply more specific to the location of the repair and this should not affect assignment to one of the MS–DRGs for vaginal delivery.

As we discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19863 through 19864), we reviewed claims data involving the examples provided by the requestor involving ICD–10–PCS procedure code 0UQKXZZ (Repair hymen, external approach). Our clinical advisors agreed with the requestor that reporting of this procedure code should not affect assignment to one of the MS–DRGs for vaginal delivery. We stated that, as discussed in section II.F.15.a. of the preamble of the proposed rule, we were proposing to change the designation for a number of procedure codes from O.R. procedures to non-O.R. procedures. Included in that proposal were ICD–10–PCS procedure codes 0UQGXZZ (Repair vagina, external approach) and 0UQMXZZ (Repair vulva, external approach). Consistent with the change in designation for these procedure codes, we also proposed to designate ICD–10–PCS procedure code 0UQKXZZ (Repair hymen, external approach) as a non-O.R. procedure. The procedure by itself would generally not require the resources of an operating room. If the procedure is performed following a vaginal delivery, it is the vaginal delivery procedure code 10E0XZZ (Delivery of products of conception) that determines the MS–DRG assignment because this code is designated as a non-O.R. procedure affecting the MS–DRG.

Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19864), we proposed to change the designation of ICD–10–PCS procedure code 0UQKXZZ (Repair hymen, external approach) to a non-O.R. procedure. We stated that this redesignation will enable more appropriate MS–DRG assignment for these cases by eliminating erroneous assignment to MS–DRGs 987 through 989. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of ICD–10–PCS procedure code 0UQKXZZ from an O.R. procedure to a non-O.R. procedure.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of ICD–10–PCS procedure code 0UQKXZZ (Repair hymen, external approach) from an O.R. procedure to a non-O.R. procedure, effective October 1, 2017.

d. Non-O.R. Procedures in MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms)

Under MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms), there are 11 surgical MS–DRGs. Of these 11 surgical MS–DRGs, there are 5 MS–DRGs containing GROUPER logic that includes ICD–10–PCS procedure codes designated as O.R. procedures as well as non-O.R. procedures that affect the MS–DRG. These five MS–DRGs are MS–DRGs 823, 824, and 825 (Lymphoma and Non-Acute Leukemia with Other O.R. Procedure with MCC, with CC and without CC/MCC, respectively) and MS–DRGs 829 and 830 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Other O.R. Procedure with CC/MCC and without CC/MCC, respectively). We

refer the reader to the ICD–10 Version 34 MS–DRG Definitions Manual which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2017-IPPS-Final-Rule-Home-Page-Items/FY2017-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending* for the complete list of ICD–10–PCS procedure codes assigned to these five MS–DRGs under MDC 17.

We reviewed the list of 244 ICD–10–PCS non-O.R. procedure codes currently assigned to these 5 MS–DRGs. Of these 244 procedure codes, we determined that 55 of the procedure codes do not warrant being designated as non-O.R. procedures that affect these MS–DRGs because they describe procedures that would generally not require a greater intensity of resources for facilities to manage the cases included in the definition (logic) of these MS–DRGs. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19864), we proposed that the 55 ICD–10–PCS procedure codes listed in Table 6P.3c. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be removed from the logic for MS–DRGs 823, 824, 825, 829, and 830 as non-O.R. procedures affecting the MS–DRG. We also proposed to revise the titles for these five MS–DRGs by deleting the reference to ''O.R.'' in the title. Specifically, we proposed to revise the titles for MS–DRGs 823, 824, and 825 to ''Lymphoma and Non-Acute Leukemia with Other Procedure with MCC, with CC and without CC/MCC'', respectively, and we proposed to revise the titles for MS–DRGs 829 and 830 to ''Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Other Procedure with CC/MCC and without CC/MCC'', respectively. We invited public comments on our proposals.

Comment: Commenters supported the proposal to remove the 55 ICD–10–PCS procedure codes listed in Table 6P.3c. associated with the proposed rule from the logic for MS–DRGs 823, 824, 825, 829, and 830 as non-O.R. procedures affecting the MS–DRG. Commenters also supported the proposal to revise the titles for MS–DRGs 823, 824, and 825, as well as for MS–DRGs 829 and 830.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to remove the 55 ICD–10–PCS procedure codes listed in Table 6P.3c. associated with the proposed rule and this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) from the logic for MS–DRGs 823, 824, 825, 829, and 830 as non-O.R. procedures affecting the MS–DRG, effective October 1, 2017. We also are finalizing our proposal to revise the titles for MS–DRGs 823, 824, and 825 to ''Lymphoma and Non-Acute Leukemia with Other Procedure with MCC, with CC and without CC/MCC'', respectively, and to revise the titles for MS–DRGs 829 and 830 to ''Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Other Procedure with CC/MCC and without CC/MCC'', respectively, effective October 1, 2017.

G. Recalibration of the FY 2018 MS–DRG Relative Weights

1. Data Sources for Developing the Relative Weights

In developing the FY 2018 system of weights, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19864), we proposed to use two data sources: Claims data and cost report data. As in previous years, the claims data source is the MedPAR file. This file is based on fully coded diagnostic and procedure data for all Medicare inpatient hospital bills. The FY 2016 MedPAR data used in this final rule include discharges occurring on October 1, 2015, through September 30, 2016, based on bills received by CMS through March 31, 2017, from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which at that time were under a waiver from the IPPS). The FY 2016 MedPAR file used in calculating the relative weights includes data for approximately 9,647,256 Medicare discharges from IPPS providers. Discharges for Medicare beneficiaries enrolled in a Medicare Advantage managed care plan are excluded from this analysis. These discharges are excluded when the MedPAR ''GHO Paid'' indicator field on the claim record is equal to ''1'' or when the MedPAR DRG payment field, which represents the total payment for the claim, is equal to the MedPAR ''Indirect Medical Education (IME)'' payment field, indicating that the claim was an ''IME only'' claim submitted by a teaching hospital on behalf of a beneficiary enrolled in a Medicare Advantage managed care plan. In addition, the March 31, 2017 update of the FY 2016 MedPAR file complies with version 5010 of the X12 HIPAA Transaction and Code Set Standards, and includes a variable called ''claim type.'' Claim type ''60'' indicates that the claim was an inpatient claim paid as fee-for-service. Claim types ''61,'' ''62,'' ''63,'' and ''64'' relate to encounter claims, Medicare Advantage IME claims, and HMO no-pay claims. Therefore, the calculation of the relative weights for FY 2018 also excludes claims with claim type values not equal to ''60.'' The data exclude CAHs, including hospitals that subsequently became CAHs after the period from which the data were taken. We note that the FY 2018 relative weights are based on the ICD–10–CM diagnoses and ICD–10–PCS procedure codes from the FY 2016 MedPAR claims data, grouped through the ICD–10 version of the FY 2018 GROUPER (Version 35).

The second data source used in the cost-based relative weighting methodology is the Medicare cost report data files from the HCRIS. Normally, we use the HCRIS dataset that is 3 years prior to the IPPS fiscal year. Specifically, we are using cost report data from the March 31, 2017 update of the FY 2015 HCRIS for calculating the final FY 2018 cost-based relative weights.

2. Methodology for Calculation of the Relative Weights

As we explain in section II.E.2. of the preamble of this final rule, we are calculating the FY 2018 relative weights based on 19 CCRs, as we did for FY 2017. The methodology we used to calculate the FY 2018 MS–DRG cost-based relative weights based on claims data in the FY 2016 MedPAR file and data from the FY 2015 Medicare cost reports is as follows:

- To the extent possible, all the claims were regrouped using the FY 2018 MS–DRG classifications discussed in sections II.B. and II.F. of the preamble of this final rule.
- The transplant cases that were used to establish the relative weights for heart and heart-lung, liver and/or intestinal, and lung transplants (MS–DRGs 001, 002, 005, 006, and 007, respectively) were limited to those Medicare-approved transplant centers that have cases in the FY 2016 MedPAR file. (Medicare coverage for heart, heart-lung, liver and/or intestinal, and lung transplants is limited to those facilities that have received approval from CMS as transplant centers.)
- Organ acquisition costs for kidney, heart, heart-lung, liver, lung, pancreas, and intestinal (or multivisceral organs) transplants continue to be paid on a reasonable cost basis. Because these acquisition costs are paid separately from the prospective payment rate, it is

necessary to subtract the acquisition charges from the total charges on each transplant bill that showed acquisition charges before computing the average cost for each MS–DRG and before eliminating statistical outliers.

- Claims with total charges or total lengths of stay less than or equal to zero were deleted. Claims that had an amount in the total charge field that differed by more than $30.00 from the sum of the routine day charges, intensive care charges, pharmacy charges, implantable devices charges, supplies and equipment charges, therapy services charges, operating room charges, cardiology charges, laboratory charges, radiology charges, other service charges, labor and delivery charges, inhalation therapy charges, emergency room charges, blood and blood products charges, anesthesia charges, cardiac catheterization charges, CT scan charges, and MRI charges were also deleted.
- At least 92.2 percent of the providers in the MedPAR file had charges for 14 of the 19 cost centers. All claims of providers that did not have charges greater than zero for at least 14 of the 19 cost centers were deleted. In other words, a provider must have no more than five blank cost centers. If a provider did not have charges greater than zero in more than five cost centers, the claims for the provider were deleted.
- Statistical outliers were eliminated by removing all cases that were beyond 3.0 standard deviations from the geometric mean of the log distribution of both the total charges per case and the total charges per day for each MS–DRG.
- Effective October 1, 2008, because hospital inpatient claims include a POA indicator field for each diagnosis present on the claim, only for purposes of relative weight-setting, the POA indicator field was reset to ''Y'' for ''Yes'' for all claims that otherwise have an ''N'' (No) or a ''U'' (documentation insufficient to determine if the condition was present at the time of inpatient admission) in the POA field.

Under current payment policy, the presence of specific HAC codes, as indicated by the POA field values, can generate a lower payment for the claim. Specifically, if the particular condition is present on admission (that is, a ''Y'' indicator is associated with the diagnosis on the claim), it is not a HAC, and the hospital is paid for the higher severity (and, therefore, the higher weighted MS–DRG). If the particular condition is not present on admission (that is, an ''N'' indicator is associated with the diagnosis on the claim) and there are no other complicating conditions, the DRG GROUPER assigns the claim to a lower severity (and, therefore, the lower weighted MS–DRG) as a penalty for allowing a Medicare inpatient to contract a HAC. While the POA reporting meets policy goals of encouraging quality care and generates program savings, it presents an issue for the relative weight-setting process. Because cases identified as HACs are likely to be more complex than similar cases that are not identified as HACs, the charges associated with HAC cases are likely to be higher as well. Therefore, if the higher charges of these HAC claims are grouped into lower severity MS–DRGs prior to the relative weight-setting process, the relative weights of these particular MS–DRGs would become artificially inflated, potentially skewing the relative weights. In addition, we want to protect the integrity of the budget neutrality process by ensuring that, in estimating payments, no increase to the standardized amount occurs as a result of lower overall payments in a previous year that stem from using weights and case-mix that are based on lower severity MS–DRG assignments. If this would occur, the anticipated cost savings from the HAC policy would be lost.

To avoid these problems, we reset the POA indicator field to ''Y'' only for relative weight-setting purposes for all claims that otherwise have an ''N'' or a ''U'' in the POA field. This resetting ''forced'' the more costly HAC claims into the higher severity MS–DRGs as appropriate, and the relative weights calculated for each MS–DRG more closely reflect the true costs of those cases.

In addition, in the FY 2013 IPPS/LTCH PPS final rule, for FY 2013 and subsequent fiscal years, we finalized a policy to treat hospitals that participate in the Bundled Payments for Care Improvement (BPCI) initiative the same as prior fiscal years for the IPPS payment modeling and ratesetting process without regard to hospitals' participation within these bundled payment models (that is, as if hospitals were not participating in those models under the BPCI initiative). The BPCI initiative, developed under the authority of section 3021 of the Affordable Care Act (codified at section 1115A of the Act), is comprised of four broadly defined models of care, which link payments for multiple services beneficiaries receive during an episode of care. Under the BPCI initiative, organizations enter into payment arrangements that include financial and performance accountability for episodes of care. For FY 2018, as we proposed, we are continuing to include all applicable data from subsection (d) hospitals participating in BPCI Models 1, 2, and 4 in our IPPS payment modeling and ratesetting calculations. We refer readers to the FY 2013 IPPS/LTCH PPS final rule for a complete discussion on our final policy for the treatment of hospitals participating in the BPCI initiative in our ratesetting process. For additional information on the BPCI initiative, we refer readers to the CMS' Center for Medicare and Medicaid Innovation's Web site at: *http://innovation.cms.gov/initiatives/Bundled-Payments/index.html* and to section IV.H.4. of the preamble of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53341 through 53343).

The charges for each of the 19 cost groups for each claim were standardized to remove the effects of differences in area wage levels, IME and DSH payments, and for hospitals located in Alaska and Hawaii, the applicable cost-of-living adjustment. Because hospital charges include charges for both operating and capital costs, we standardized total charges to remove the effects of differences in geographic adjustment factors, cost-of-living adjustments, and DSH payments under the capital IPPS as well. Charges were then summed by MS–DRG for each of the 19 cost groups so that each MS–DRG had 19 standardized charge totals. Statistical outliers were then removed. These charges were then adjusted to cost by applying the national average CCRs developed from the FY 2015 cost report data.

The 19 cost centers that we used in the relative weight calculation are shown in the following table. The table shows the lines on the cost report and the corresponding revenue codes that we used to create the 19 national cost center CCRs. In the FY 2018 IPPS/LTCH PPS proposed rule, we stated that if stakeholders have comments about the groupings in this table, we may consider those comments as we finalize our policy. However, we did not receive any comments on the groupings in this table, and therefore, we are finalizing the groupings as proposed.

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Routine Days	Private Room Charges	011X and 014X		Adults & Pediatrics (General Routine Care)	C_1_C5_30	C_1_C6_30	D3_HOS_C2_30
	Semi-Private Room Charges	012X, 013X and 016X-0”CC Rs»X					
	Ward Charges	015X					
Intensive Days	Intensive Care Charges	020X		Intensive Care Unit	C_1_C5_31	C_1_C6_31	D3_HOS_C2_31

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
	Coronary Care Charges	021X		Coronary Care Unit	C_1_C5_32	C_1_C6_32	D3_HOS_C2_32
				Burn Intensive Care Unit	C_1_C5_33	C_1_C6_33	D3_HOS_C2_33
				Surgical Intensive Care Unit	C_1_C5_34	C_1_C6_34	D3_HOS_C2_34

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
				Other Special Care Unit	C_1_C5_35	C_1_C6_35	D3_HOS_C2_35
Drugs	Pharmacy Charges	025X, 026X and 063X		Intravenous Therapy	C_1_C5_64	C_1_C6_64	D3_HOS_C2_64
						C_1_C7_64	
				Drugs Charged To Patient	C_1_C5_73	C_1_C6_73	D3_HOS_C2_73
						C_1_C7_73	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Supplies and Equipment	Medical/Surgical Supply Charges	0270, 0271, 0272, 0273, 0274, 0277, 0279, and 0621, 0622, 0623		Medical Supplies Charged to Patients	C_1_C5_71	C_1_C6_71	D3_HOS_C2_71
						C_1_C7_71	
	Durable Medical Equipment Charges	0290, 0291, 0292 and 0294-0299		DME-Rented	C_1_C5_96	C_1_C6_96	D3_HOS_C2_96
						C_1_C7_96	
	Used Durable Medical Charges	0293		DME-Sold	C_1_C5_97	C_1_C6_97	D3_HOS_C2_97

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
						C_1_C7_97	
Implantable Devices		0275, 0276, 0278, 0624		Implantable Devices Charged to Patients	C_1_C5_72	C_1_C6_72	D3_HOS_C2_72
						C_1_C7_72	
Therapy Services	Physical Therapy Charges	042X		Physical Therapy	C_1_C5_66	C_1_C6_66	D3_HOS_C2_66
						C_1_C7_66	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
	Occupational Therapy Charges	043X		Occupational Therapy	C_1_C5_67	C_1_C6_67	D3_HOS_C2_67
						C_1_C7_67	
	Speech Pathology Charges	044X and 047X		Speech Pathology	C_1_C5_68	C_1_C6_68	D3_HOS_C2_68
						C_1_C7_68	
Inhalation Therapy	Inhalation Therapy Charges	041X and 046X		Respiratory Therapy	C_1_C5_65	C_1_C6_65	D3_HOS_C2_65
						C_1_C7_65	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Operating Room	Operating Room Charges	036X		Operating Room	C_1_C5_50	C_1_C6_50	D3_HOS_C2_50
						C_1_C7_50	
		071X		Recovery Room	C_1_C5_51	C_1_C6_51	D3_HOS_C2_51
						C_1_C7_51	
Labor & Delivery	Operating Room Charges	072X		Delivery Room and Labor Room	C_1_C5_52	C_1_C6_52	D3_HOS_C2_52

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
						C_1_C7_52	
Anesthesia	Anesthesia Charges	037X		Anesthesi-ology	C_1_C5_53	C_1_C6_53	D3_HOS_C2_53
						C_1_C7_53	
Cardiology	Cardiology Charges	048X and 073X		Electro-cardiology	C_1_C5_69	C_1_C6_69	D3_HOS_C2_69
						C_1_C7_69	
Cardiac Catheteri-		0481		Cardiac Catheterization	C_1_C5_59	C_1_C6_59	D3_HOS_C2_59

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
zation							
						C_1_C7_59	
Laboratory	Laboratory Charges	030X, 031X, and 075X		Laboratory	C_1_C5_60	C_1_C6_60	D3_HOS_C2_60
						C_1_C7_60	
				PBP Clinic Laboratory Services	C_1_C5_61	C_1_C6_61	D3_HOS_C2_61
						C_1_C7_61	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
		074X, 086X		Electro-Encephalography	C_1_C5_70	C_1_C6_70	D3_HOS_C2_70
						C_1_C7_70	
Radiology	Radiology Charges	032X, 040X		Radiology – Diagnostic	C_1_C5_54	C_1_C6_54	D3_HOS_C2_54
						C_1_C7_54	
		028x, 0331, 0332, 0333, 0335, 0339, 0342		Radiology – Therapeutic	C_1_C5_55	C_1_C6_55	D3_HOS_C2_55
		0343 and 344		Radioisotope	C_1_C5_56	C_1_C6_56	D3_HOS_C2_56

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
						C_1_C7_56	
Computed Tomography (CT) Scan	CT Scan Charges	035X		Computed Tomography (CT) Scan	C_1_C5_57	C_1_C6_57	D3_HOS_C2_57
						C_1_C7_57	
Magnetic Resonance Imaging (MRI)	MRI Charges	061X		Magnetic Resonance Imaging (MRI)	C_1_C5_58	C_1_C6_58	D3_HOS_C2_58
						C_1_C7_58	
Emergency Room	Emergency Room	045x		Emergency	C_1_C5_91	C_1_C6_91	D3_HOS_C2_91

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
	Charges						
						C_1_C7_91	
Blood and Blood Products	Blood Charges	038x		Whole Blood & Packed Red Blood Cells	C_1_C5_62	C_1_C6_62	D3_HOS_C2_62
						C_1_C7_62	
	Blood Storage / Processing	039x		Blood Storing, Processing, & Transfusing	C_1_C5_63	C_1_C6_63	D3_HOS_C2_63
						C_1_C7_63	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Other Services	Other Service Charge	0002-0099, 022X, 023X, 024X,052X, 053X					
		055X-060X, 064X-070X, 076X-078X, 090X-095X and 099X					
	Renal Dialysis	0800X		Renal Dialysis	C_1_C5_74	C_1_C6_74	D3_HOS_C2_74
	ESRD Revenue Setting Charges	080X and 082X-088X				C_1_C7_74	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
				Home Program Dialysis	C_1_C5_94	C_1_C6_94	D3_HOS_C2_94
						C_1_C7_94	
	Outpatient Service Charges	049X		ASC (Non Distinct Part)	C_1_C5_75	C_1_C6_75	D3_HOS_C2_75
	Lithotripsy Charge	079X				C_1_C7_75	
				Other Ancillary	C_1_C5_76	C_1_C6_76	D3_HOS_C2_76
						C_1_C7_76	
	Clinic Visit Charges	051X		Clinic	C_1_C5_90	C_1_C6_90	D3_HOS_C2_90

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
						C_1_C7_90	
				Observation beds	C_1_C5_92.01	C_1_C6_92.01	D3_HOS_C2_92.01
						C_1_C7_92.01	
	Professional Fees Charges	096X, 097X, and 098X		Other Outpatient Services	C_1_C5_93	C_1_C6_93	D3_HOS_C2_93
						C_1_C7_93	
	Ambulance Charges	054X		Ambulance	C_1_C5_95	C_1_C6_95	D3_HOS_C2_95
						C_1_C7_95	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
				Rural Health Clinic	C_1_C5_88	C_1_C6_88	D3_HOS_C2_88
						C_1_C7_88	
				FQHC	C_1_C5_89	C_1_C6_89	D3_HOS_C2_89
						C_1_C7_89	

3. Development of National Average CCRs

We developed the national average CCRs as follows:

Using the FY 2015 cost report data, we removed CAHs, Indian Health Service hospitals, all-inclusive rate hospitals, and cost reports that represented time periods of less than 1 year (365 days). We included hospitals located in Maryland because we include their charges in our claims database. We then created CCRs for each provider for each cost center (see prior table for line items used in the calculations) and removed any CCRs that were greater than 10 or less than 0.01. We normalized the departmental CCRs by dividing the CCR for each department by the total CCR for the hospital for the purpose of trimming the data. We then took the logs of the normalized cost center CCRs and removed any cost center CCRs where the log of the cost center CCR was greater or less than the mean log plus/minus 3 times the standard deviation for the log of that

cost center CCR. Once the cost report data were trimmed, we calculated a Medicare-specific CCR. The Medicare-specific CCR was determined by taking the Medicare charges for each line item from Worksheet D–3 and deriving the Medicare-specific costs by applying the hospital-specific departmental CCRs to the Medicare-specific charges for each line item from Worksheet D–3. Once each hospital's Medicare-specific costs were established, we summed the total Medicare-specific costs and divided by the sum of the total Medicare-specific charges to produce national average, charge-weighted CCRs.

After we multiplied the total charges for each MS–DRG in each of the 19 cost centers by the corresponding national average CCR, we summed the 19 ''costs'' across each MS–DRG to produce a total standardized cost for the MS–DRG. The average standardized cost for each MS–DRG was then computed as the total standardized cost for the MS–DRG divided by the transfer-adjusted case count for the MS–DRG. The average cost for each MS–DRG was then divided by the national average standardized cost per case to determine the relative weight.

The FY 2018 cost-based relative weights were then normalized by an adjustment factor of 1.737382 so that the average case weight after recalibration was equal to the average case weight before recalibration. The normalization adjustment is intended to ensure that recalibration by itself neither increases nor decreases total payments under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act.

The 19 national average CCRs for FY 2018 are as follows:

Group	CCR
Routine Days	0.458
Intensive Days	0.373
Drugs	0.194
Supplies & Equipment	0.297
Implantable Devices	0.332
Therapy Services	0.321
Laboratory	0.120
Operating Room	0.191
Cardiology	0.112
Cardiac Catheterization	0.117
Radiology	0.153
MRIs	0.079
CT Scans	0.038
Emergency Room	0.171
Blood and Blood Products	0.322
Other Services	0.365
Labor & Delivery	0.412
Inhalation Therapy	0.169
Anesthesia	0.089

Since FY 2009, the relative weights have been based on 100 percent cost weights based on our MS–DRG grouping system.

When we recalibrated the DRG weights for previous years, we set a threshold of 10 cases as the minimum number of cases required to compute a reasonable weight. In the FY 2018 IPPS/LTCH PPS proposed rule, we proposed to use that same case threshold in recalibrating the MS–DRG relative weights for FY 2018. Using data from the March 2017 update of the FY 2016 MedPAR file, there are 7 MS–DRGs that contain fewer than 10 cases. We note that two MS–DRGs that were included as low-volume MS–DRGs in the proposed rule, MS–DRG 016 (Autologous Bone Marrow Transplant with CC/MCC) and MS–DRG 017 (Autologous Bone Marrow Transplant without CC/MCC), are no longer included in this list because, as discussed in section II.F.17.a. of the preamble of this final rule, we are maintaining the current Pre-MDC logic for the procedures assigned to those MS–DRGs in FY 2018. For FY 2018, because we do not have sufficient MedPAR data to set accurate and stable cost relative weights for these low-volume MS–DRGs, we proposed to compute relative weights for the low-volume MS–DRGs by adjusting their FY 2017 relative weights by the percentage change in the average weight of the cases in other MS–DRGs. The crosswalk table based on data from the December 2016 update of the FY 2016 MedPAR file was included in the proposed rule. We invited public comments on our proposals.

Comment: Some commenters requested a transition period for substantial reductions in relative weights in order to facilitate payment stability. Specifically, some commenters asked CMS to establish a cap of 10 percent for the degree to which a payment weight may decline in FY 2018 relative to FY 2017. Other commenters also suggested the possibility of a phase-in or multi-year transition period in cases of substantial fluctuation of payment rates. Commenters suggested that large decreases appear to result from the transition from ICD–9 coding to ICD–10 coding in the claims data used to establish the relative weights. These commenters also expressed concern that the proposed weights for MS–DRGs with significant reductions in relative weights would be too low to cover the costs of caring for patients, while other commenters expressed concern about access to such services.

Commenters also indicated that the reductions to MS–DRG relative weights resulting from the transition from ICD–9 coding to ICD–10 coding are in contrast to the goal of ICD–10 to accurately replicate ICD–9 assignments and avoid unintended payment redistribution. One commenter asserted that because IPPS is a prospective payment system, the future claims data should result in an upward adjustment to these MS–DRGs for FY 2019. The commenter believed that hospitals should not be penalized as significantly while the FY 2018 rates are in effect.

Response: In considering these public comments, we examined the MS–DRGs with proposed relative weights that were significantly lower than the FY 2017 relative weights. While we do not believe it is normally appropriate to address relative weight fluctuations that appear to be driven by changes in the underlying data, in this particular circumstance, we share the commenters' concern that, for a limited number of MS–DRGs, this may be more extensively related to the implementation of ICD–10 coding and believe this issue requires further analysis. In the interim, in response to these comments, we are adopting a temporary one-time measure for FY 2018 for MS–DRGs where the relative weight would have declined by more than 20 percent from the FY 2017 relative weight. We believe this policy is consistent with our general authority to assign and update appropriate weighting factors under sections 1886(d)(4)(B) and (C) of the Act. Specifically, for these MS–DRGs, the relative weight will be set at 80 percent of the FY 2017 final relative weight, and we will revisit this issue in the FY 2019 rulemaking when additional ICD–10 claims data become available. We believe that 20 percent strikes an appropriate balance between addressing concerns that the relative weight changes for some MS–DRGs may be more extensively related to the implementation of ICD–10 and the fact that historically we occasionally have had appropriate relative weight changes of this magnitude. Further analysis and data will enable us to better determine the appropriateness of these changes, given the unique circumstances of the ICD–10 implementation.

After consideration of the public comments we received, we are finalizing our proposal, with the modification for recalibrating the MS–DRG relative weights for FY 2018 at 80 percent of the FY 2017 final relative weights, for those MS–DRGs where the relative weight would have declined by more than 20 percent from the FY 2017 relative weight. The crosswalk table for the low-volume MS–DRGs is shown below.

Low-volume MS–DRG	MS–DRG title	Crosswalk to MS–DRG
789	Neonates, Died or Transferred to Another Acute Care Facility.	Final FY 2017 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
790	Extreme Immaturity or Respiratory Distress Syndrome, Neonate.	Final FY 2017 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
791	Prematurity with Major Problems	Final FY 2017 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
792	Prematurity without Major Problems	Final FY 2017 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
793	Full-Term Neonate with Major Problems	Final FY 2017 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
794	Neonate with Other Significant Problems	Final FY 2017 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
795	Normal Newborn	Final FY 2017 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).

H. Add-On Payments for New Services and Technologies for FY 2018

1. Background

Sections 1886(d)(5)(K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies (sometimes collectively referred to in this section as ''new technologies'') under the IPPS. Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered new if it meets criteria established by the Secretary after notice and opportunity for public comment. Section 1886(d)(5)(K)(ii)(I) of the Act specifies that a new medical service or technology may be considered for new technology add-on payment if, based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate. We note that, beginning with discharges occurring in FY 2008, CMS transitioned from CMS–DRGs to MS–DRGs.

The regulations at 42 CFR 412.87 implement these provisions and specify three criteria for a new medical service or technology to receive the additional payment: (1) The medical service or technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies. Below we highlight some of the major statutory and regulatory provisions relevant to the new technology add-on payment criteria, as well as other information. For a complete discussion on the new technology add-on payment criteria, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51572 through 51574).

Under the first criterion, as reflected in § 412.87(b)(2), a specific medical service or technology will be considered ''new'' for purposes of new medical service or technology add-on payments until such time as Medicare data are available to fully reflect the cost of the technology in the MS–DRG weights through recalibration. We note that we do not consider a service or technology to be new if it is substantially similar to one or more existing technologies. That is, even if a technology receives a new FDA approval or clearance, it may not necessarily be considered ''new'' for purposes of new technology add-on payments if it is ''substantially similar'' to a technology that was approved or cleared by FDA and has been on the market for more than 2 to 3 years. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 through 43814), we established criteria for evaluating whether a new technology is substantially similar to an existing technology, specifically: (1) Whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; (2) whether a product is assigned to the same or a different MS–DRG; and (3) whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population. If a technology meets all three of these criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments. For a detailed discussion of the criteria for substantial similarity, we refer readers to the FY 2006 IPPS final rule (70 FR 47351 through 47352), and the FY 2010 IPPS/LTCH PPS final rule (74 FR 43813 through 43814).

Under the second criterion, § 412.87(b)(3) further provides that, to be eligible for the add-on payment for new medical services or technologies, the MS–DRG prospective payment rate otherwise applicable to discharges involving the new medical service or technology must be assessed for adequacy. Under the cost criterion, consistent with the formula specified in section 1886(d)(5)(K)(ii)(I) of the Act, to assess the adequacy of payment for a new technology paid under the applicable MS–DRG prospective payment rate, we evaluate whether the charges for cases involving the new technology exceed certain threshold amounts. Table 10 that was released with the FY 2017 IPPS/LTCH PPS final rule contains the final thresholds that we used to evaluate applications for new medical service and new technology add-on payments for FY 2018. We refer readers to the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2017-IPPS-Final-Rule-Home-Page-Items/FY2017-IPPS-Final-Rule-Tables.html* to download and view Table 10.

In the September 7, 2001 final rule that established the new technology add-on payment regulations (66 FR 46917), we discussed the issue of whether the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule at 45 CFR parts 160 and 164 applies to claims information that providers submit with applications for new medical service and new technology add-on payments. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51573) for complete information on this issue.

Under the third criterion, § 412.87(b)(1) of our existing regulations provides that a new technology is an appropriate candidate for an additional payment when it represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. For example, a new technology represents a substantial

clinical improvement when it reduces mortality, decreases the number of hospitalizations or physician visits, or reduces recovery time compared to the technologies previously available. (We refer readers to the September 7, 2001 final rule for a more detailed discussion of this criterion (66 FR 46902).)

The new medical service or technology add-on payment policy under the IPPS provides additional payments for cases with relatively high costs involving eligible new medical services or technologies, while preserving some of the incentives inherent under an average-based prospective payment system. The payment mechanism is based on the cost to hospitals for the new medical service or technology. Under § 412.88, if the costs of the discharge (determined by applying cost-to-charge ratios (CCRs) as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 50 percent of the estimated costs of the new technology or medical service (if the estimated costs for the case including the new technology or medical service exceed Medicare's payment); or (2) 50 percent of the difference between the full DRG payment and the hospital's estimated cost for the case. Unless the discharge qualifies for an outlier payment, the additional Medicare payment is limited to the full MS–DRG payment plus 50 percent of the estimated costs of the new technology or new medical service.

Section 503(d)(2) of Public Law 108–173 provides that there shall be no reduction or adjustment in aggregate payments under the IPPS due to add-on payments for new medical services and technologies. Therefore, in accordance with section 503(d)(2) of Public Law 108–173, add-on payments for new medical services or technologies for FY 2005 and later years have not been subjected to budget neutrality.

In the FY 2009 IPPS final rule (73 FR 48561 through 48563), we modified our regulations at § 412.87 to codify our longstanding practice of how CMS evaluates the eligibility criteria for new medical service or technology add-on payment applications. That is, we first determine whether a medical service or technology meets the newness criterion, and only if so, do we then make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. We amended § 412.87(c) to specify that all applicants for new technology add-on payments must have FDA approval or clearance for their new medical service or technology by July 1 of each year prior to the beginning of the fiscal year that the application is being considered.

The Council on Technology and Innovation (CTI) at CMS oversees the agency's cross-cutting priority on coordinating coverage, coding and payment processes for Medicare with respect to new technologies and procedures, including new drug therapies, as well as promoting the exchange of information on new technologies and medical services between CMS and other entities. The CTI, composed of senior CMS staff and clinicians, was established under section 942(a) of Public Law 108–173. The Council is co-chaired by the Director of the Center for Clinical Standards and Quality (CCSQ) and the Director of the Center for Medicare (CM), who is also designated as the CTI's Executive Coordinator.

The specific processes for coverage, coding, and payment are implemented by CM, CCSQ, and the local Medicare Administrative Contractors (MACs) (in the case of local coverage and payment decisions). The CTI supplements, rather than replaces, these processes by working to assure that all of these activities reflect the agency-wide priority to promote high-quality, innovative care. At the same time, the CTI also works to streamline, accelerate, and improve coordination of these processes to ensure that they remain up to date as new issues arise. To achieve its goals, the CTI works to streamline and create a more transparent coding and payment process, improve the quality of medical decisions, and speed patient access to effective new treatments. It is also dedicated to supporting better decisions by patients and doctors in using Medicare-covered services through the promotion of better evidence development, which is critical for improving the quality of care for Medicare beneficiaries.

To improve the understanding of CMS' processes for coverage, coding, and payment and how to access them, the CTI has developed an ''Innovator's Guide'' to these processes. The intent is to consolidate this information, much of which is already available in a variety of CMS documents and in various places on the CMS Web site, in a user-friendly format. This guide was published in 2010 and is available on the CMS Web site at: *http://www.cms.gov/CouncilonTechInnov/Downloads/InnovatorsGuide5_10_10.pdf.*

As we indicated in the FY 2009 IPPS final rule (73 FR 48554), we invite any product developers or manufacturers of new medical services or technologies to contact the agency early in the process of product development if they have questions or concerns about the evidence that would be needed later in the development process for the agency's coverage decisions for Medicare.

The CTI aims to provide useful information on its activities and initiatives to stakeholders, including Medicare beneficiaries, advocates, medical product manufacturers, providers, and health policy experts. Stakeholders with further questions about Medicare's coverage, coding, and payment processes, or who want further guidance about how they can navigate these processes, can contact the CTI at *CTI@cms.hhs.gov*.

We note that applicants for add-on payments for new medical services or technologies for FY 2019 must submit a formal request, including a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement, along with a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. Complete application information, along with final deadlines for submitting a full application, will be posted as it becomes available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html*. To allow interested parties to identify the new medical services or technologies under review before the publication of the proposed rule for FY 2019, the CMS Web site also will post the tracking forms completed by each applicant.

2. Public Input Before Publication of a Notice of Proposed Rulemaking on Add-On Payments

Section 1886(d)(5)(K)(viii) of the Act, as amended by section 503(b)(2) of Public Law 108–173, provides for a mechanism for public input before publication of a notice of proposed rulemaking regarding whether a medical service or technology represents a substantial clinical improvement or advancement. The process for evaluating new medical service and technology applications requires the Secretary to—

- Provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially

improves the diagnosis or treatment of Medicare beneficiaries;

- Make public and periodically update a list of the services and technologies for which applications for add-on payments are pending;
- Accept comments, recommendations, and data from the public regarding whether a service or technology represents a substantial clinical improvement; and
- Provide, before publication of a proposed rule, for a meeting at which organizations representing hospitals, physicians, manufacturers, and any other interested party may present comments, recommendations, and data regarding whether a new medical service or technology represents a substantial clinical improvement to the clinical staff of CMS.

In order to provide an opportunity for public input regarding add-on payments for new medical services and technologies for FY 2018 prior to publication of the FY 2018 IPPS/LTCH PPS proposed rule, we published a notice in the **Federal Register** on November 9, 2016 (81 FR 78814), and held a town hall meeting at the CMS Headquarters Office in Baltimore, MD, on February 14, 2017. In the announcement notice for the meeting, we stated that the opinions and presentations provided during the meeting would assist us in our evaluations of applications by allowing public discussion of the substantial clinical improvement criterion for each of the FY 2018 new medical service and technology add-on payment applications before the publication of the FY 2018 IPPS/LTCH PPS proposed rule.

Approximately 66 individuals registered to attend the town hall meeting in person, while additional individuals listened over an open telephone line. We also live-streamed the town hall meeting and posted the town hall on the CMS YouTube Web page at: *https://www.youtube.com/watch?v=9niqfxXe4oA&t=217s.* We considered each applicant's presentation made at the town hall meeting, as well as written comments submitted on the applications that were received by the due date of February 24, 2017, in our evaluation of the new technology add-on payment applications for FY 2018 in the FY 2018 IPPS/LTCH PPS proposed rule.

In response to the published notice and the February 14, 2017 New Technology Town Hall meeting, we received written comments regarding the applications for FY 2018 new technology add-on payments. We note that we do not summarize comments that are unrelated to the ''substantial clinical improvement'' criterion. As explained above and in the **Federal Register** notice announcing the New Technology Town Hall meeting (81 FR78814 through 78816), the purpose of the meeting was specifically to discuss the substantial clinical improvement criterion in regard to pending new technology add-on payment applications for FY 2018. Therefore, we did not summarize those written comments in the proposed rule. As we did in the proposed rule, we are summarizing below a general comment that we received prior to the issuance of the proposed rule that did not relate to a specific application for FY 2018 new technology add-on payments. In addition, as we did in section II.H.5. of the preamble of the proposed rule, we are summarizing comments regarding individual applications, or, if applicable, indicating that there were no comments received in response to the New Technology Town Hall meeting notice, at the end of each discussion of the individual applications.

Comment: One commenter recommended that CMS: (1) Prohibit local MACs from denying coverage and add-on payments for new medical services or technologies approved by the Secretary; and (2) broaden the criteria applied in making substantial clinical improvement determinations to require, in addition to existing criteria, that the Secretary consider whether the new technology or medical service meets one or more of the following criteria: (a) Results in a reduction of the length of a hospital stay; (b) improves patient quality of life; (c) creates long-term clinical efficiencies in treatment; (d) addresses patient-centered objectives as defined by the Secretary; or (e) meets such other criteria as the Secretary may specify.

Response: We appreciate the commenter's comments and will consider them in future rulemaking.

3. ICD–10–PCS Section ''X'' Codes for Certain New Medical Services and Technologies

As discussed in the FY 2016 IPPS/LTCH final rule (80 FR 49434), the ICD–10–PCS includes a new section containing the new Section ''X'' codes, which began being used with discharges occurring on or after October 1, 2015. Decisions regarding changes to ICD–10–PCS Section ''X'' codes will be handled in the same manner as the decisions for all of the other ICD–10–PCS code changes. That is, proposals to create, delete, or revise Section ''X'' codes under the ICD–10–PCS structure will be referred to the ICD–10 Coordination and Maintenance Committee. In addition, several of the new medical services and technologies that have been, or may be, approved for new technology add-on payments may now, and in the future, be assigned a Section ''X'' code within the structure of the ICD–10–PCS. We posted ICD–10–PCS Guidelines on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-PCS-and-GEMs.html*, including guidelines for ICD–10–PCS Section ''X'' codes. We encourage providers to view the material provided on ICD–10–PCS Section ''X'' codes.

4. Revision of the Reference to an ICD–9–CM Code in § 412.87(b)(2) of the Regulations

As we discussed in the FY 2018 IPS/LTCH PPS proposed rule (82 FR 19871), the existing regulations under § 412.87(b)(2) state that a medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD–9–CM code assigned to the new service or technology (depending on when a new code is assigned and data on the new service or technology become available for DRG recalibration). After CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical service or technology, the medical service or technology will no longer be considered ''new'' under the criterion of this section.

As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49454), HIPAA covered entities are required, as of October 1, 2015, to use the ICD–10 coding system (ICD–10–PCS codes for procedures and ICD–10–CM codes for diagnoses), instead of the ICD–9–CM coding system, to report diagnoses and procedures for Medicare hospital inpatient services provided to Medicare beneficiaries as classified under the MS–DRG system and paid for under the IPPS. The language in § 412.87(b)(2) only references an ''ICD–9–CM code.'' Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19871), we proposed to revise the regulations at § 412.87(b)(2) to replace the term ''ICD–9–CM code'' with the term ''inpatient hospital code,'' as defined in section 1886(d)(5)(K)(iii) of the Act. Section 1886(d)(5)(K)(iii) of the Act defines an ''inpatient hospital code'' as any code that is used with respect to inpatient hospital services for which payment may be made under this subsection of the Act and includes an alphanumeric code issued under the International Classification of Diseases, 9th Revision, Clinical Modification (''ICD–9–CM'')

and its subsequent revisions. We invited public comments on our proposal.

We did not receive any public comments on this proposal. Therefore, we are finalizing our proposal to revise the regulations at § 412.87(b)(2) to replace the term ''ICD–9–CM code'' with the term ''inpatient hospital code'', as defined in section 1886(d)(5)(K)(iii) of the Act.

5. FY 2018 Status of Technologies Approved for FY 2017 Add-On Payments

a. CardioMEMS™ HF (Heart Failure) Monitoring System

CardioMEMS, Inc. submitted an application for new technology add-on payments for FY 2015 for the CardioMEMS™ HF (Heart Failure) Monitoring System, which is an implantable hemodynamic monitoring system comprised of an implantable sensor/monitor placed in the distal pulmonary artery. Pulmonary artery hemodynamic monitoring is used in the management of heart failure. The CardioMEMS™ HF Monitoring System measures multiple pulmonary artery pressure parameters for an ambulatory patient to measure and transmit data via a wireless sensor to a secure Web site.

The CardioMEMS™ HF Monitoring System utilizes radiofrequency (RF) energy to power the sensor and to measure pulmonary artery (PA) pressure and consists of three components: An Implantable Sensor with Delivery Catheter, an External Electronics Unit, and a Pulmonary Artery Pressure Database. The system provides the physician with the patient's PA pressure waveform (including systolic, diastolic, and mean pressures) as well as heart rate. The sensor is permanently implanted in the distal pulmonary artery using transcatheter techniques in the catheterization laboratory where it is calibrated using a Swan-Ganz catheter. PA pressures are transmitted by the patient at home in a supine position on a padded antenna, pushing one button which records an 18-second continuous waveform. The data also can be recorded from the hospital, physician's office, or clinic.

The hemodynamic data, including a detailed waveform, are transmitted to a secure Web site that serves as the Pulmonary Artery Pressure Database, so that information regarding PA pressure is available to the physician or nurse at any time via the Internet. Interpretation of trend data allows the clinician to make adjustments to therapy and can be used along with heart failure signs and symptoms to adjust medications.

The applicant received FDA approval on May 28, 2014. After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for the CardioMEMS™ HF Monitoring System and consideration of the public comments we received in response to the FY 2015 IPPS/LTCH PPS proposed rule, we approved the CardioMEMS™ HF Monitoring System for new technology add-on payments for FY 2015 (79 FR 49940). Cases involving the CardioMEMS™ HF Monitoring System that are eligible for new technology add-on payments are identified by either ICD–10–PCS procedure code 02HQ30Z (Insertion of pressure sensor monitoring device into right pulmonary artery, percutaneous approach) or ICD–10–PCS procedure code 02HR30Z (Insertion of pressure sensor monitoring device into left pulmonary artery, percutaneous approach). With the new technology add-on payment application, the applicant stated that the total operating cost of the CardioMEMS™ HF Monitoring System is $17,750. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the device or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the CardioMEMS™ HF Monitoring System is $8,875. We refer the reader to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49937) for complete details on the CardioMEMS™ HF Monitoring System.

Our policy is that a medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology. Our practice has been to begin and end new technology add-on payments on the basis of a fiscal year, and we have generally followed a guideline that uses a 6-month window before and after the start of the fiscal year to determine whether to extend the new technology add-on payment for an additional fiscal year. In general, we extend add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the fiscal year (70 FR 47362).

With regard to the newness criterion for the CardioMEMS™ HF Monitoring System, we considered the beginning of the newness period to commence when the CardioMEMS™ HF Monitoring System was approved by the FDA on May 28, 2014. Because the 3-year anniversary date of the entry of the CardioMEMS™ HF Monitoring System onto the U.S. market (May 28, 2017) would occur prior to the beginning of FY 2018, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19871–19872), we proposed to discontinue new technology add-on payments for this technology for FY 2018. We invited public comments on this proposal.

Comment: Commenters agreed with our proposal to discontinue new technology add-on payments for the CardioMEMS™ HF Monitoring System.

Response: As we proposed, we are discontinuing new technology add-on payments for the CardioMEMS™ HF Monitoring System for FY 2018. The 3-year anniversary date of the product's entry onto the U.S. market occurred prior to the beginning of FY 2018. Therefore, the technology is not eligible for new technology add-on payments for FY 2018 because the technology will no longer meet the ''newness'' criterion.

b. Defitelio® (Defibrotide)

Jazz Pharmaceuticals submitted an application for new technology add-on payments for FY 2017 for defibrotide (Defitelio®), a treatment for patients diagnosed with hepatic veno-occlusive disease (VOD) with evidence of multiorgan dysfunction. VOD, also known as sinusoidal obstruction syndrome (SOS), is a potentially life-threatening complication of hematopoietic stem cell transplantation (HSCT), with an incidence rate of 8 percent to 15 percent. Diagnoses of VOD range in severity from what has been classically defined as a disease limited to the liver (mild) and reversible, to a severe syndrome associated with multi-organ dysfunction or failure and death. Patients treated with HSCT who develop VOD with multi-organ failure face an immediate risk of death, with a mortality rate of more than 80 percent when only supportive care is used. The applicant asserted that Defitelio® improves the survival rate of patients diagnosed with VOD with multi-organ failure by 23 percent.

Defitelio® received Orphan Drug Designation for the treatment of VOD in 2003 and for the prevention of VOD in 2007. It has been available to patients as an investigational drug through an expanded access program since 2007. The applicant's New Drug Application (NDA) for Defitelio® received FDA approval on March 30, 2016. The applicant confirmed that Defitelio® was not available on the U.S. market as of the FDA NDA approval date of March 30, 2016. According to the applicant, commercial packaging could not be completed until the label for Defitelio® was finalized with FDA approval, and that commercial shipments of Defitelio®

to hospitals and treatment centers began on April 4, 2016. Therefore, we agreed that, based on this information, the newness period for Defitelio® begins on April 4, 2016, the date of its first commercial availability.

The applicant received unique ICD–10–PCS procedure codes to describe the use of Defitelio® that became effective October 1, 2016. The approved procedure codes are XW03392 (Introduction of defibrotide sodium anticoagulant into peripheral vein, percutaneous approach) and XW04392 (Introduction of defibrotide sodium anticoagulant into central vein, percutaneous approach).

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for Defitelio® and consideration of the public comments we received in response to the FY 2017 IPPS/LTCH PPS proposed rule, we approved Defitelio® for new technology add-on payments for FY 2017 (81 FR 56906). With the new technology add-on payment application, the applicant estimated that the average Medicare beneficiary would require a dosage of 25 mg/kg/day for a minimum of 21 days of treatment. The recommended dose is 6.25 mg/kg given as a 2-hour intravenous infusion every 6 hours. Dosing should be based on a patient's baseline body weight, which is assumed to be 70 kg for an average adult patient. All vials contain 200 mg at a cost of $825 per vial. Therefore, we determined that cases involving the use of the Defitelio® technology would incur an average cost per case of $151,800 (70 kg adult × 25 mg/kg/day × 21 days = 36,750 mg per patient/200 mg vial = 184 vials per patient × $825 per vial = $151,800). Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment amount for a case involving the use of Defitelio® is $75,900.

Because the 3-year anniversary date of the entry of Defitelio® onto the U.S. market will occur after FY 2018 (April 4, 2019), we proposed to continue new technology add-on payments for this technology for FY 2018. We proposed that the maximum payment for a case involving Defitelio® would remain at $75,900 for FY 2018. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19872), we invited public comments on our proposal to continue new technology add-on payments for Defitelio®.

Comment: One commenter agreed with CMS' proposal to continue new technology add-on payments for Defitelio®.

Response: We appreciate the commenter's support. We are finalizing our proposal to continue new technology add-on payments for Defitelio® for FY 2018. The maximum new technology add-on payment for a case involving Defitelio® will remain at $75,900 for FY 2018.

c. GORE® EXCLUDER® Iliac Branch Endoprosthesis (Gore IBE Device)

W. L. Gore and Associates, Inc. submitted an application for new technology add-on payments for the GORE® EXCLUDER® Iliac Branch Endoprosthesis (GORE IBE device) for FY 2017. The device consists of two components: The Iliac Branch Component (IBC) and the Internal Iliac Component (IIC). The applicant indicated that each endoprosthesis is pre-mounted on a customized delivery and deployment system allowing for controlled endovascular delivery via bilateral femoral access. According to the applicant, the device is designed to be used in conjunction with the GORE® EXCLUDER® AAA Endoprosthesis for the treatment of patients requiring repair of common iliac or aortoiliac aneurysms. When deployed, the GORE IBE device excludes the common iliac aneurysm from systemic blood flow, while preserving blood flow in the external and internal iliac arteries.

With regard to the newness criterion, the applicant received pre-market FDA approval of the GORE IBE device on February 29, 2016. The applicant submitted a request for an unique ICD–10–PCS procedure code and was granted approval for the following procedure codes to describe the use of this technology: 04VC0EZ (Restriction of right common iliac artery with branched or fenestrated intraluminal device, one or two arteries, open approach); 04VC0FZ (Restriction of right common iliac artery with branched or fenestrated intraluminal device, three or more arteries, open approach); 04VC3EZ (Restriction of right common iliac artery with branched or fenestrated intraluminal device, one or two arteries, percutaneous approach); 04VC3FZ (Restriction of right common iliac artery with branched or fenestrated intraluminal device, three or more arteries, percutaneous approach); 04VC4EZ (Restriction of right common iliac artery with branched or fenestrated intraluminal device, one or two arteries, percutaneous approach); 04VC4FZ (Restriction of right common iliac artery with branched or fenestrated intraluminal device, three or more arteries, percutaneous endoscopic, approach); 04VD0EZ (Restriction of left common iliac artery with branched or fenestrated intraluminal device, one or two arteries, open approach); 04VD0FZ (Restriction of left common iliac artery with branched or fenestrated, intraluminal device, three or more arteries, open approach); 04VD3EZ (Restriction of left common iliac artery with branched or fenestrated intraluminal device, one or two arteries, percutaneous approach); 04VD3FZ (Restriction of left common iliac artery with branched or fenestrated intraluminal device, three or more arteries, percutaneous approach); 04VD4EZ (Restriction of left common iliac artery with branched or fenestrated intraluminal device, one or two arteries, percutaneous endoscopic approach); and 04VD4FZ (Restriction of left common iliac artery with branched or fenestrated intraluminal device, three or more arteries, percutaneous endoscopic approach). These new ICD–10–PCS procedure codes became effective on October 1, 2016. After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for the GORE IBE device and consideration of the public comments we received in response to the FY 2017 IPPS/LTCH PPS proposed rule, we approved the GORE IBE device for new technology add-on payments for FY 2017 (81 FR 56909). With the new technology add-on payment application, the applicant indicated that the total operating cost of the GORE IBE device is $10,500. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the device or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the GORE IBE device is $5,250.

With regard to the newness criterion for the GORE IBE device, we considered the beginning of the newness period to commence when the GORE IBE device received FDA approval on February 29, 2016. Because the 3-year anniversary date of the entry of the GORE IBE device onto the U.S. market will occur after FY 2018 (February 28, 2019), in the FY 2018 IPPS/LTCH PPS proposed rule, we proposed to continue new technology add-on payments for this technology for FY 2018. We proposed that the maximum payment for a case involving the GORE IBE device would remain at $5,250 for FY 2018. We invited public comments on our proposal to continue

new technology add-on payments for the GORE IBE device.

Comment: Some commenters supported CMS' proposal to continue new technology add-on payments for the GORE IBE device.

Response: We appreciate the commenters' support. We are finalizing our proposal to continue new technology add-on payments for the GORE IBE device for FY 2018. The maximum new technology add-on payment for a case involving the GORE IBE device will remain at $5,250 for FY 2018.

d. Praxbind® Idarucizumab

Boehringer Ingelheim Pharmaceuticals, Inc. submitted an application for new technology add-on payments for FY 2017 for Praxbind® Idarucizumab (Idarucizumab), a product developed as an antidote to reverse the effects of PRADAXAR (Dabigatran), which is also manufactured by Boehringer Ingelheim Pharmaceuticals, Inc.

Dabigatran is an oral direct thrombin inhibitor currently indicated: (1) To reduce the risk of stroke and systemic embolism in patients who have been diagnosed with nonvalvular atrial fibrillation (NVAF); (2) for the treatment of deep venous thrombosis (DVT) and pulmonary embolism (PE) in patients who have been administered a parenteral anticoagulant for 5 to 10 days; (3) to reduce the risk of recurrence of DVT and PE in patients who have been previously treated; and (4) for the prophylaxis of DVT and PE in patients who have undergone hip replacement surgery. Currently, unlike the anticoagulant Warfarin, there is no specific way to reverse the anticoagulant effect of Dabigatran in the event of a major bleeding episode. Idarucizumab is a humanized fragment antigen binding (Fab) molecule, which specifically binds to Dabigatran to deactivate the anticoagulant effect, thereby allowing thrombin to act in blood clot formation. The applicant stated that Idarucizumab represents a new pharmacologic approach to neutralizing the specific anticoagulant effect of Dabigatran in emergency situations.

Idarucizumab was approved by the FDA on October 16, 2015. Based on the FDA indication for Idarucizumab, the product can be used in the treatment of patients who have been diagnosed with NVAF and administered Dabigatran to reverse life-threatening bleeding events, or who require emergency surgery or medical procedures and rapid reversal of the anticoagulant effects of Dabigatran is necessary and desired.

The applicant received unique ICD–10–PCS procedure codes that became effective October 1, 2016, to describe the use of this technology. The approved procedure codes are XW03331 (Introduction of Idarucizumab, Dabigatran reversal agent into peripheral vein, percutaneous approach, New Technology Group 1) and XW04331 (Introduction of Idarucizumab, Dabigatran reversal agent into central vein, percutaneous approach, New Technology Group 1).

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for Idarucizumab and consideration of the public comments we received in response to the FY 2017 IPPS/LTCH PPS proposed rule, we approved Idarucizumab for new technology add-on payments for FY 2017 (81 FR 56897). With the new technology add-on payment application, the applicant indicated that the total operating cost of Idarucizumab is $3,500. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving Idarucizumab is $1,750.

With regard to the newness criterion for Idarucizumab, we considered the beginning of the newness period to commence when Idarucizumab was approved by the FDA on October 16, 2015. Because the 3-year anniversary date of the entry of Idarucizumab onto the U.S. market will occur after FY 2018 (October 15, 2018), in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19873), we proposed to continue new technology add-on payments for this technology for FY 2018. We proposed that the maximum payment for a case involving Idarucizumab would remain at $1,750 for FY 2018. We invited public comments on our proposal to continue new technology add-on payments for Idarucizumab.

Comment: Several commenters supported CMS' proposal to continue new technology add-on payments for Idarucizumab.

Response: We appreciate the commenters' support. We are finalizing our proposal to continue new technology add-on payments for Idarucizumab for FY 2018. The maximum new technology add-on payment for a case involving Idarucizumab will remain at $1,750 for FY 2018.

e. Lutonix® Drug Coated Balloon PTA Catheter and In.PACT™ Admiral™ Paclitaxel Coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter

Two manufacturers, CR Bard Inc. and Medtronic, submitted applications for new technology add-on payments for FY 2016 for LUTONIX® Drug-Coated Balloon (DCB) Percutaneous Transluminal Angioplasty (PTA) Catheter (LUTONIX®) and IN.PACT™ Admiral™ Paclitaxel Coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter (IN.PACT™ Admiral™), respectively. Both of these technologies are drug-coated balloon angioplasty treatments for patients diagnosed with peripheral artery disease (PAD). Typical treatments for patients with PAD include angioplasty, stenting, atherectomy and vascular bypass surgery. PAD most commonly occurs in the femoropopliteal segment of the peripheral arteries, is associated with significant levels of morbidity and impairment in quality of life, and requires treatment to reduce symptoms and prevent or treat ischemic events.[1] Treatment options for symptomatic PAD include noninvasive treatment such as medication and life-style modification (for example, exercise programs, diet, and smoking cessation) and invasive options, which include endovascular treatment and surgical bypass. The 2013 American College of Cardiology and American Heart Association (ACC/AHA) guidelines for the management of PAD recommend endovascular therapy as the first-line treatment for femoropopliteal artery lesions in patients suffering from claudication (Class I, Level A recommendation).[2]

According to both applicants, LUTONIX® and IN.PACT™ Admiral™ are the first drug coated balloons that can be used for treatment of patients who are diagnosed with PAD. In the FY 2016 IPPS/LTCH PPS final rule, we stated that because cases eligible for the two devices would group to the same MS–DRGs and we believe that these devices are substantially similar to each

[1] Tepe G, Zeller T, Albrecht T, Heller S, Schwarzwalder U, Beregi JP, Claussen CD, Oldenburg A, Scheller B, Speck U., Local delivery of paclitaxel to inhibit restenosis during angioplasty of the leg, N Engl J Med 2008, 358: 689–99.

[2] Anderson JL, Halperin JL, Albert NM, Bozkurt B, Brindis RG, Curtis LH, DeMets D, Guyton RA, Hochman JS, Kovacs RJ, Ohman EM, Pressler SJ, Sellke FW, Shen WK., Management of patients with peripheral artery disease (compilation of 2005 and 2011 ACCF/AHA guideline recommendations): A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, J Am Coll Cardiol 2013, 61:1555–70. Available at: *http://dx.doi.org/10.1016/j.jacc.2013.01.004.*

other (that is, they are intended to treat the same or similar disease in the same or similar patient population and are purposed to achieve the same therapeutic outcome using the same or similar mechanism of action), we evaluated both technologies as one application for new technology add-on payments under the IPPS. The applicants submitted separate cost and clinical data, and we reviewed and discussed each set of data separately. However, we made one determination regarding new technology add-on payments that applied to both devices. We believe that this is consistent with our policy statements in the past regarding substantial similarity. Specifically, we have noted that approval of new technology add-on payments would extend to all technologies that are substantially similar (66 FR 46915), and we believe that continuing our current practice of extending a new technology add-on payment without a further application from the manufacturer of the competing product or a specific finding on cost and clinical improvement if we make a finding of substantial similarity among two products is the better policy because we avoid—

- Creating manufacturer-specific codes for substantially similar products;
- Requiring different manufacturers of substantially similar products from having to submit separate new technology add-on payment applications;
- Having to compare the merits of competing technologies on the basis of substantial clinical improvement; and
- Bestowing an advantage to the first applicant representing a particular new technology to receive approval (70 FR 47351).

CR Bard, Inc. received FDA approval for LUTONIX® on October 9, 2014. Commercial sales in the U.S. market began on October 10, 2014. Medtronic received FDA approval for IN.PACT™ Admiral™ on December 30, 2014. Commercial sales in the U.S. market began on January 29, 2015.

In accordance with our policy, we stated in the FY 2016 IPPS\LTCH PPS final rule (80 FR 49463) that we believe it is appropriate to use the earliest market availability date submitted as the beginning of the newness period. Accordingly, for both devices, we stated that the beginning of the newness period will be October 10, 2014.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for the LUTONIX® and IN.PACT™ Admiral™ technologies and consideration of the public comments we received in response to the FY 2016 IPPS/LTCH PPS proposed rule, we approved the LUTONIX® and IN.PACT™ Admiral™ technologies for new technology add-on payments for FY 2016 (80 FR 49469). Cases involving the LUTONIX® and IN.PACT™ Admiral™ technologies that are eligible for new technology add-on payments are identified using one of the ICD–10–PCS procedure codes in the following table:

ICD–10–PCS code	Code description
047K041	Dilation of right femoral artery with drug-eluting intraluminal device using drug-coated balloon, open approach.
047K0D1	Dilation of right femoral artery with intraluminal device using drug-coated balloon, open approach.
047K0Z1	Dilation of right femoral artery using drug-coated balloon, open approach.
047K341	Dilation of right femoral artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous approach.
047K3D1	Dilation of right femoral artery with intraluminal device using drug-coated balloon, percutaneous approach.
047K3Z1	Dilation of right femoral artery using drug-coated balloon, percutaneous approach.
047K441	Dilation of right femoral artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047K4D1	Dilation of right femoral artery with intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047K4Z1	Dilation of right femoral artery using drug-coated balloon, percutaneous endoscopic approach.
047L041	Dilation of left femoral artery with drug-eluting intraluminal device using drug-coated balloon, open approach.
047L0D1	Dilation of left femoral artery with intraluminal device using drug-coated balloon, open approach.
047L0Z1	Dilation of left femoral artery using drug-coated balloon, open approach.
047L341	Dilation of left femoral artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous approach.
047L3D1	Dilation of left femoral artery with intraluminal device using drug-coated balloon, percutaneous approach.
047L3Z1	Dilation of left femoral artery using drug-coated balloon, percutaneous approach.
047L441	Dilation of left femoral artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047L4D1	Dilation of left femoral artery with intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047L4Z1	Dilation of left femoral artery using drug-coated balloon, percutaneous endoscopic approach.
047M041	Dilation of right popliteal artery with drug-eluting intraluminal device using drug-coated balloon, open approach.
047M0D1	Dilation of right popliteal artery with intraluminal device using drug-coated balloon, open approach.
047M0Z1	Dilation of right popliteal artery using drug-coated balloon, open approach.
047M341	Dilation of right popliteal artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous approach.
047M3D1	Dilation of right popliteal artery with intraluminal device using drug-coated balloon, percutaneous approach.
047M3Z1	Dilation of right popliteal artery using drug-coated balloon, percutaneous approach.
047M441	Dilation of right popliteal artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047M4D1	Dilation of right popliteal artery with intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047M4Z1	Dilation of right popliteal artery using drug-coated balloon, percutaneous endoscopic approach.
047N041	Dilation of left popliteal artery with drug-eluting intraluminal device using drug-coated balloon, open approach.
047N0D1	Dilation of left popliteal artery with intraluminal device using drug-coated balloon, open approach.
047N0Z1	Dilation of left popliteal artery using drug-coated balloon, open approach.
047N341	Dilation of left popliteal artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous approach.
047N3D1	Dilation of left popliteal artery with intraluminal device using drug-coated balloon, percutaneous approach.
047N3Z1	Dilation of left popliteal artery using drug-coated balloon, percutaneous approach.
047N441	Dilation of left popliteal artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047N4D1	Dilation of left popliteal artery with intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047N4Z1	Dilation of left popliteal artery using drug-coated balloon, percutaneous endoscopic approach.

As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49469), each of the applicants submitted operating costs for its DCB. The manufacturer of the LUTONIX® stated that a mean of 1.37 drug-coated balloons was used during the LEVANT 2 clinical trial. The acquisition price for the hospital will be $1,900 per drug-coated balloon, or $2,603 per case (1.37 × $1,900). The applicant projected that approximately 8,875 cases will involve use of the LUTONIX® for FY 2016. The manufacturer for the IN.PACT™ Admiral™ stated that a mean of 1.4 drug-coated balloons was used during the IN.PACT™ Admiral™ DCB arm. The acquisition price for the hospital will be $1,350 per drug-coated balloon, or $1,890 per case (1.4 × $1,350). The applicant projected that approximately 26,000 cases will involve use of the IN.PACT™ Admiral™ for FY 2016.

For FY 2016, we based the new technology add-on payment for cases involving these technologies on the weighted average cost of the two DCBs described by the ICD–10–PCS procedure codes listed above (which are not manufacturer specific). Because ICD–10 codes are not manufacturer specific, we cannot set one new technology add-on payment amount for IN.PACT™ Admiral™ and a different new technology add-on payment amount for LUTONIX®; both technologies will be captured by using the same ICD–10–PCS procedure code. As such, we stated that we believe that the use of a weighted average of the cost of the standard DCBs based on the projected number of cases involving each technology to determine the maximum new technology add-on payment would be most appropriate. To compute the weighted cost average, we summed the total number of projected cases for each of the applicants, which equaled 34,875 cases (26,000 plus 8,875). We then divided the number of projected cases for each of the applicants by the total number of cases, which resulted in the following case-weighted percentages: 25 percent for the LUTONIX® and 75 percent for the IN.PACT™ Admiral™. We then multiplied the cost per case for the manufacturer specific DCB by the case-weighted percentage (0.25 * $2,603 = $662.41 for LUTONIX® and 0.75 * $1,890 = $1,409.03 for the IN.PACT™ Admiral™). This resulted in a case-weighted average cost of $2,071.45 for DCBs. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the device or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum payment for a case involving the LUTONIX® or IN.PACT™ Admiral™ DCBs is $1,035.72.

With regard to the newness criterion for the LUTONIX® and IN.PACT™ Admiral™ technologies, we considered the beginning of the newness period to commence when LUTONIX® gained entry onto the U.S. market on October 10, 2014. As discussed previously in this section, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. Because the 3-year anniversary date of the entry of LUTONIX® onto the U.S. market (October 10, 2017) will occur in the first half of FY 2018, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19875), we proposed to discontinue new technology add-on payments for both the LUTONIX® and IN.PACT™ Admiral™ technologies for FY 2018. We invited public comments on this proposal.

Comment: Some commenters supported CMS' proposal to discontinue new technology add-on payments for both the LUTONIX® and IN.PACT™ Admiral™ technologies for FY 2018.

Response: We appreciate the commenters' support. As we proposed, we are discontinuing new technology add-on payments for both the LUTONIX® and IN.PACT™ Admiral™ technologies for FY 2018. The 3-year anniversary date of the product's entry onto the U.S. market occurs in the first half of FY 2018. Therefore, the technology is not eligible for new technology add-on payments for FY 2018 because the technology will no longer meet the ''newness'' criterion.

f. MAGEC® Spinal Bracing and Distraction System (MAGEC® Spine)

Ellipse Technologies, Inc. submitted an application for new technology add-on payments for FY 2017 for the MAGEC® Spine. According to the applicant, the MAGEC® Spine has been developed for use in the treatment of children diagnosed with severe spinal deformities, such as scoliosis. The system can be used in the treatment of skeletally immature patients less than 10 years of age who have been diagnosed with severe progressive spinal deformities associated with or at risk of Thoracic Insufficiency Syndrome (TIS).

The MAGEC® Spine consists of a (spinal growth) rod that can be lengthened through the use of magnets that are controlled by an external remote controller (ERC). The rod(s) can be implanted into children as young as 2 years of age. According to the applicant, use of the MAGEC® Spine has proven to be successfully used in the treatment of patients diagnosed with scoliosis who have not been responsive to other treatments.

The MAGEC® Spine initially received FDA clearance for use of the predicate device, which used a Harrington Rod on February 27, 2014. The applicant verified that, due to manufacturing delays, the MAGEC® Spine was not available for implant until April 1, 2014. Specifically, the complete MAGEC® Spine system was produced and available for shipment for the first implant on April 1, 2014. Therefore, the newness period for the MAGEC® Spine began on April 1, 2014. Subsequent FDA clearance was granted for use of the modified device, which uses a shorter 70 mm rod on September 18, 2014. After minor modification of the product, the MAGEC® Spine received FDA clearances on March 24, 2015, and May 29, 2015, respectively.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for the MAGEC® Spine and consideration of the public comments we received in response to the FY 2017 IPPS/LTCH PPS proposed rule, we approved the MAGEC® Spine for new technology add-on payments for FY 2017 (81 FR 56891). Cases involving the MAGEC® Spine that are eligible for new technology add-on payments are identified by ICD–10–PCS procedure codes XNS0032 (Reposition of lumbar vertebra using magnetically controlled growth rod(s), open approach); XNS0432 (Reposition of lumbar vertebra using magnetically controlled growth rod(s), percutaneous endoscopic approach); XNS3032 (Reposition of cervical vertebra using magnetically controlled growth rod(s), open approach); XNS3432 (Reposition of cervical vertebra using magnetically controlled growth rod(s), percutaneous endoscopic approach); XNS4032 (Reposition of thoracic vertebra using magnetically controlled growth rod(s), open approach); and XNS4432 (Reposition of thoracic vertebra using magnetically controlled growth rod(s).

With the new technology add-on payment application, the applicant stated that the total operating cost of the MAGEC® Spine was $17,500 for a single rod and $35,000 for a dual rod. It is historical practice for CMS to make the new technology add-on payment based on the average cost of the technology and not the maximum. For example, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53358), we approved new technology add-on payments for

DIFICID™ based on the average dosage of 6.2 days, rather than the maximum 10-day dosage. The applicant noted that 20 percent of cases use a single rod, while 80 percent of cases use a dual rod. As a result, the weighted average cost for a single and dual MAGEC® Spine is $31,500 (((0.2 * $17,500) + (0.8 * $35,000))). Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the device or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the MAGEC® Spine is $15,750. We refer the reader to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56888) for complete details on the MAGEC® Spine.

With regard to the newness criterion for the MAGEC® Spine, we considered the beginning of the newness period to commence when the MAGEC® Spine was produced and available for shipment for the first implant on April 1, 2014. As discussed previously in this section, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. Because the 3-year anniversary date of the entry of the MAGEC® Spine onto the U.S. market (April 1, 2017) would occur prior to the beginning of FY 2018, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19876), we proposed to discontinue new technology add-on payments for this technology for FY 2018. We invited public comments on this proposal.

Comment: Some commenters supported CMS' proposal to discontinue new technology add-on payments for the MAGEC® Spine for FY 2018. Some commenters supported the continuation of the new technology add-on payments for MAGEC® Spine for FY 2018. The manufacturer also requested that CMS extend new technology add-on payments for MAGEC® Spine. The manufacturer provided the following reasons to extend the new technology add-on payment:

- Based on internal data, there have not been enough cases to provide the stimulus that the new technology add-on payments program intended.
- The patient population for which the new technology add-on payment applies is very small, estimated at less than or equal to 10 percent of the total annual cases.
- The new technology add-on payment has been available for approximately 9 months. Given the small number of patients, providers have not had enough cases yet to utilize the new technology add-on payments in the way the program intended.
- Extension of the new technology add-on payment for FY 2018 would allow more patients to gain access to MAGEC® rods. The manufacturer stated that this has clinical benefits as noted in the literature, but also ultimately helps payers, including CMS. The manufacturer stated that payer costs of treatment are reduced over the course of care when MAGEC® rods are used vs. traditional growth rods.
- Extending the new technology add-on payment for MAGEC® Spine has minimal budgetary impact due again to the small patient population.

The manufacturer cited the importance of the new technology add-on payments to MAGEC® Spine and stated that extending the new technology add-on payment would help make the technology more accessible.

Response: We thank the commenters for their comments. With regard to the technology's newness, the timeframe that a new technology can be eligible to receive new technology add-on payments ends when data documenting the use and cost of the procedures become available. Section 412.87(b)(2) states that, a medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD–9–CM code (or, as finalized earlier in this section, the inpatient hospital code) assigned to the new service or technology (depending on when a new code is assigned and data on the new service or technology become available for DRG recalibration). Section 412.87(b)(2) also states, after CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical service or technology, the medical service or technology will no longer be considered ''new'' under the applicable criteria. Therefore, as discussed in the FY 2005 IPPS final rule (69 FR 49003), if the costs of the technology are included in the charge data, and the MS–DRGs have been recalibrated using that data, the technology can no longer be considered ''new'' for the purposes of this provision.

In addition, similar to our discussion in the FY 2006 IPPS final rule (70 FR 47349), we do not believe that case volume is a relevant consideration for making the determination as to whether a product is ''new.'' Consistent with the statute and our implementing regulations, a technology no longer qualifies as ''new'' once it is more than 2 to 3 years old, irrespective of how frequently it has been used in the Medicare population. Therefore, if a product is more than 2 to 3 years old, we consider its costs to be included in the MS–DRG relative weights, whether its use in the Medicare population has been frequent or infrequent.

Therefore, based on all of the reasons stated above, the MAGEC® Spine is no longer considered ''new'' for purposes of new technology add-on payments for FY 2018. Therefore, we are finalizing our proposal to discontinue making new technology add-on payments for the MAGEC® Spine for FY 2018.

g. Vistogard™ (Uridine Triacetate)

BTG International Inc., submitted an application for new technology add-on payments for the Vistogard™ for FY 2017. Vistogard™ was developed as an emergency treatment for Fluorouracil toxicity.

Chemotherapeutic agent 5-fluorouracil (5–FU) is used to treat specific solid tumors. It acts upon deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) in the body, as uracil is a naturally occurring building block for genetic material. Fluorouracil is a fluorinated pyrimidine. As a chemotherapy agent, Fluorouracil is absorbed by cells and causes the cell to metabolize into byproducts that are toxic and used to destroy cancerous cells. According to the applicant, the byproducts fluorodoxyuridine monophosphate (F–dUMP) and floxuridine triphosphate (FUTP) are believed to do the following: (1) Reduce DNA synthesis; (2) lead to DNA fragmentation; and (3) disrupt RNA synthesis. Fluorouracil is used to treat a variety of solid tumors such as colorectal, head and neck, breast, and ovarian cancer. With different tumor treatments, different dosages, and different dosing schedules, there is a risk for toxicity in these patients. Patients may suffer from fluorouracil toxicity/death if 5–FU is delivered in slight excess or at faster infusion rates than prescribed. The cause of overdose can happen for a variety of reasons including: Pump malfunction, incorrect pump programming or miscalculated doses, and accidental or intentional ingestion.

Vistogard™ is an emergency treatment for Fluorouracil toxicity and is a prodrug of uridine. Once the drug is metabolized into uridine, it competes with the toxic byproduct FUTP in binding to RNA, thereby reducing the impact FUTP has on cell death.

The Vistogard™ received FDA approval on December 11, 2015. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56910), we stated that we agreed with the manufacturer that, due to the

delay in availability, the date the newness period begins for Vistogard™ is March 2, 2016, instead of December 11, 2015.

The applicant noted that the Vistogard™ is the first FDA-approved antidote used to reverse fluorouracil toxicity. The applicant received a unique ICD–10–PCS procedure code that became effective October 1, 2016, to describe the use of this technology. The approved procedure code is XW0DX82 (Introduction of Uridine Triacetate into Mouth and Pharynx, External Approach, New Technology Group 2).

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for Vistogard™ and consideration of the public comments we received in response to the FY 2017 IPPS/LTCH PPS proposed rule, we approved Vistogard™ for new technology add-on payments for FY 2017 (81 FR 56912). With the new technology add-on payment application, the applicant stated that the total operating cost of Vistogard™ is $75,000. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving Vistogard™ is $37,500.

As noted previously, with regard to the newness criterion for the Vistogard™, we considered the beginning of the newness period to commence on March 2, 2016. Because the 3-year anniversary date of the entry of the Vistogard™ onto the U.S. market (March 2, 2019) will occur after FY 2018, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19876), we proposed to continue new technology add-on payments for this technology for FY 2018. We proposed that the maximum payment for a case involving the Vistogard™ would remain at $37,500 for FY 2018. We invited public comments on our proposal to continue new technology add-on payments for the Vistogard™.

Comment: The manufacturer commented that, as of April 1, 2017, pricing for Vistogard™ has changed. The manufacturer noted that the wholesale acquisition cost (WAC) for Vistogard™ is now $80,260 for a 20-dose pack (or $4,013.00 per each 10g packet of oral granules). Given the current price for Vistogard™, the manufacturer requested that CMS revise the maximum payment per case to $40,130, or 50 percent of the revised WAC.

Response: According to the manufacturer, as noted in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56912), the WAC of Vistogard™ was $3,750.00 per each 10g packet of oral granules. The recommended adult dosing per the Vistogard™ label is 10g (one packet every 6 hours for a minimum of 20 doses over 5 days). The total cost was 20 packets × WAC of $3,750.00 per packet, which equaled $75,000 per patient.

Using the updated WAC provided by the manufacturer, we performed an additional cost analysis to determine if Vistogard would meet the cost criterion. We determined that the price increase would increase the amount that the inflated average standardized case-weighted charge per case exceeds the average case-weighted threshold amount. Therefore, Vistogard™ would still meet the cost criterion.

We are finalizing our proposal to continue new technology add-on payments for Vistogard™ for FY 2018. Using the revised pricing, the maximum new technology add-on payment for a case involving Vistogard™ is $40,130 for FY 2018.

h. Blinatumomab (BLINCYTO®)

Amgen, Inc. submitted an application for new technology add-on payments for FY 2016 for Blinatumomab (BLINCYTO®), a bi-specific T-cell engager (BiTE) used for the treatment of Philadelphia chromosome-negative (Ph−) relapsed or refractory (R/R) B-cell precursor acute-lymphoblastic leukemia (ALL), which is a rare aggressive cancer of the blood and bone marrow. Approximately 6,050 individuals are diagnosed with Ph− R/R B-cell precursor ALL in the United States each year, and approximately 2,400 individuals, representing 30 percent of all new cases, are adults. Ph− R/R B-cell precursor ALL occurs when there are malignant transformations of B-cell or T-cell progenitor cells, causing an accumulation of lymphoblasts in the blood, bone marrow, and occasionally throughout the body. As a bi-specific T-cell engager, the BLINCYTO® technology attaches to a molecule on the surface of the tumorous cell, as well as to a molecule on the surface of normal T-cells, bringing the two into closer proximity and allowing the normal T-cell to destroy the tumorous cell. Specifically, the BLINCYTO® technology attaches to a cell identified as CD19, which is present on all of the cells of the malignant transformations that cause Ph− R/R B-cell precursor ALL and helps attract the cell into close proximity of the T-cell CD3 with the intent of getting close enough to allow the T-cell to inject toxins that destroy the cancerous cell. According to the applicant, the BLINCYTO® technology is the first, and the only, bi-specific CD19-directed CD3 T-cell engager single-agent immunotherapy approved by the FDA.

BLINCYTO® is administered as a continuous IV infusion delivered at a constant flow rate using an infusion pump. A single cycle of treatment consists of 28 days of continuous infusion, and each treatment cycle is followed by 2 weeks without treatment prior to administering any further treatments. A course of treatment would consist of two phases. Phase 1 consists of initial inductions or treatments intended to achieve remission followed by additional inductions and treatments to maintain consolidation; or treatments given after remission has been achieved to prolong the duration. During Phase 1 of a single treatment course, up to two cycles of BLINCYTO® are administered, and up to three additional cycles are administered during consolidation. The recommended dosage of BLINCYTO® administered during the first cycle of treatment is 9 mcg per day for the first 7 days of treatment. The dosage is then increased to 28 mcg per day for 3 weeks until completion. During Phase 2 of the treatment course, all subsequent doses are administered as 28 mcg per day throughout the entire duration of the 28-day treatment period.

With regard to the newness criterion, the BLINCYTO® technology received FDA approval on December 3, 2014, for the treatment of patients diagnosed with Ph− R/R B-cell precursor ALL, and the product gained entry onto the U.S. market on December 17, 2014.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for BLINCYTO® and consideration of the public comments we received in response to the FY 2016 IPPS/LTCH PPS proposed rule, we approved BLINCYTO® for new technology add-on payments for FY 2016 (80 FR 49449). Cases involving BLINCYTO® that are eligible for new technology add-on payments are identified using one of the following ICD–10–PCS procedure codes: XW03351 (Introduction of Blinatumomab antineoplastic immunotherapy into peripheral vein, percutaneous approach, New Technology Group 1), or XW04351 (Introduction of Blinatumomab antineoplastic immunotherapy into central vein, percutaneous approach, New Technology Group 1).

As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49449), the

applicant recommended that CMS consider and use the cost of the full 28-day inpatient treatment cycle as the expected length of treatment when determining the maximum new technology add-on payment for cases involving the BLINCYTO®, rather than the average cost of lesser number of days used as other variables. For the reasons discussed, we disagreed with the applicant and established the maximum new technology add-on payment amount for a case involving the BLINCYTO® technology for FY 2016 using the weighted average of the cycle 1 and cycle 2 observed treatment length. Specifically, in the Phase II trial, the most recent data available, 92 patients received cycle 1 treatment for an average length of 21.2 days, and 52 patients received cycle 2 treatment for an average length of 10.2 days. The weighted average of cycle 1 and cycle 2 treatment length is 17 days. We noted that a small number of patients also received 3 to 5 treatment cycles. However, based on the data provided, these cases do not appear to be typical at this point and we excluded them from this calculation. We noted that, if we included all treatment cycles in this calculation, the weighted average number of days of treatment is much lower, 10 days. Using the clinical data provided by the applicant, we stated that we believe setting the maximum new technology add-on payment amount for a case involving the BLINCYTO® technology for FY 2016 based on a 17-day length of treatment cycle is representative of historical and current practice. We also stated that, for FY 2017, if new data on length of treatment are available, we would consider any such data in evaluating the maximum new technology add-on payment amount. However, we did not receive any new data from the applicant to evaluate for FY 2017.

In the application, the applicant estimated that the average Medicare beneficiary would require a dosage of 9mcg/day for the first 7 days under the first treatment cycle, followed by a dosage of 28mcg/day for the duration of the treatment cycle, as well as all days included in subsequent cycles. All vials contain 35mcg at a cost of $3,178.57 per vial. The applicant noted that all vials are single-use. Therefore, we determined that cases involving the use of the BLINCYTO® technology would incur an average cost per case of $54,035.69 (1 vial/day × 17 days × $3,178.57/vial). Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment amount for a case involving the use of the BLINCYTO® is $27,017.85.

With regard to the newness criterion for BLINCYTO®, we consider the beginning of the newness period to commence when the product gained entry onto the U.S. market on December 17, 2014. As discussed previously in this section, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. Because the 3-year anniversary date of the entry of the BLINCYTO® onto the U.S. market will occur in the first half of FY 2018 (December 17, 2017), in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19877), we proposed to discontinue new technology add-on payments for this technology for FY 2018. We invited public comments on this proposal.

Comment: Some commenters supported CMS' proposal to discontinue new technology add-on payments for BLINCYTO®. The applicant (the manufacturer) disagreed with the proposal to discontinue new technology add-on payments for BLINCYTO®. The manufacturer stated that CMS is discontinuing the new technology add-on payment in advance of the 3-year statutory limit. The manufacturer requested that CMS reconsider and extend the new technology add-on payments for FY 2018.

The manufacturer explained that the continuation of new technology add-on payments for BLINCYTO® in FY 2018 is well within CMS' statutory authority and would permit CMS to bolster its claims data for rate-setting to ensure that it can meaningfully recalibrate the MS–DRG weights to reflect the costs of BLINCYTO® in accordance with the policy objectives of the statute. The manufacturer stated that section 1886(d)(5)(K) of the Act gives CMS authority to grant new technology add-on payments to new technologies to ''provide for the collection of data with respect to the costs of a new medical service or technology [. . .] for a period of not less than 2 years and not more than 3 years beginning on the date on which an inpatient hospital code is issued with respect to the service or technology.'' The manufacturer also stated that the regulation at 42 CFR 412.87(b)(2) is phrased similarly and reads that ''A medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD–9–CM code assigned to the new service or technology (depending on when a new code is assigned and data on the new service or technology become available for DRG recalibration). After CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical service or technology, the medical service or technology will no longer be considered 'new' under the criterion of this section.''

The manufacturer stated that BLINCYTO® received FDA approval on December 3, 2014, gained entry onto the U.S. market on December 17, 2014, and was issued an inpatient hospital code (ICD–10–PCS code) on October 1, 2015. Therefore, the manufacturer asserted that, as of October 1, 2017, BLINCYTO® will have received the new technology add-on payment for the minimum permitted duration of 2 years, and is eligible, by statute and regulation, for an additional year new technology add-on payments.

The manufacturer also stated that CMS explained in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56877) that ''a specific medical service or technology will be considered 'new' for purposes of new technology add-on payments until such time as Medicare data are available to *fully reflect the cost of the technology* in the MS–DRG weights through recalibration'' and that only once the MS–DRGs have been recalibrated to reflect the costs of a new medical technology should new technology add-on payments cease. The manufacturer believed that the above quoted regulation likewise links the termination of new technology add-on payments to having data to incorporate the item into the calibration of the inpatient payment groupings. The manufacturer also cited the FY 2011 IPPS final rule (75 FR 50138) and stated that CMS has acknowledged in previous rulemaking that, in some cases, there may be valid reasons to extend new technology add-on payment status, including, for example, when ''there may be few to no Medicare data available for the new service or technology following FDA approval'' to achieve the objective of appropriately recalibrating MS–DRG weights. The manufacturer believed that if insufficient data are collected on the technology to ''fully reflect the cost of the technology'' in the MS–DRG weights, there would be a valid reason to continue the new technology add-on payment.

The manufacturer stated that claims of BLINCYTO® in the FY 2016

MedPAR, which is used for FY 2018 MS–DRG recalibration, are insufficient in number and do not fully reflect the cost of BLINCYTO® in the MS–DRG recalibration. The applicant stated that, in the FY 2016 MedPAR claims, there were a total of 145 BLINCYTO® claims eligible for the new technology add-on payment, 111 of which were distributed across 6 MS–DRGs that the technology most frequently mapped to. The manufacturer noted that this claims volume represents less than 1 percent of the over 10,000 patient discharge claims for these 6 MS–DRGs. As a result of this low claims volume, both objectively and relative to the frequency of the relevant MS–DRGs on patient discharge claims, the manufacturer believed it is very unlikely that the fundamental objective of the new technology add-on payment to provide time to collect sufficient data to recalibrate MS–DRG weights to ''*fully reflect the cost of the technology*'' can be achieved by discontinuing the new technology add-on payment status for BLINCYTO®.

The manufacturer stated that it recognizes that CMS has a general practice (not set forth in its regulations) for technologies that have had new technology add-on payments for 2 fiscal years to only provide an additional year of new technology add-on payment if the 3-year anniversary of the product's FDA approval is during the second half of the fiscal year unless CMS receives evidence of a documented delay in making the product available on the market. The manufacturer believed that this general practice should not be followed here because of the paucity of data on BLINCYTO®. The manufacturer noted that CMS does not apply the general practice when there is a delay in market availability, ostensibly because that delay has an impact on the availability of data for use in inpatient hospital payment rate setting. The manufacturer asserted that when there is a paucity of data from the first of the 2 years of the new technology add-on payment, CMS should continue making new technology add-on payments for a third year to ensure that when it incorporates the item into the inpatient payment system, it has enough data to do so.

Further, the manufacturer noted that BLINCYTO® demonstrated significant improvements in overall survival, complete remission, and event-free survival in comparison to standard of care chemotherapy in adult patients with Ph − R/R B-cell precursor ALL. The manufacturer stated that extending new technology add-on payments for BLINCYTO® would continue to support access to this novel therapy.

Response: We thank the commenters for their comments. With regard to the technology's newness, as discussed in the FY 2005 IPPS final rule (69 FR 49003), the timeframe that a new technology can be eligible to receive new technology add-on payments begins when data become available. As the manufacturer noted in its comments, § 412.87(b)(2) clearly states that a medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD–9–CM code (or, as finalized earlier in this section, the inpatient hospital code) assigned to the new service or technology (depending on when a new code is assigned and data on the new service or technology become available for DRG recalibration). Section 412.87(b)(2) also specifies that after CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical service or technology, the medical service or technology will no longer be considered ''new'' under the criterion of the section. The period of newness does not necessarily start with the approval date for the medical service or technology, and does not necessarily start with the issuance of a distinct code. Instead, it begins with availability of the product on the U.S. market, which is when data become available. As the manufacturer noted, we considered the newness period for BLINCYTO® to commence when the product gained entry onto the U.S. market on December 17, 2014. We have consistently applied this standard, and believe that it is most consistent with the purpose of new technology add-on payments.

While CMS may consider a documented delay in a technology's availability on the U.S. market in determining when the newness period begins, its policy for determining whether to extend new technology add-on payments for a third year generally applies regardless of the claims volume for the technology after the start of the newness period. Similar to our discussion earlier and in the FY 2006 IPPS final rule (70 FR 47349), we do not believe that case volume is a relevant consideration for making the determination as to whether a product is ''new.'' Consistent with the statute, a technology no longer qualifies as ''new'' once it is more than 2 to 3 years old, irrespective of how frequently it has been used in the Medicare population. Similarly, this same determination is applicable no matter how many MS–DRGs the technology is spread across. Therefore, if a product is more than 2 to 3 years old, we consider its costs to be included in the MS–DRG relative weights whether its use in the Medicare population has been frequent or infrequent.

Based on the reasons stated above, BLINCYTO® is no longer considered ''new'' for purposes of new technology add-on payments for FY 2018. We are finalizing our proposal to discontinue making new technology add-on payments for BLINCYTO® for FY 2018.

6. FY 2018 Applications for New Technology Add-On Payments

We received nine applications for new technology add-on payments for FY 2018. Three applicants withdrew their applications prior to the issuance of the FY 2018 IPPS/LTCH PPS proposed rule. Two applicants, Kite Pharma and IsoRay Medical, Inc., in conjunction with GammaTile LLC, withdrew their applications for KTE–C19 (axicabtagene ciloleucel) and GammaTile™, respectively, prior to the issuance of this FY 2018 IPPS/LTCH PPS final rule.

In addition, in accordance with the regulations under § 412.87(c), applicants for new technology add-on payments must have FDA approval or clearance by July 1 of each year prior to the beginning of the fiscal year that the application is being considered. One applicant, Celator Pharmaceuticals, Inc. for VYXEOS™, did not receive FDA approval for its technology by July 1, 2017. Therefore, VYXEOS™ is not eligible for consideration for new technology add-on payments for FY 2018. We are not including in this final rule the descriptions and discussions of this application which was included in the FY 2018 IPPS/LTCH PPS proposed rule. We note that we did receive public comments on this application. However, because VYXEOS™ is ineligible for new technology add-on payments for FY 2018 because it did not receive FDA approval by July 1, 2017, we are not summarizing nor responding to public comments regarding the new technology criteria for this application in this final rule. We note that the applicant did request that we make an exception to the July 1 deadline if it were to receive FDA approval prior to the beginning of FY 2018. However, we did not propose any changes to the regulations at § 412.87(c), and we believe the request is out of scope for this final rule.

A discussion of the three remaining applications is presented below.

a. Bezlotoxumab (ZINPLAVA™)

Merck & Co., Inc. submitted an application for new technology add-on payments for ZINPLAVA™ for FY 2018. ZINPLAVA™ is indicated to reduce

recurrence of *Clostridium difficile* infection (CDI) in adult patients who are receiving antibacterial drug treatment for a diagnosis of CDI who are at high risk for CDI recurrence. ZINPLAVA™ is not indicated for the treatment of the presenting episode of CDI and is not an antibacterial drug.

Clostridium difficile (*C-diff*) is a disease-causing anaerobic, spore forming bacteria that can affect the gastrointestinal (GI) tract. Some people carry the *C-diff* bacterium in their intestines, but never develop symptoms of an infection. The difference between asymptomatic colonization and pathogenicity is caused primarily by the production of an enterotoxin (Toxin A) and/or a cytotoxin (Toxin B). The presence of either or both toxins can lead to symptomatic CDI, which is defined as the acute onset of diarrhea with a documented infection with toxigenic *C-diff,* or the presence of either toxin A or B. The GI tract contains millions of bacteria, commonly referred to as ''normal flora'' or ''good bacteria,'' which play a role in protecting the body from infection. Antibiotics can kill these good bacteria and allow the *C-diff* bacteria to multiply and release toxins that damage the cells lining the intestinal wall, resulting in a CDI. CDI is a leading cause of hospital-associated gastrointestinal illnesses. Persons at increased risk for CDI include people who are treated with current or recent antibiotic use, people who have encountered current or recent hospitalization, people who are older than 65 years, immunocompromised patients, and people who have recently had a diagnosis of CDI. CDI symptoms include, but are not limited to, diarrhea, abdominal pain, and fever. CDI symptoms range in severity from mild (abdominal discomfort, loose stools) to severe (profuse, watery diarrhea, severe pain, and high fevers). Severe CDI can be life-threatening and, in rare cases, can cause bowel rupture, sepsis and organ failure. CDI is responsible for 14,000 deaths per year in the United States.

C-diff produces two virulent, pro-inflammatory toxins, Toxin A and Toxin B, which target host colonocytes (that is, large intestine endothelial cells) by binding to endothelial cell surface receptors via combined repetitive oligopeptide (CROP) domains. These toxins cause the release of inflammatory cytokines leading to intestinal fluid secretion and intestinal inflammation. The applicant asserted that ZINPLAVA™ targets Toxin B sites within the CROP domain rather than the *C-diff* organism itself. According to the applicant, by targeting *C-diff* Toxin B, ZINPLAVA™ neutralizes Toxin B, prevents large intestine endothelial cell inflammation, symptoms associated with CDI, and reduces the recurrence of CDI. ZINPLAVA™ binds to sites within the CROP domain, which prevents Toxin B from binding to the host cell, thereby preventing the inflammation and symptoms associated with CDI. ZINPLAVA™ is used concomitantly with standard of care (SOC) antibiotics. Typical treatment of CDI includes antibiotic therapy using vancomycin, metronidazole, fidaxomicin, or other antibiotics. Alternative therapies include fecal microbiota transplant (FMT) and the use of probiotics.

The primary goal of CDI treatment is resolving the infection. Antibacterial drug treatment remains the cornerstone of treatment of CDI. However, this treatment option alone may not be adequate for patients diagnosed with recurrent CDI. A major concern with respect to a CDI is that even when treatment with an antibacterial drug of a primary infection is successful, generally, 25 percent to 30 percent of patients experience a recurrence of the infection within days or weeks of the presenting episode's symptom resolution. The risk of recurrence increases to 65 percent with subsequent CDI episodes. Disease recurrence results from continued disruption of the intestinal microbiota by SOC CDI antibiotics (or use of other antibiotics used to treat non-gastrointestinal conditions), combined with persistence of resistant *C-diff* spores (relapse) or acquisition of new spores from the environment (reinfection).

Antibacterial drug use may inhibit the intestinal microbiota from reestablishing itself, allowing *C-diff* spores potentially to germinate and colonize the intestines when the antibacterial drug is discontinued. If regrowth of *C-diff* overtakes the reestablishment of the intestinal microbiota, then spore germination and toxin production from vegetative *C-diff* may restart the cycle of CDI and the need for subsequent treatment. These challenges highlight the need for nonantibiotic therapies. ZINPLAVA™ targets Toxin B rather than the *C-diff* bacteria itself. According to the applicant, unlike antibacterial drugs, ZINPLAVA™ is a human monoclonal antibody and does not affect the microbiota. According to the applicant, ZINPLAVA™ neutralizes *C-diff* Toxin B and reduces recurrence of CDI. ZINPLAVA™ is given concomitantly during the course of SOC antibacterial treatment of a CDI.

With respect to the newness criterion, ZINPLAVA™ received FDA approval on October 21, 2016, for reduction of recurrence of CDI in patients receiving antibacterial drug treatment for CDI and who are at high risk of CDI recurrence. ZINPLAVA™ became commercially available on February 10, 2017. Therefore, the newness period for ZINPLAVA™ began on February 10, 2017.

The applicant submitted a request for a unique ICD–10–PCS procedure code and was granted approval for the following procedure codes: XW033A3 (Introduction of bezlotoxumab monoclonal antibody, into peripheral vein, percutaneous approach, New Technology Group 3) and XW043A3 (Introduction of bezlotoxumab monoclonal antibody, into central vein, percutaneous approach, New Technology Group 3).

As discussed above, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, according to the applicant, ZINPLAVA™ is a human monoclonal antibody with an innovative mechanism of action. The applicant asserted that ZINPLAVA™ is a novel treatment, with a unique mechanism of action relative to SOC CDI antibiotics that target *C-diff.* The applicant explained that ZINPLAVA™ is the first human monoclonal antibody that targets and neutralizes *C. diff* Toxin B because the technology specifically binds to and neutralizes *C-diff* Toxin B (which is an exotoxin that contributes to intestinal tissue damage and immune system effects that underlie the symptoms of CDI) and inhibits binding of the toxin to mammalian cells. The applicant further asserted that the administration of ZINPLAVA™, in addition to standard of care antibacterial drug treatment, reduces CDI recurrence by providing passive immunity against Toxin B resulting from persistent or newly acquired *C-diff* spores. According to the applicant, ZINPLAVA™ is the only FDA-approved treatment indicated for reducing CDI recurrence as adjunctive therapy in adult patients who are receiving antibacterial drug treatment for CDI and who are at high risk for CDI recurrence.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant maintained that patients who may be eligible to receive treatment using ZINPLAVA™ could be in an acute-care hospital setting for a wide

variety of reasons and may develop a secondary CDI as a hospital-acquired infection and, therefore, cases representing patients that may be eligible for treatment using the technology can map to a wide range of MS–DRGs. ZINPLAVA™ is indicated for patients receiving SOC treatment for CDI and who are at a high risk for CDI recurrence. In order to identify the range of MS–DRGs for which cases representing patients that may be eligible for treatment using ZINPLAVA™ may map to, the applicant identified all MS–DRGs containing cases that represent patients presenting with CDI as a primary or secondary diagnosis. The applicant used FY 2015 MedPAR data to map the identified cases to 543 MS–DRGs, with 12 MS–DRGs accounting for approximately 40 percent of all cases. The applicant segmented these cases based on age because patients 65 years and older are at higher risk for CDI recurrence. Based on the FY 2015 MedPAR data, MS–DRG distribution was found to be similar, irrespective of CDI status (primary or secondary), for patients over 65 years of age and those under 65 years of age. The top 7 MS–DRGs across both age groups account for nearly 54 percent (over 65 years of age) and 49 percent (under 65 years of age). The applicant further segmented these cases to determine if status of CDI as a primary or secondary diagnosis influenced MS–DRG mapping. Regardless of age, when CDI is the primary diagnosis, approximately 98 percent of patient cases map to the same 3 MS–DRGs: MS–DRG 371 (Major Gastrointestinal Disorders and Peritoneal Infections with MCC); MS–DRG 372 (Major Gastrointestinal Disorders and Peritoneal Infections with CC); and MS–DRG 373 (Major Gastrointestinal Disorders and Peritoneal Infections without CC/MCC), respectively. Potential cases representing patients who may be eligible for treatment with ZINPLAVA™ would be assigned to the same MS–DRGs as cases representing patients who receive SOC treatment for a diagnosis of CDI.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, according to the applicant, ZINPLAVA™ is administered concomitantly or as adjunctive therapy with SOC antibacterial treatment for recurrent CDI. The applicant stated that ZINPLAVA™ is indicated to reduce recurrence of CDI in adult patients at high risk of CDI recurrence who are receiving antibacterial drug treatment for CDI. According to the applicant, the addition of ZINPLAVA™ to SOC antibacterial drug treatment reduces CDI recurrence by providing passive immunity against Toxin B resulting from persistent or newly acquired *C-diff* spores. ZINPLAVA™ is used to reduce recurrence of the same or similar type of disease (CDI) and to treat a similar patient population receiving SOC therapy for the treatment of recurrent CDI.

We stated in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19879) that, based on the applicant's statements presented above, because ZINPLAVA™ has a unique mechanism of action, we did not believe that the technology is substantially similar to existing technologies and, therefore, meets the newness criterion. We invited public comments on whether ZINPLAVA™ meets the newness criterion.

Comment: The applicant submitted comments in agreement with CMS' belief that ZINPLAVA™ meets the newness criterion for new technology add-on payments. The applicant reiterated that ZINPLAVA™ is the only FDA approved treatment indicated for reducing CDI recurrence as adjunctive therapy in adult patients who are receiving antibacterial drug treatment for CDI and who are at risk for CDI recurrence. The applicant agreed that ZINPLAVA™ is not substantially similar to existing technologies and, therefore, meets the newness criterion.

Response: We appreciate the comments submitted by the applicant on whether ZINPLAVA™ meets the newness criterion. After review of the information provided by the applicant and consideration of its comments, we believe that ZINPLAVA™ meets the newness criterion and we consider the technology to be ''new'' as of February 10, 2017, when the technology became commercially available.

With regard to the cost criterion, the applicant conducted the following analysis to demonstrate that the technology meets the cost criterion. In order to identify the range of MS–DRGs that cases representing potential patients who may be eligible for treatment using ZINPLAVA™ may map to, the applicant identified all MS–DRGs for patients diagnosed with CDI as a primary or secondary diagnosis. Specifically, the applicant searched the FY 2015 MedPAR file for claims that included target patients over 65 years of age and identified cases reporting diagnoses of CDI by ICD–9–CM diagnosis code 008.45 (Intestinal infection due to Clostridium difficile) as a primary or secondary diagnosis. This resulted in 139,135 cases across 543 MS–DRGs, with approximately 40 percent of all cases mapping to the following 12 MS–DRGs: MS–DRG 177 (Respiratory Infections and Inflammations with MCC); MS–DRG 193 (Simple Pneumonia and Pleurisy with MCC); MS–DRG 291(Heart Failure and Shock with MCC); MS–DRGs 371, 372, and 373 (Major Gastrointestinal Disorders and Peritoneal Infections with MCC, with CC, and without CC/MCC, respectively); MS–DRGs 682 and 683 (Renal Failure with MCC and with CC, respectively); MS–DRG 853 (Infectious and Parasitic Diseases with O.R. Procedure with MCC); MS–DRGs 870, 871, and 872 (Septicemia or Severe Sepsis with Mechanical Ventilation >96 Hours, with MCC, and without MCC, respectively).

Using the 139,135 identified cases, the average unstandardized case-weighted charge per case was $80,677. The applicant then standardized the charges. The applicant did not remove charges for the current treatment because, as discussed above, ZINPLAVA™ will be used concomitantly with SOC antibacterial treatments for the treatment of CDI as an additive, or adjunctive treatment option, to reduce the recurrence of CDI infection. The applicant then applied the 2-year inflation factor of 1.098446 from the FY 2017 IPPS/LTCH PPS final rule (81 FR 57286) to inflate the charges from FY 2015 to FY 2017. The applicant noted that the anticipated price for ZINPLAVA™ has yet to be determined; therefore, no charges for ZINPLAVA™ were added in the analysis. Based on the FY 2017 IPPS/LTCH PPS Table 10 thresholds, the average case-weighted threshold amount was $56,871. The inflated average case-weighted standardized charge per case was $78,929. Because the inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion. The applicant noted that the inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount without the average per patient cost of the technology. As such, the applicant anticipated that the inclusion of the cost of ZINPLAVA™, at any price point, will further increase charges above the average case-weighted threshold amount. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19879), we invited public comments on whether ZINPLAVA™ meets the cost criterion.

Comment: The applicant submitted comments reiterating its cost analysis

results. Specifically, the applicant stated that as indicated in the FY 2015 MedPAR data analysis summarized above, the average case-weighted standardized charge per case exceeded the average case-weighted threshold amount. As noted in the proposed rule, at the time the applicant submitted its application, the applicant indicated that the price of ZINPLAVA™ had not yet been determined. However, because the inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount without the average per-patient cost of the technology, the applicant contended that the inclusion of the cost of ZINPLAVA , at any price point, would further increase charges above the average case-weighted threshold amount.

The applicant noted, in supplemental information submitted to CMS, the wholesale acquisition cost (WAC) of ZINPLAVA™ (which is supplied as a 1000 mg/40 mL (25 mg/mL) solution in a single-dose vial) is $3,800 per vial. The recommended dosage of ZINPLAVA™ is a single 10 mg/kg dose administered as an IV infusion based on patient body weight. Because each vial contains 1,000 mg of ZINPLAVA™, a single vial provides the complete recommended dose for a single patient who weighs 100 kg or less.

As noted in the applicant's supplemental submission, to estimate the anticipated average charge submitted by hospitals for ZINPLAVA™, the applicant assumed that hospitals will mark up the cost for ZINPLAVA™ by 200 percent. A 200 percent mark-up of the $3,800 WAC results in a total charge of $7,600 for ZINPLAVA™. The applicant added the anticipated charge for ZINPLAVA™ of $7,600 to the previously determined inflated average case-weighted standardized charge per case of $78,929. This resulted in a revised inflated average case-weighted standardized charge per case of $86,529, which still exceeds the average case-weighted threshold amount of $56,871.

Response: After consideration of the comments we received, we agree that ZINPLAVA™ meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that the addition of ZINPLAVA™ to SOC antibacterial drug treatment reduces CDI recurrence because it provides passive immunity against Toxin B resulting from persistent or newly acquired *C-diff* spores.

The applicant conducted two Phase III studies, MODIFY I and MODIFY II. The primary endpoint of the studies was recurrent CDI within 12 weeks after completion of treatment with ZINPLAVA™. The first study design initially included actoxumab, an antitoxin A monoclonal antibody treatment arm that was later discontinued due to a high failure rate and increase in mortality compared to other treatment arms.[3] Clinical data on ZINPLAVA™ is provided exclusively from the FDA briefing document available on the FDA Web site at: *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Anti-InfectiveDrugsAdvisoryCommittee*. Information is also provided in the package insert by the manufacturer, Merck & Company, Inc. The FDA briefing provided data on the safety and efficacy of ZINPLAVA™. The FDA considered sustained clinical responses defined as clinical cure of the initial CDI episode and the absence of CDI recurrence as an appropriate endpoint to assess the efficacy of ZINPLAVA™ in the prevention of CDI recurrences.

In MODIFY I trial, the clinical cure rate of the presenting CDI episode was lower in the ZINPLAVA™ arm as compared to the placebo arm, whereas in MODIFY II trial the clinical cure rate was lower in the placebo arm as compared to the ZINPLAVA™ arm. Additional analyses showed that, by 3 weeks post study drug infusion, the clinical cure rates of the presenting CDI episode were similar between treatment arms.

In MODIFY I, the rate of sustained clinical response was numerically in favor of ZINPLAVA™ (60.1 percent) in comparison to placebo (55.2 percent) with an adjusted difference and 95 percent CI of 4.8 percent (−2.1 percent; 11.7 percent). In MODIFY II, the proportion of subjects with sustained clinical response in the ZINPLAVA™ arm (66.8 percent) was also higher than in the placebo arm (52.1 percent) with an adjusted difference of 14.6 percent and 95 percent CI (7.8 percent; 21.4 percent). The treatment did not significantly decrease mortality. Recurrence rates, including CDI-related hospital readmission rates, reportedly were between 10 and 25 percent. No clinically meaningful differences in the exposure of bezlotoxumab were found between patients 65 years of age and older and patients under 65 years of age.

In the Phase III trials, the safety profile of ZINPLAVA™ was similar overall to that of placebo. However, heart failure was reported more commonly in the two Phase III clinical trials of ZINPLAVA™-treated patients compared to placebo-treated patients. These adverse reactions occurred primarily in patients with underlying congestive heart failure (CHF). In patients with a history of CHF, 12.7 percent (15/118) of ZINPLAVA™-treated patients and 4.8 percent (5/104) of placebo-treated patients had the serious adverse reaction of heart failure during the 12-week study period. In addition, in patients with a history of CHF, there were more deaths in ZINPLAVA™-treated patients (19.5 percent (23/118)) than in placebo-treated patients (12.5 percent (13/104)) during the 12-week study period. We stated in the proposed rule that we were concerned regarding the safety of ZINPLAVA™ in patients diagnosed with CHF. In regards to safety, data from the MODIFY I and MODIFY II studies suggest few adverse events associated with ZINPLAVA™, with no significant differences in the number of serious adverse events, deaths or discontinuations of study drug that occurred between the ZINPLAVA™ and the placebo groups. However, both the ZINPLAVA™ and the ZINPLAVA™ plus actoxumab treatment groups experienced more episodes of cardiac failure (defined as acute or chronic cardiac failure) then compared to the placebo group (2.2 percent versus 1 percent). We stated in the proposed rule that we were unsure if the cardiac failure reported in the studies may be the result of a higher number of baseline patients with heart failure in the treatment arms or the result of an adverse effect to ZINPLAVA™. Therefore, we stated that we were concerned with regard to the adverse event of cardiac failure of ZINPLAVA™.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19880), we invited public comments on whether ZINPLAVA™ meets the substantial clinical improvement criterion. We noted that we did not receive any written public comments in response to the New Technology Town Hall meeting notice regarding the application of ZINPLAVA™ for new technology add-on payments.

Comment: The applicant submitted comments regarding the substantial clinical improvement criterion. The applicant reiterated that the addition of ZINPLAVA™ to standard of care antibacterial drug treatment reduces the risk of CDI recurrence in adult patients who are at high risk for CDI recurrence because it provides passive immunity against Toxin B resulting from persistent or newly acquired *C. difficile* spores. The applicant noted CMS'

[3] Wilcox MH et al. Bezlotoxumab for Prevention of Recurrent Clostridium difficile Infection. N Engl J Med. 2017 Jan 26;376(4):305–317.

concern, as described in the proposed rule, regarding the reported adverse event of cardiac failure with ZINPLAVA™. The applicant provided additional information concerning serious adverse events (SAEs) observed in the Phase III trials, and also included a series of analyses performed in the 41 subjects with an SAE of cardiac failure, as well as a discussion of analyses performed in a subset of patients with a baseline history of CHF.

The applicant noted that SAEs were collected for the full 12-week follow-up period in the both Phase III trials (P001 + P002). Amongst the 2344 Phase III trial subjects, 29.8 percent of subjects experienced an SAE during the 12-week follow-up period. According to the applicant, the proportion of subjects with a SAE was lower in the active treatment groups compared with placebo (bezlotoxumab, 29.4 percent; actoxumab + bezlotoxumab, 27.3 percent; and placebo, 32.7 percent). The most frequently reported SAEs across all treatment groups were CDI (4.7 percent), pneumonia (2.0 percent), sepsis (1.8 percent), cardiac failure (1.7 percent), diarrhea (1.6 percent), and urinary tract infection (1.5 percent). A higher percentage of subjects in the active treatment groups reported SAEs of cardiac failure compared with placebo (bezlotoxumab, 2.2 percent; actoxumab + bezlotoxumab, 2.2 percent; and placebo, 0.9 percent), whereas a higher percentage of subjects reported SAEs of CDI, pneumonia, and sepsis in the placebo group compared with the bezlotoxumab and actoxumab + bezlotoxumab groups. The incidence for other frequently reported SAEs was similar across groups. SAEs generally reflected the underlying comorbidities and advanced age of the subjects enrolled.

The applicant also further characterized the observed numerical imbalance of subjects experiencing cardiac failure SAEs in bezlotoxumab-containing versus placebo treatment groups, by performing a series of analyses in the 41 subjects with an SAE of cardiac failure. The applicant noted the baseline characteristics of the 41 subjects who experienced an SAE of cardiac failure. As compared with the All patients as treated (APaT) population for the integrated Phase III trials (P001 + P002) dataset, the 41 subjects were older, almost all were inpatients at the time of enrollment, had a higher incidence of comorbid conditions (as evidenced by Charlson Comorbidity Index and Horn's Index), and a higher incidence of severe CDI. Across the treatment groups, nearly 90 percent had a medical history of including at least one cardiac condition and approximately 70 percent had a history of cardiac failure and/or cardiomyopathy. Therefore, the applicant believed that any assessment of the safety profile of this morbidly ill patient population must be interpreted with caution.

The applicant provided an analysis of the safety profile of the 41 subjects with cardiac failure SAEs with respect to timing to cardiac failure SAE and death. In the placebo group, 5 of 7 subjects experienced an SAE of cardiac failure before Week 4, while in the bezlotoxumab and actoxumab + bezlotoxumab groups, the majority of such events occurred after Week 4. None of the cardiac failure SAEs was deemed drug related by the investigator. Among subjects with a cardiac failure SAE, a higher proportion of subjects in the placebo group than in the bezlotoxumab group died before Week 4. The applicant noted that the events were often associated with concurrent conditions such as infection and/or worsening CDI that are known to exacerbate CHF, thereby further supporting the assessments that these events were not drug related. Overall, according to the applicant, these findings do not support a clear association between cardiac failure and bezlotoxumab, especially recognizing the severe baseline morbidity of the subjects and the lack of a temporal association of the event and any associated death.

The applicant reiterated that heart failure is listed in the warnings and precautions section of the prescribing information for ZINPLAVA™ to describe the higher incidence of heart failure reported in the two Phase III trials in subjects who received ZINPLAVA™ compared with those who received placebo, primarily in patients with underlying CHF. The warnings and precautions section of the ZINPLAVA™ label states, in part, that in patients with a history of CHF, ZINPLAVA™ ''should be reserved for use when the benefit outweighs the risk.'' Although the overall safety profile of ZINPLAVA™ was found to be acceptable, the FDA considered that this information was clinically relevant. Furthermore, the applicant stated that ZINPLAVA™ has also recently been authorized for use by the European Medicines Agency (EMA) and that there is no heart failure warning in the EU prescribing information.

Response: We appreciate the additional information and analysis provided by the applicant in response to our concerns regarding the adverse event of cardiac failure. We are satisfied that the warnings and precautions section of the drug's label clearly state that ''ZINPLAVA™ should be reserved for use when the benefit outweighs the risk'' for patients with a history of congestive heart failure (CHF). We agree that ZINPLAVA™ represents a substantial clinical improvement over existing technologies because, based on the studies provided by the applicant, it reduces CDI recurrence by providing passive immunity against Toxin B resulting from persistent or newly acquired *C-diff* spores. After consideration of the public comments we received, we have determined that ZINPLAVA™ meets all of the criteria for approval of new technology add-on payments. Therefore, we are approving new technology add-on payments for ZINPLAVA™ for FY 2018. Cases involving ZINPLAVA™ that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure codes XW033A3 and XW043A3.

In its application, the applicant estimated that the average Medicare beneficiary would require a dosage of 10 mg/kg administered as an IV infusion over 60 minutes as a single dose. According to the applicant, the WAC for one dose is $3,800. Under 42 CFR 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment amount for a case involving the use of ZINPLAVA™ is $1,900 for FY 2018. In keeping with the current ZINPLAVA™ label, CMS expects ZINPLAVA™ will be prescribed for adult patients who are receiving antibacterial drug treatment for a diagnosis of CDI who are at high risk for CDI recurrence, and after consideration of its current warnings and precautions section which indicates for patients with a history of CHF, ZINPLAVA™ should be reserved for use when the benefit outweighs the risk.

b. EDWARDS INTUITY Elite™ Valve System (INTUITY) and LivaNova Perceval Valve (Perceval)

Two manufacturers, Edwards Lifesciences and LivaNova, submitted applications for new technology add-on payments for FY 2018 for the INTUITY Elite™ Valve System (INTUITY) and the Perceval Valve (Perceval), respectively. Both of these technologies are prosthetic aortic valves inserted using surgical aortic valve replacement (AVR). We note that, while Edwards Lifesciences submitted an application for new technology add-on payments for

FY 2017 for the INTUITY valve, FDA approval was not received by July 1, 2016, and, therefore, the device was not eligible for consideration for new technology add-on payments for FY 2017.

Aortic valvular disease is relatively common, primarily manifested by aortic stenosis. Most aortic stenosis is due to calcification of the valve, either on a normal tri-leaflet valve or on a congenitally bicuspid valve. The resistance to outflow of blood is progressive over time, and as the size of the aortic orifice narrows, the heart must generate increasingly elevated pressures to maintain blood flow. Symptoms such as angina, heart failure, and syncope eventually develop, and portend a very serious prognosis. There is no effective medical therapy for aortic stenosis, so the diseased valve must be replaced or, less commonly, repaired.

The INTUITY valve incorporates the expansion feature of a catheter implanted valve, but is designed to be placed during cardiac surgery. The manufacturer explained that the INTUITY valve requires fewer stitches to hold the device in place because of the balloon expanded design and, therefore, can be inserted more quickly than a standard valve, and also facilitates minimally invasive cardiac surgery; that is, use of a smaller incision to allow faster recovery. The manufacturer of the INTUITY valve indicated that the device is comprised of: (1) A bovine pericardial aortic bioprosthetic valve; (2) a balloon expandable stainless steel frame; and (3) a textured sealing cloth. The manufacturer of the Perceval valve indicated that the Perceval valve device is comprised of: (1) Sizers used to determine the correct size of the prosthesis; (2) a dual holder used for positioning and deployment (available in two models, one for sternal approaches and one for MIS); (3) a ''smart clip'' to assist during assembly of the valve on the dual holder to prevent release during positioning; (4) a dual collapser used to evenly reduce the diameter of the prosthesis allowing it to mount onto the holder prior to implantation; (5) a dual collapser base used to allow proper positioning; and (6) a postdilation catheter used for in situ dilation of the prosthesis after implantation (available in two models, one for sternal approaches and one for MIS). According to both applicants, the INTUITY valve and the Perceval valve are the first sutureless, rapid deployment aortic valves that can be used for the treatment of patients who are candidates for surgical AVR. The applicants indicated that the two new device innovations facilitate MIS approaches through: (1) The device rapid deployment mechanisms; and (2) the design of the prosthetic valve that allows for markedly fewer to no sutures to securely fasten the prosthetic valve to the aortic orifice. The applicants explained that both of these aspects of their devices are credited with the reduction of operating time.

As noted, according to both applicants, the INTUITY valve and the Perceval valve are the first sutureless, rapid deployment aortic valves that can be used for the treatment of patients who are candidates for surgical AVR. Because potential cases representing patients who are eligible for treatment using the INTUITY and the Perceval aortic valve devices would group to the same MS–DRGs, and we believe that these devices are intended to treat the same or similar disease in the same or similar patient population, and are purposed to achieve the same therapeutic outcome using the same or similar mechanism of action, we believe these two devices are substantially similar to each other and that it is appropriate to evaluate both technologies as one application for new technology add-on payments under the IPPS.

With respect to the newness criterion, the INTUITY valve received FDA approval on August 12, 2016, and was commercially available on the U.S. market on August 19, 2016. The Perceval valve received FDA approval on January 8, 2016, and was commercially available on the U.S. market on February 29, 2016. We believe that, in accordance with our policy, it is appropriate to use the earliest market availability date submitted as the beginning of the newness period. Therefore, we stated in the proposed rule that based on our policy, with regard to both devices, if the technologies are approved for new technology add-on payments, we believe that the beginning of the newness period would be February 29, 2016. In addition, both applicants indicated that ICD–10–PCS code X2RF032 (Replacement of Aortic Valve using Zooplastic Tissue, Rapid Deployment Technique, Open Approach, New Technology Group 2) would identify procedures involving the use of the devices when surgically implanted.

We previously stated that, because we believe these two devices are substantially similar to each other, we believe it is appropriate to evaluate both technologies as one application for new technology add-on payment under the IPPS. The applicants submitted separate cost and clinical data, and we reviewed and discuss each set of data separately. However, we stated in the proposed rule that we intend to make one determination regarding new technology add-on payments that will apply to both devices. We believe that this is consistent with our policy statements in the past regarding substantial similarity. Specifically, we have noted that approval of new technology add-on payments would extend to all technologies that are substantially similar (66 FR 46915), and we believe that continuing our current practice of extending new technology add-on payments without a further application from the manufacturer of the competing product, or a specific finding on cost and clinical improvement if we make a finding of substantial similarity among two products is the better policy because we avoid—

- Creating manufacturer-specific codes for substantially similar products;
- Requiring different manufacturers of substantially similar products to submit separate new technology applications;
- Having to compare the merits of competing technologies on the basis of substantial clinical improvement; and
- Bestowing an advantage to the first applicant representing a particular new technology to receive approval (70 FR 47351).

We explained in the proposed rule that if these substantially similar technologies were submitted for review in different (and subsequent) years, rather than the same year, we would evaluate and make a determination on the first application and apply that same determination to the second application. However, because the technologies have been submitted for review in the same year, we believe that it is appropriate to consider both sets of cost data and clinical data in making a determination and we do not believe that it is possible to choose one set of data over another set of data in an objective manner.

As stated above, we believe that the INTUITY valve and the Perceval valve are substantially similar to each other for purposes of analyzing these two applications as one application. As we stated in the proposed rule, we also need to determine whether the INTUITY valve and the Perceval valve are substantially similar to existing technologies prior to their approval by the FDA and their release on the market. As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be

considered ''new'' for purposes of new technology add-on payments.

With respect to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant for the INTUITY valve asserted that its unique design, which utilizes features that were not previously included in conventional aortic valves, constitutes a new mechanism of action. The deployment mechanism allows for rapid deployment. The expandable frame can reshape the native valve's orifice, creating a larger and more efficiently shaped effective orifice area. In addition, the expandable skirt allows for structural differentiation upon fixation of the valve requiring 3 permanent, guiding sutures rather than the 12 to 18 permanent sutures used to fasten standard prosthetic aortic valves. The applicant for the Perceval valve described the Perceval valve's mechanism of action as including: (a) No permanent sutures; (b) a dedicated delivery system that increases the surgeon's visibility; (c) an enabler of minimally invasive approach; (d) a complexity reduction and reproducibility of the procedure; and (e) a unique device assembly and delivery systems.

With respect to the second and third criteria, whether a product is assigned to the same or a different MS–DRG and whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant for the INTUITY valve indicated that the technology is used in the treatment of the same patient population and potential cases representing patients that may be eligible for treatment using the INTUITY valve would be assigned to the same MS–DRGs as cases involving the use of other prosthetic aortic valves (that is, MS–DRGs 216 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC), 217 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with CC), 218 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization without CC/MCC), 219 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC), 220 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with CC), and 221 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization without CC/MCC).

The applicant for the Perceval valve also indicated that the Perceval valve device is used in the treatment of the same patient population and potential cases representing patients that may be eligible for treatment using the technology would be assigned to the same MS–DRGs (MS–DRGs 216 through 221) as cases involving the use of other prosthetic aortic valves.

We stated in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19881) that after considering the materials included with both applications, we remained concerned as to whether the mechanism of action described by the applicants represents an improvement to an existing surgical technique and technology or a new technology. While the INTUITY and Perceval valves address some of the challenges posed by implantation of existing valves, including improving the visibility of the orifice and the physiological function of the valves, we stated that we did not believe that their mechanisms of action are fundamentally different from that of other aortic valves. As one of the applicants stated in its application, the goal of the prosthetic aortic valve is to mimic the native valve that it has replaced via the incorporation of three leaflets that open and close in response to pressure gradients developed during the cardiac cycle. We stated that we believe that the INTUITY and Perceval valves are the same or similar to other prosthetic aortic valves used to treat the same or similar diagnoses.

In the proposed rule, we invited public comments on whether the mechanism of action of the sutureless, rapid deployment of the INTUITY and Perceval valves differs from the mechanism of action of standard AVR valves and whether the technologies meet the newness criterion.

Comment: The applicant for the INTUITY valve, as well as several physicians that have performed surgeries implanting the INTUITY, stated that the mechanism of action differs from that of standard aortic valves because of the expeditious implantation, rapid deployment, and improved hemodynamics. The applicant also emphasized innovative aspects about the INTUITY that were described in its application, such as the flexible delivery system, the ability to reshape the native valve's orifice, and the balloon expandable stented frame and subannular skirt. The applicant emphasized that minimally invasive aortic valve replacement has not been widely adopted because of greater technical challenge and longer cross-clamp times, but that the INTUITY facilitates minimally invasive surgery by addressing both of these challenges.

One commenter, who also manufactures heart valves, indicated that it shared CMS' concern about whether the mechanism of action constitutes a new technology. This commenter indicated that prosthetic aortic valves fall into two categories: Traditional, open surgical and minimally invasive, and that differences in design of the valves are intended to address challenges in surgical valve replacement, including surgical technique, reduction in complications, improvement in hemodynamics, or resistance to calcification. The commenter stated that all prosthetic aortic valves are substantially similar to each other. The commenter described the steps involved in placing surgical valves, and indicated that the applicants' devices introduce a new technique for securing a surgically implanted bioprosthetic heart valve to the annulus and surrounding structures, but that the mechanism of action is unchanged. The commenter also noted that rapid deployment surgical aortic valves were introduced into clinical practice in 1963.

Response: We thank the commenters for the details and input on whether INTUITY and Perceval meet the newness criterion. While we appreciate the additional information provided by the commenter that did not believe these valves represented a new technology, we believe that based on comments from the manufacturer and physicians who have used the INTUITY device, the mechanism of action for the INTUITY and Perceval is different from other aortic valves. Specifically, as the manufacturer and other physicians emphasized in their comments, the technical features of the valve provide the ability to improve clinical function beyond the opening and closing of the valve leaflets and allow it to perform more efficiently than a standard valve. Thus, as these commenters noted, a prosthetic aortic valve inserted using surgical AVR with its insertion process improves the physiologic function of the outflow track of the new valve. After further review of the information provided by the applicant and consideration of the public comments we received, we believe that INTUITY and Perceval meet the newness criterion. Therefore, we consider the technology to be ''new'' as of February 29, 2016, when the Perceval valve became commercially available.

As we stated above, each applicant submitted separate analyses regarding the cost criterion for each of their devices, and both applicants maintained that their device meets the cost criterion. We summarize each analysis below.

With regard to the cost criterion, the INTUITY valve's applicant researched the FY 2015 MedPAR claims data file to identify cases representing patients who may be potential recipients of treatment using the INTUITY valve. The applicant identified claims that reported an ICD–9–CM diagnosis code of 424.1 (Aortic valve disorder), in combination with an ICD–9–CM procedure code of 35.21 (Replacement of aortic valve with tissue) or 35.22 (Open and other replacement of aortic valve). The applicant also identified cases with or without a coronary artery bypass graft (CABG) using the ICD–9–CM procedure codes in the table below.

ICD–9–CM code	Code description
36.10	Aortocoronary bypass for heart revascularization, not otherwise specified
36.11	(Aorto)coronary bypass of one coronary artery.
36.12	(Aorto)coronary bypass of two coronary arteries.
36.13	(Aorto)coronary bypass of three coronary arteries.
36.14	(Aorto)coronary bypass of four or more coronary arteries.
36.15	Single internal mammary-coronary artery bypass.
36.16	Double internal mammary-coronary artery bypass.
36.17	Abdominal-coronary artery bypass.

The applicant identified a total of 25,173 cases that mapped to MS–DRGs 216 through 221. Of these cases, the applicant identified 10,251 CABG cases and 14,922 non-CABG cases. According to the applicant, patients that undergo a procedure without need of a concomitant CABG are more likely to receive treatment with the INTUITY valve than patients in need of a concomitant CABG. Therefore, the applicant weighted the non-CABG cases at 90 percent of total cases and the CABG cases at 10 percent of total cases under each of the six MS–DRGs. The final case count is a weighted average of 14,455 cases.

The applicant calculated an average unstandardized charge per case of $192,506 for all cases. The applicant then removed 100 percent of the charges for pacemakers, investigational devices, and other implants that would not be required for patients receiving treatment using the INTUITY valve. The applicant standardized the charges and then applied an inflation factor of 1.098446, which is the 2-year inflation factor in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57286), to update the charges from FY 2015 to FY 2017. The applicant calculated the average expected charge for the INTUITY valve based on the current list price of the device. Although the applicant submitted data related to the cost of the INTUITY valve, the applicant noted that the cost of the device is proprietary information. To add charges for the device, the applicant assumed a hospital mark-up of approximately 300 percent, based on the current average CCR for implantable devices (0.331) as reported in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56876). Based on the FY 2017 IPPS/LTCH PPS Table 10 thresholds, the average case-weighted threshold amount was $170,321. The applicant computed an inflated average case-weighted standardized charge per case of $194,291, which is $23,970 above the average case-weighted threshold amount. Because the inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19882), we thanked the applicant for the analysis above. However, we indicated that we would like more information from the applicant regarding how it decided upon which cases to include in the sensitivity analysis, as well as further details about how and on what basis the applicant weighted CABG and non-CABG cases. We invited public comments on whether the INTUITY valve meets the cost criterion. We summarize the public comment we received from the applicant regarding its cost analysis later in this section.

With regard to the cost criterion in reference to the Perceval valve, the applicant conducted the following analysis. The applicant examined FY 2015 MedPAR claims data that included cases reporting an ICD–9 procedure code of 35.21 or 35.22, in combination with diagnosis code: 424.1. Noting that MS–DRGs 216 through 221 contained 97 percent of these cases, the applicant limited its analysis to these 6 MS–DRGs. The applicant identified 25,193 cases across these MS–DRGs, resulting in an average case-weighted unstandardized charge per case of $173,477. The applicant then standardized charges using FY 2015 standardization factors and applied an inflation factor of 1.089846 from the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25271). The applicant indicated that the technology meets the cost criterion by applying the inflation factor from the proposed rule and, therefore, would meet the cost criterion by applying the higher inflation factor from the final rule.

Included in the average case-weighted standardized charge per case were charges for the current valve prosthesis. Therefore, the applicant removed all charges associated with revenue center 0278, and calculated the adjusted average case-weighted standardized charge per case by subtracting these charges from the standardized charge per case. The applicant then added the charge for the new technology by taking the anticipated hospital cost of the new technology and dividing it by the national average implantable devices CCR of 0.331. The applicant then added the charge for the new technology to the inflated average case-weighted standardized charges per case to arrive at the final inflated average case-weighted standardized charge per case, which was then case-weighted based on the distribution of cases within the six MS–DRGs. This resulted in an inflated average case-weighted standardized charge per case of $206,109. Using the FY 2017 IPPS Table 10 thresholds, the average case-weighted threshold amount was $173,477. Because the inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19882), we invited public comments on whether the Perceval technology meets the cost criterion. We did not receive any public comments concerning the costs for the Perceval technology.

Comment: The applicant for the INTUITY valve stated that it based its initial sensitivity analysis on 14,455 cases that reflected the weighted mix of CABG and non-CABG cases, as the findings in European trials indicated that INTUITY was predominantly performed on patients who did not have a concomitant CABG during their inpatient stay. The applicant stated that

because the INTUITY is intended for use in all surgical aortic valve replacement procedures, regardless of whether the patient also receives CABG, it reran the cost threshold analysis including all 25,173 target cases in the FY 2015 MedPAR with an ICD–9–CM diagnosis code of 424.1 (Aortic valve disorder), in combination with an ICD–9–CM procedure code of 35.21 (Replacement of aortic valve with tissue) or 35.22 (Open and other replacement of aortic valve) that mapped to MS–DRGs 216 through 221. The applicant presented a summary table, which indicated that the case weighted threshold was $173,463, the final inflated case weighted standardized charge per case was $206,329, and the difference is $32,866.

Response: We appreciate the applicant's submission of this additional information. Based on review of the sensitivity analysis included in the original application and subsequent analysis included in the INTUITY applicant's public comment, as well as the cost analyses set forth in both applicants' original applications as set forth above, we have determined that both the INTUITY and the Perceval valve meet the cost criterion.

With regard to substantial clinical improvement for the INTUITY valve, the applicant asserted that several aspects of the valve system represent a substantial clinical improvement over existing technologies. The applicant believed that the flexible deployment arm allows improved surgical access and visualization, making the surgery less challenging for the surgeon, improving the likelihood that the surgeon can use a minimally invasive approach. According to the applicant, the assembly of the device only allows the correct valve size to be fitted, which ensures that the valve does not slip or migrate, which prevents paravalvular leaks and patient prosthetic mismatch. The applicant indicated that the device improves clinical outcomes for patients undergoing minimally invasive AVR and full-sternotomy AVR. The applicant stated that the rapid deployment technology enables reduced operative time, specifically cross-clamp time, thereby reducing the period of myocardial ischemia. In addition, the applicant indicated that the device offers a reduction in operative time for full-sternotomy AVR. The applicant noted that clinical results document significant patient outcome and utilization improvements, including improved patient satisfaction, faster return to normal activity, decreased post-operative pain, reduced mortality and decreased complications, including need for reoperation due to bleeding, reduced recovery time, reduced length of stay (both ICU and overall), more access to minimally invasive surgery, and improved hemodynamics.

The INTUITY valve has been tested clinically in several trials. In the TRITON trial (Kocher et al., 2013 [4]), 287 patients diagnosed with aortic stenosis underwent surgery in 1 of 6 European centers. The first 149 patients received the first generation Model 8300A valve, and the next 138 patients received the second generation Model 8300AB. The average age of the patients was 75.7 years. Early, 30-day mortality was 1.7 percent (5/287), the post-op valve gradient was low, and 75 percent of the patients improved functionally. A total of 4 valves were explanted in the final 30 days due to bleeding, and 3 were explanted later for paravalvular leak, endocarditis, and aortic root aneurysms. Follow-up extended to 3 years (mean 1.8 years).

Implantation of the INTUITY valve using minimally invasive surgery was compared with conventional aortic valve replacement via full sternotomy in the CADENCE–MIS randomized trial (Borger et al., 2015 [5]) of 100 patients treated in 1 of 5 centers in Germany. The authors found no significant difference in 30-day mortality, the need for pacemaker implantation, significant paravalvular regurgitation, and quality of life scores at 3 months. Aortic cross-clamp time was significantly reduced from 54.0 to 41.3 minutes ($p < 0.0001$), and cardiopulmonary bypass time was reduced from 74.4 to 68.8 minutes ($p = 0.21$). Early clinical outcomes were similar: No significant differences in mortality, reoperation, or other clinical outcomes. The aortic valve gradient was significantly lower in the MIS group: 8.5 versus 10.3 mmHg.

The TRANSFORM trial (Barnhart et al. 2017 [6]) was a single-arm, non-randomized, multicenter trial, in which 839 patients underwent rapid deployment AVR surgery. The average age of the patients was 73.5 years. The mean cross-clamp time and cardiopulmonary bypass times for full sternotomy were 49.3 ± 26.9 min and 69.2 ± 34.7 min, respectively, and for MIS, 63.1 ± 25.4 min and 84.6 ± 33.5 min, respectively. The authors compared these times to STS database comparators: For full sternotomy, 76.3 minutes and 104.2 minutes, respectively, and for MIS, 82.9 minutes and 111.4 minutes, respectively. All cause early mortality was 0.8 percent, mean EOA at 1 year was 1.7 cm^2; mean gradient, 10.3 mmHg; and moderate and severe PVL, 1.2 percent and 0.4 percent, respectively. The authors indicated that the INTUITY valve ''. . . may lead to a relative reduction in aortic cross-clamp time and cardiopulmonary bypass time'' and ''may confer benefits to patients, such as decreased mortality and morbidity.'' The authors noted the possibility of potential bias resulting from the level of experience of the study surgeons relative to typical cardiac surgeons. In addition, long-term follow-up is not available, and study comparators from the Society of Thoracic Surgeons (STS) database were not matched.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25057), after reviewing the studies provided by the applicant with its application for FY 2017, we expressed some specific concerns. We indicated that we were concerned that the INTUITY valve does not have sufficient advantages over alternative surgically implanted valves to constitute a substantial clinical improvement. We noted that, while some of the studies included with the application demonstrate reduced aortic cross-clamp time, conventional aortic valve replacement was used in the comparison group. Therefore, it is unclear whether the reduced aortic cross-clamp time is associated with the use of the INTUITY valve or as a result of the MIS surgery in general.

In response to these concerns, the INTUITY valve's applicant stated that the INTUITY valve is associated with significant clinical benefits outside of the benefits achieved by use of an MIS approach. The applicant referenced the sub-study of the TRANSFORM trial, which compared the MISAVR with the INTUITY valve to MISAVR with a conventional valve, stating that the results indicated reduced cross-clamp time and other benefits that are not simply a function of the MIS approach. The applicant also referenced trials that indicated that the INTUITY valve had excellent hemodynamic performance

[4] Kocher AA, Laufer G, Haverich A, et al. One-year outcomes of the surgical treatment of aortic stenosis with a next generation surgical aortic valve (TRITON) trial: A prospective multicenter study of rapid-deployment aortic valve replacement with the EDWARDS INTUITY valve system. J Thorac Cardiovasc Surg 2013;145:110–116.

[5] Borger MA, Moustafine V, Conradi L, et al. A randomized multicenter trial of minimally invasive rapid deployment versus conventional full sternotomy aortic valve replacement. Ann Thorac Surg 2015; 99:17–25.

[6] Barnhart, G.A. et al. (2017). TRANSFORM (Multicenter Experience with Rapid Deployment Edwards INTUITY Valve System for Aortic Valve Replacement) US clinical trial: Performance of a rapid deployment aortic valve. *The Journal of Thoracic and Cardiovascular Surgery, 153,* 241–251.

(Haverich et al.,[7] Borger et al.,[8] Barnhart et al.,[9]) one of which found a significant improvement in functional status (Haverich et al.).

After considering the studies provided by the INTUITY valve applicant, in the proposed rule, we stated that we were concerned about the possibility of potential bias resulting from the level of experience of the study surgeons relative to typical cardiac surgeons, as well as the lack of long-term follow-up in these studies.

Comment: The applicant stated that there are three key points to support the improved clinical performance of the INTUITY. First, there is a sufficient body of evidence across multiple clinical studies demonstrating improved clinical and hemodynamic performance versus traditionally implanted surgical valves. Second, these improvements are not simply a result of a minimally invasive surgical approach. Third, collectively, these points validate the premise that the technical features of the INTUITY are the primary contributor of the improved clinical outcomes, and that non-INTUITY procedures done with a minimally invasive surgical approach generally have longer cross-clamp and operative times. Physicians that have implanted the INTUITY valve also indicated that the INTUITY valve reduces cardiopulmonary bypass time and cross-clamp time, both of which have been shown to reduce complications.

The applicant also stated that its studies included surgeons with varied degrees of experience, and that over 62 physicians participated in the US INTUITY trials, which reduces the impact of surgeon bias and allows for greater generalizability of results. The applicant stated that while no study is free of bias, the INTUITY has been shown to have consistent results in both clinical trials and the real-world setting. The applicant further supplemented its application with recently published 5-year follow-up data (Laufer et al., 2017),[10] which found sustained benefits, including effective orifice area (EOA) improvements, low pressure gradients, and reductions in left ventricular mass, as well as excellent survival rates.

A manufacturer that also manufactures heart valves stated that the studies cited by the INTUITY applicant have potential bias resulting from the level of experience of the study surgeons relative to typical cardiac surgeons, as well as a lack of long-term follow-up. This commenter noted that, in the CADENCE–MIS trial, key outcome measures did not differ statistically significantly at 3 months between the randomized arms of the study, but that the rate of pacemaker implants was higher in the INTUITY group. This commenter noted that while transaortic valve gradients are reported as significantly lower, the study population was small, and that the comparator devices are not all representative of best in class gradients. This commenter also pointed to the high rate of pacemaker implants in the TRANSFORM trial, and mentioned a recent manuscript that reported that early pacemaker implantation after aortic valve replacement was associated with an increased risk of death.[11]

Response: While we appreciate the concerns raised by one commenter regarding the studies that examined the INTUITY valve, we believe the manufacturer addresses our concerns.

With regard to substantial clinical improvement for the Perceval valve, the applicant submitted several studies examining the Perceval valve. The following discussion summarizes some of these studies.

Pollari and colleagues[12] (2014) utilized a propensity score analysis to examine 82 matched pairs as part of a larger trial that included 566 patients treated with bioprosthetic aortic valve replacement, 166 of which received treatment using the Perceval sutureless valve and 400 of which received treatment using a stented valve. Aortic cross-clamp, cardiopulmonary bypass, and operation times were significantly shorter in the group that received treatment using the Perceval sutureless valve. The Perceval sutureless group also had shorter ICU stays, hospital stays, and intubation times, and lower incidence of postoperative atrial fibrillation and respiratory insufficiency. The authors noted that, despite the promising preliminary results, longer follow-up is warranted before drawing definite conclusions.

In a nonrandomized trial of 100 patients in a German hospital, Santarpino and colleagues[13] (2013) found that procedures completed using the Perceval valve were associated with significantly shorter cross-clamp and cardiopulmonary bypass times (40 ± 13.8 and 69 ± 19.1 versus 66 ± 20.4 and 105 ± 34.8) relative to conventional stented bioprosthetic valves, as well as less frequent use of blood transfusions, shorter ICU stays and shorter use of intubation. In contrast, Gilmanov and colleagues[14] (2013) found that a MIS approach resulted in improved outcomes, albeit longer aortic cross-clamp times. A meta-analysis by Hurley and colleagues[15] (2015) found reduced cross-clamp and cardiopulmonary bypass times, but found a significantly higher permanent pacemaker rate with the use of Perceval sutureless valves.

A study conducted by Dalen and colleagues[16] (2015) used propensity score matching to examine early post-operative outcomes and 2-year survival between 171 pairs of patients who underwent ministernotomy using the Perceval device or a full sternotomy with stented prosthesis. There were no differences in 30-day mortality or 2-year survival between the groups. The aortic cross-clamp time and cardiopulmonary bypass time were shorter, and there were fewer blood transfusions in the group that received treatment using the Perceval device. However, this group was also at higher risk for post-operative permanent pacemaker implantation.

We stated in the proposed rule that, after reviewing the publications submitted by the applicant, we are concerned that the lack of randomization and blinded investigators may have influenced the outcomes in many of the studies provided. For example, in the discussion following

[7] Haverich, A, et al. (2014), Three-year hemodynamic performance, left ventricular mass regression, and prosthetic-patient mismatch after rapid deployment aortic valve replacement in 287 patients. J Thorac Cardiovasc Surg, 148(6), 2854–60.

[8] Borger MA, Moustafine V, Concadi L, et al. A randomized multicenter trial of minimally invasive rapid deployment versus conventional full sternotomy aortic valve replacement. Ann Thorac Surg 2015; 99:17–25.

[9] Barnhart, G.A. et al. (2017). TRANSFORM (Multicenter Experience with Rapid Deployment Edwards INTUITY Valve System for Aortic Valve Replacement) US clinical trial: Performance of a rapid deployment aortic valve. *The Journal of Thoracic and Cardiovascular Surgery, 153,* 241–251.

[10] Laufer, G et al. (2017). Long-term outcomes of a rapid deployment aortic valve: Data up to 5 years. European Journal of Cardiothorac Surgery, 2017 Apr 26.

[11] Greason et al. (2017). Long-Term Mortality Effect of Early Pacemaker Implantation after Surgical Aortic Valve Replacement. The Society of Thoracic Surgeons.

[12] Pollari, F. (2014), Better short-term outcome by using sutureless valves: A propensity-matched score analysis, Ann Thorac Surg, 98; 611–6.

[13] Santarpino, G. et al. (2013), The Perceval S aortic valve has the potential of shortening surgical time: Does it also result in improved outcome?, Ann Thorac Surg, 96, 77–81.

[14] Gilmanov, D. (2013), Minimally invasive and conventional aortic valve replacement: a propensity score analysis, Ann Thorac Surg, 96, 837–843.

[15] Hurley et al., ''A Meta-Analysis Examining Differences in Short-Term Outcomes Between Sutureless and Conventional Aortic Valve Prostheses,'' Innovations 2015; 10:375–382.

[16] Daleán, M. (2015), Aortic valve replacement through full sternotomy with a stented bioprosthesis versus minimally invasive sternotomy with a sutureless bioprosthesis, Eur J Cardiothorac Surg 2015; doi:10.1093/ejcts/ezv014.

Santarpino et al.'s 2013 study, one of the participants suggested that medical decision-making regarding ventilation times, ICU times, and blood transfusions may be affected by the knowledge of investigators as to which valve the patient received treatment using. Also, as indicated above with respect to the INTUITY valve, the experience of the surgeons in these studies may be confounding factors that may have influenced the length of surgical procedures and/or surgical outcomes.

Comment: One manufacturer that produces heart valves stated that the evidence for the Perceval device suffers from lack of randomization and blinding of investigators. This commenter cited a brief by the Health Technology Assessment Information Services of ECRI summarizing the most recent evidence about the LivaNova Perceval valve. The brief cited a range of values for clinical outcomes, suggesting the importance in variation in technique. This commenter also compiled a table of gradients for aortic heart valves, including those of the applicants, and stated that the gradients are comparable to conventional surgical devices but are not best-in-class.

Response: While we acknowledge the concerns raised by one commenter regarding the Perceval valve, we recognize that studies in general may have some limitations. We also note that the studies submitted by the manufacturer indicate that the Perceval valve is associated with fewer blood transfusions and significantly shorter aortic cross-clamp, cardiopulmonary bypass, and operation times. The Perceval sutureless group also had shorter ICU stays, hospital stays, and intubation times, and lower incidence of postoperative atrial fibrillation and respiratory insufficiency.

In the proposed rule, we invited public comments on whether rapid deployment valves, specifically the INTUITY and Perceval valves, meet the substantial clinical improvement criterion. We noted that we did not receive any written public comments regarding the INTUITY and Perceval valves in response to the New Technology Town Hall meeting notice.

We agree with the manufacturers that the INTUITY and Perceval valves represent a substantial clinical improvement for the following reasons: The rapid deployment technology enables reduced operative time for minimally invasive AVR and full-sternotomy AVR. Additionally, the device improves cross-clamp time, thereby reducing the period of myocardial ischemia. The improved patient outcomes were also reflected in improved patient satisfaction, faster return to normal activity, decreased postoperative pain, reduced mortality and decreased complications, including need for reoperation due to bleeding, reduced recovery time, reduced length of stay (both ICU and overall), and improved hemodynamics. In addition, the newly published 5-year data further support the substantial clinical improvement of this technology.

For the reasons described above and after consideration of the public comments we received, we have determined that the INTUITY and Perceval valve meet all of the criteria for approval of new technology add-on payments for FY 2018. Each of the applicants submitted cost information for its valve. The manufacturer of the INTUITY valve stated that the cost of the valve is $12,500. The applicant projected that 1,750 cases will involve the use of INTUITY in FY 2018. The manufacturer of the Perceval valve stated that the cost of the valve is $11,500. The applicant projected that 679 cases will involve the use of the Perceval valve in FY 2018.

New technology add-on payments for cases involving these technologies will be based on the weighted average cost of the two valves described by the ICD–10–PCS procedure code X2RF032 (Replacement of Aortic Valve using Zooplastic Tissue, Rapid Deployment Technique, Open Approach, New Technology Group 2). Because ICD–10 codes are not manufacturer specific, we cannot set one new technology add-on payment amount for INTUITY and a different new technology add-on payment amount for the Perceval valve; both technologies will be captured by using the same ICD–10–PCS procedure code. As such, we believe that the use of a weighted average of the cost of the standard valves based on the projected number of cases involving each technology to determine the maximum new technology add-on payment would be most appropriate. To compute the weighted cost average, we summed the total number of projected cases for each of the applicants, which equaled 2,429 cases (1,750 plus 679). We then divided the number of projected cases for each of the applicants by the total number of cases, which resulted in the following case-weighted percentages: 72 percent for the INTUITY and 28 percent for the Perceval valve. We then multiplied the cost per case for the manufacturer specific valve by the case-weighted percentage (0.72 * $12,500 = $9,005.76 for INTUITY and 0.28 * $11,500 = $3,214.70 for the Perceval valve). This resulted in a case-weighted average cost of $12,220.46 for the valves. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the device or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the INTUITY or Perceval valves is $6,110.23 for FY 2018.

c. Ustekinumab (Stelara®)

Janssen Biotech submitted an application for new technology add-on payments for the Stelara® induction therapy for FY 2018. Stelara® received FDA approval as an intravenous (IV) infusion treatment of Crohn's disease (CD) on September 23, 2016, which added a new indication for the use of Stelara® and route of administration for this monoclonal antibody. IV infusion of Stelara® is indicated for the treatment of adult patients (18 years and older) diagnosed with moderately to severely active CD who have: (1) Failed or were intolerant to treatment using immunomodulators or corticosteroids, but never failed a tumor necrosis factor (TNF) blocker; or (2) failed or were intolerant to treatment using one or more TNF blockers. Stelara® for IV infusion has only one purpose, induction therapy. Stelara® must be administered intravenously by a health care professional in either an inpatient hospital setting or an outpatient hospital setting.

Stelara® for IV infusion is packaged in single 130mg vials. Induction therapy consists of a single IV infusion dose using the following weight-based dosing regimen: patients weighing less than (<) 55kg are administered 260mg of Stelara® (2 vials); patients weighing more than (>) 55kg, but less than (<) 85kg are administered 390mg of Stelara® (3 vials); and patients weighing more than (>) 85kg are administered 520mg of Stelara® (4 vials). An average dose of Stelara® administered through IV infusion is 390mg (3 vials). Maintenance doses of Stelara® are administered at 90mg, subcutaneously, at 8-week intervals and may occur in the outpatient hospital setting.

CD is an inflammatory bowel disease of unknown etiology, characterized by transmural inflammation of the gastrointestinal (GI) tract. Symptoms of CD may include fatigue, prolonged diarrhea with or without bleeding, abdominal pain, weight loss and fever. CD can affect any part of the GI tract including the mouth, esophagus, stomach, small intestine, and large intestine.

Conventional pharmacologic treatments of CD include antibiotics, mesalamines, corticosteroids,

immunomodulators, tumor necrosis alpha (TNFα) inhibitors, and anti-integrin agents. Surgery may be necessary for some patients diagnosed with CD in which conventional therapies have failed. The applicant asserted that use of Stelara® offers an alternative to conventional pharmacologic treatments, and has been shown to be successful in the treatment of patients who have failed treatment using the conventional agents currently being used for a diagnosis of CD, including TNFα inhibitors.

Although the precise cause of CD is unknown, the environment, genetics, and the patient's immune system are thought to play a role in this form of inflammatory bowel disease (IBD). Conventional pharmacologic therapy is directed against many different inflammatory mediators that produce inflammation and ultimately lead to gastrointestinal damage. The applicant asserted that it is of paramount importance to have a variety of pharmacologic agents that can address the proper inflammatory mediator for a particular patient. The applicant also asserted that, while the currently available anti-inflammatory agents used in the treatment of a diagnosis of CD are excellent medications, these agents do not successfully treat all patients diagnosed with CD, nor do they reliably sustain disease remission once a response has been achieved. The applicant believed that the use of Stelara® offers an alternative to currently available treatment options.

With regard to the newness criterion, Stelara® is not a newly formulated drug. Stelara®, administered subcutaneously, received FDA approval in 2009 (September 25, 2009) for the treatment of moderate to severe plaque psoriasis in adults. Its IV use for the treatment of patients diagnosed with CD was approved by the FDA in 2016 (September 23, 2016). With regard to the new use of an existing technology, in the September 1, 2001 final rule (66 FR 46915), we stated that if the new use of an existing technology was for treating patients not expected to be assigned to the same MS–DRG as the patients receiving the existing technology, it may be considered for approval, but it must also meet the cost and substantial clinical improvement criteria in order to qualify for the new technology add-on payment. We do not believe that potential cases representing patients that may be eligible for treatment with the new use of the Stelara® for IV treatment of a diagnosis of CD would be assigned to the same MS–DRGs as cases treated using the prior indications.

As discussed above, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, we stated in the proposed rule that we were concerned that Stelara®'s mechanism of action does not appear to differ from the mechanism of action of other monoclonal antibodies, which also target unique gastrointestinal-selective cytokines. The applicant believed that the Stelara® uses a different mechanism of action than other medications currently available for the treatment of patients diagnosed with CD. However, we stated that we believe that the mechanism of action for the new use of the Stelara® may be similar to the mechanism of action of other cytokine-selective monoclonal antibodies that disrupt cytokine mediated signals crucial to the inflammatory process in patients diagnosed with CD.

The applicant stated that the Stelara® is a human IgG1 monoclonal antibody that binds with specificity to the p40 protein subunit, which is common to both the interleukin-12 (IL–12) and interleukin (IL–23) cytokines. IL–12 and IL–23 are naturally occurring cytokines that are involved in inflammatory and immune responses, such as natural killer cell activation and CD4+ T-cell differentiation and activation. In *in vitro* models, the Stelara® was shown to disrupt IL–12 and IL–23 mediated signaling and cytokine cascades by blocking the interaction of these cytokines with a shared cell-surface receptor chain, IL–12Rβ1. The cytokines IL–12 and IL–23 have been implicated as important contributors to chronic inflammation. According to the applicant, IV induction therapy quickly achieves optimal blood levels of Stelara® so that blockade of IL–12 and IL–23 is most effective. This level of blockade is not achieved with subcutaneous administration.

The applicant further stated that other available CD anti-inflammatory or immune modulator therapies do not target the IL–12/IL–23p40 substrate. Rather, these therapies may target other integrin pairs such as the alpha4- beta7 integrins. Therefore, the applicant believed that the Stelara® drug is not substantially similar to any other approved drug for the treatment of moderately to severely active CD. As previously noted, the applicant asserted that, while the currently available agents are excellent medications, these agents do not successfully treat all patients diagnosed with CD, nor do these agents reliably sustain remission once a clinical response has been achieved. According to the applicant, the new use of the Stelara® offers an alternative to currently available treatment options, and has been shown to be successful in the treatment of patients who have failed treatment with the conventional agents currently being used for a diagnosis of CD, including TNF blockers. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19885), we stated that we are concerned that the Stelara®'s mechanism of action is similar to that of other immune system suppressors used in the treatment of patients diagnosed with moderately to severely active CD because other cytokine-selective monoclonal antibodies also disrupt cytokine mediated signals crucial to the inflammatory process in patients diagnosed with CD.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant maintained that MS–DRGs 386, 387, and 385 (Inflammatory Bowel Disease with CC, without CC/MCC, and with MCC, respectively) and MS–DRGs 330, 329 and 331 (Major Small and Large Bowel Procedures with CC, without CC/MCC, and with MCC, respectively) are used to identify cases representing patients who may potentially be eligible for treatment using the Stelara®. The applicant researched claims data from the FY 2015 MedPAR file and found 10,344 cases. About 85 percent of potentially eligible cases mapped to MS–DRGs for inflammatory bowel disease and most of the remainder of cases mapped to MS–DRGs for bowel surgery. In the proposed rule, we stated that we believe that potential cases involving Stelara® induction therapy may be assigned to the same MS–DRGs as cases representing patients who have been treated using currently available treatment options.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, according to the applicant, currently available pharmacologic treatments include antibiotics, mesalamines, corticosteroids, immunomodulators, tumor necrosis alfa (TNFα) inhibitors and anti-integrins. The applicant stated that the new use of the Stelara® for IV infusion is indicated for the treatment of adults (18 years and older) diagnosed with moderately to severely active CD

who have: (1) Failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed treatment using a TNF blocker; or (2) failed or were intolerant to treatment with one or more TNF blockers. The applicant asserted that Stelara® for induction therapy is not substantially similar to other treatment options because it does not involve the treatment of the same or similar type of patient population. Patients who are eligible for treatment using the Stelara® induction therapy have failed other CD treatment modalities. The applicant believed that the subset of primary and secondary nonresponder patients to TNF inhibitor treatments is a patient population unresponsive to, or ineligible for, currently available treatments for diagnoses of moderate to severe CD. Based on the indications for the use of Stelara®, there is a class of patients who failed, or were intolerant to, treatment using immunomodulators or corticosteroids, but never failed treatment using a TNF blocker. The applicant indicated that, for those patients who never failed treatment with a TNF blocker, this class of patients can be recognized as two separate patient populations: One population of patients who have never received treatment using a TNF blocker, or the other population of patients who have received and responded to treatment using a TNF blocker. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19885), we stated that we believe that, if the new use of the Stelara® has the same mechanism of action as other immune system suppressors such as TNF blockers, the patient population that did not receive treatment using a TNF blocker may not be a new patient population because those patients may be able to receive treatment using, and would successfully respond to treatment using, a TNF blocker. Moreover, if the mechanism of action is the same as other immune system suppressors, we stated that we believe that the new use of the Stelara® may be targeted at a new patient population in some circumstances and instances, but we are concerned that it may not be targeted at a new patient population in all circumstances and instances.

In the proposed rule, we invited public comments on whether the Stelara® meets the newness criterion.

Comment: Several commenters stated that Stelara® has a different mechanism of action than other immune system suppressors. The applicant also submitted comments acknowledging that CMS accurately noted that other monoclonal antibodies targeting unique gastrointestinal-selective cytokines are currently marketed for the treatment of CD. The applicant noted that a critical differentiator is that Stelara® targets the IL–12 and IL–23 regulatory cytokines while other monoclonal antibodies used to treat Crohn's disease are either TNF inhibitors or anti-integrin monoclonal antibodies. The applicant stated that, as a result, Stelara® has a different mechanism of action for reducing the inflammatory response in CD than other monoclonal antibodies used to treat the disease. Furthermore, the applicant stated that while many patients respond to TNF inhibition, 20 to 25 percent of them will not respond, regardless of the TNF inhibitor employed or the dose provided. By targeting the IL–12 and IL–23 regulatory cytokines that may be responsible for the inflammation producing the patient's symptoms, the applicant stated that Stelara® has a different mechanism of action designed to treat patients that failed other Crohn's disease treatments. The applicant believed that this distinction makes Stelara® new and different for treating some patients with Crohn's disease. The applicant provided comments reflecting that clinicians have learned that different patients with Crohn's disease require different types of cytokine inhibition to target the inflammatory process *in each particular patient.* The applicant believed that this is an example of personalized medicine—choosing the right biologic for the right patient at the right time. Therefore, according to the applicant, Stelara®'s mechanism of action provides a treatment option for patients with CD where others have been unsuccessful.

Response: We appreciate the comments we received from the applicant on whether or not Stelara® meets the newness criterion.

After consideration of the public comments we received, we believe that Stelara® has a unique mechanism of action because it is unique from other immune system suppressors in that it targets the IL–12 and IL–23 regulatory cytokines. Therefore, Stelara® meets the newness criterion for new technology add-on payments.

With regard to the cost criterion, the applicant conducted the following analysis to demonstrate that Stelara® meets the cost criterion. The applicant searched claims from the FY 2015 MedPAR file for cases with a principal ICD–9–CM diagnosis of 555.x (Regional Enteritis), which are cases of a diagnosis of Crohn's Disease that may be eligible for treatment using Stelara®.

The applicant identified 10,344 cases that mapped to 35 MS–DRGs. Approximately 85 percent of cases mapped to the following Inflammatory Bowel MS–DRGs: MS–DRGs 385 (Inflammatory Bowel Disease with MCC), 386 (Inflammatory Bowel Disease with CC), and 387 (Inflammatory Bowel Disease without CC/MCC). Similarly, 11 percent of the cases mapped to the following MS–DRGs for bowel surgery: MS–DRGs 329 (Major Small and Large Bowel Procedures with MCC), 330 (Major Small and Large Bowel Procedures with CC), and 331 (Major Small and Large Bowel Procedures without CC/MCC). The remaining cases (4 percent) represented all other digestive system disorders.

Using the 10,344 identified cases, the average unstandardized case-weighted charge per case was $39,935. The applicant then standardized the charges. The applicant did not remove charges for the current treatment because as discussed above Stelara® is indicated for use in patients who fail other treatments. The applicant then applied the 2-year inflation factor of 1.098446 from the FY 2017 IPPS/LTCH PPS final rule (81 FR 57286) to inflate the charges from FY 2015 to FY 2017. The applicant then added charges for the Stelara® technology. Specifically, the applicant assumed that hospitals would mark up Stelara® IV to the same extent that they currently mark-up Stelara® SC (J3357, ustekinumab, 1 mg). The applicant used the actual hospital mark-up based on charges in the CY 2017 OPPS/ASC proposed rule file (OPPS claims incurred and paid in CY 2015). Based on the FY 2017 IPPS/LTCH PPS Table 10 thresholds, the average case-weighted threshold amount was $55,023. The inflated average case-weighted standardized charge per case was $69,826. Because the inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19886), we invited public comments on whether Stelara® meets the cost criterion.

Comment: The applicant submitted public comments reiterating its cost analysis results. According to the applicant, the inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount. The applicant maintained that the technology meets the cost criterion.

Response: After consideration of the public comments we received, we agree that Stelara® meets the cost criterion.

With regard to the third criterion, whether a technology represents a substantial clinical improvement over existing technologies, according to the

applicant, the new use of the Stelara® has been shown to produce clinical response and remission in patients diagnosed with moderate to severe CD who have failed treatment using conventional therapies, including antibiotics, mesalamine, corticosteroids, immunomodulators, and TNFα inhibitors. Stelara® has been commercially available on the U.S. market for the treatment of patients diagnosed with psoriasis (PsO) since 2009 and the treatment of patients diagnosed with psoriatic arthritis (PsA) since 2013, and the applicant has maintained a safety registry, which enrolled over 12,000 patients since 2007. According to the applicant, the drug has been extremely well-tolerated, and the safety profile in patients diagnosed with CD has been consistent with that experienced in cases representing patients diagnosed with PsO and PsA.

The applicant presented the results of three pivotal trials involving over 1,300 patients diagnosed with moderate to severe CD. All three trials utilized a multicenter, double-blind, placebo controlled study design. There were two single-dose IV induction trials, which included patients who had failed treatment using one or more TNFα inhibitors (UNITI–1) (N = 741), and patients who had failed treatment using corticosteroids and/or immunomodulators (UNITI–2) (N = 628). Responders to the single IV induction dose were then eligible to be enrolled in a maintenance trial (IM–UNITI) (N = 397), which began 8 weeks after administration of the single IV induction dose. IM–UNITI patients were given subcutaneous Stelara® and were treated for 44 weeks. Over half of the patients treated with 90 mg of Stelara® every 12 weeks were able to achieve remission; a highly significant response compared to placebo, according to the applicant. The results of these trials have been published by the *New England Journal of Medicine* and the applicant provided the published studies.[17] The published study supported the applicant's assertion that Stelara® single IV dose induces response and remission in patients diagnosed with moderately to severely active CD that is refractory to either TNF antagonists or conventional therapy. Of the patients in the IM–UNITI trial receiving subcutaneous Stelara® at 8 weeks or 12 weeks, 53.1 percent and 48 percent, respectively, were in remission at week 44 as compared with 35.9 percent of those patients receiving treatment using placebo.

The applicant submitted published results of a multicenter, double-blind, placebo controlled Phase III study of Stelara®.[18] In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19886), we indicated that we were concerned that the study did not effectively establish the need for Stelara® induction therapy. Also, the median age of patients in the study was 37 years, and we stated that we were concerned that the study did not include a significant amount of older patients.

We also indicated that we were concerned that we do not have enough information to determine that the new use of the Stelara® is a substantial clinical improvement over existing technologies for the treatment of moderate to severe CD. We noted that the UNITI–1, UNITI–2, and IMUNITI trials were completed to evaluate efficacy and safety of Stelara®, not superiority of Stelara® to current conventional therapy. Our concerns were based on a lack of head-to-head trials comparing IV induction and maintenance Stelara® therapy with conventional therapy in patients diagnosed with moderate to severe CD that are also primary and secondary nonresponders to treatment using TNF alpha inhibitor[19] therapy. We recognized the subset of primary and secondary nonresponder patients to TNF inhibitor treatments as a patient population unresponsive to, or ineligible for, currently available treatments for diagnoses of moderate to severe CD. However, we stated that we believe that this primary and secondary TNF alpha inhibitor non-responder patient population represents patients that experience a gap in treatment for diagnoses of moderate to severe CD. Specifically, we recognized the nonresponder patient population as described by Simon et al.[20] as those patients who are TNF inhibitor immunogenicity failures, pharmacokinetic failures, and/or pharmacodynamics failures. We also noted the supplement data in Feagan et al.'s publication[21] summarized the primary and secondary nonresponders in UNITI–1. However, we stated that we were not clear how the inclusion of the TNF alpha inhibitor intolerant patients with primary and secondary TNF alpha inhibitor failure patients impacts the final comparison of the placebo and treatment arms. In addition, we noted that, in the UNITI–1, UNITI–2, and IMUNITI studies, all treatment arms were allowed to continue conventional treatments for diagnoses of CD throughout the study. We stated that we were concerned that it is difficult to determine whether the new use of the Stelara® represents a substantial clinical improvement over existing technologies with the concomitant use of other conventional CD medications throughout the duration of the UNITI–1, UNITI–2, and IMUNITI studies.

Also, as mentioned earlier, based on the indications for the use of the Stelara®, there is a class of patients who failed, or were intolerant to, treatment with immunomodulators or corticosteroids, but never failed treatment using a TNF blocker. According to the applicant, for those patients who never failed treatment using a TNF blocker, this patient population can be recognized as two separate patient populations: One patient population representing patients who never received treatment using a TNF blocker; or the other patient population representing patients who received and responded to treatment using a TNF blocker. In the patient population that did not receive treatment using a TNF blocker, we stated that we were unsure if the new use of the Stelara® represents a substantial clinical improvement because it is possible that some patients will have a positive response to treatment using a TNF blocker and will not respond successfully to treatment using Stelara®, or some patients may have a positive response to both treatment using a TNF blocker and using Stelara®, or some patients may not respond to treatment using a TNF blocker, but will have a positive response to treatment using Stelara®.

In the proposed rule, we invited public comments on whether the Stelara® meets the substantial clinical improvement criterion. We noted that we did not receive any written public comments in response to the New Technology Town Hall meeting notice regarding the application of Stelara® for new technology add-on payments.

Comment: The applicant submitted public comments addressing CMS' concerns. The applicant stated that the first dose of any therapy may be considered induction therapy. The applicant reiterated the results of its early trials which demonstrated that

[17] Feagan, W.J., et al. (2016) Ustekinumab as Induction and Maintenance Therapy for Crohn' Disease. The New England Journal of Medicine. 2016 Nov 17; 3745(20):1946–60.

[18] Ibid.

[19] Ibid.

[20] Simon E.G., et al., (2016) Ustekinumab for the treatment of Crohn's disease: can it find its niche? Therapeutic Advances in Gastroenterology. 2016 Jan; 9(1):26–36.

[21] Feagan, W.J., et al. (2016) Ustekinumab as Induction and Maintenance Therapy for Crohn' Disease. The New England Journal of Medicine. 2016 Nov 17; 3745(20):1946–60.

intravenous induction therapy was superior to subcutaneous administration and that higher intravenous doses appeared to be more efficacious than lower subcutaneous doses. The applicant noted that IBD experts are generally in agreement that higher doses of biologics are required at the outset to induce remission, while lower and less frequent doses may be adequate to maintain remission in a maintenance setting.

The applicant also submitted comments addressing CMS' concerns with regards to the lack of head-to-head clinical trials comparing IV induction and maintenance Stelara® therapy with conventional therapy in patients diagnosed with moderate to severe CD that are also primary and secondary nonresponders to treatment using TNF alpha inhibitor therapy. The applicant stated that the UNITI trials were, in fact, head-to-head trials—the placebo group was receiving active treatment and was not truly a placebo group. Those patients continued the conventional therapies they were taking prior to study entry. The applicant noted that the UNITI induction trials covered the breadth of CD patients and that the UNITI–2 population had failed either corticosteroids and/or immunomodulators—these drugs are both recognized as standard conventional therapy for CD according to the applicant. The UNITI–1 population had failed at least one TNF inhibitor; in fact, approximately 50 percent had failed greater than one. This patient population, according to the applicant, is considered to be the most difficult group to treat in that they had, in most cases, already failed not only non-biologic therapy with corticosteroids and/or immunomodulators, but TNF inhibitors as well. The applicant summarized that the trials should be considered head-to-head comparing Stelara® to conventional therapies.

Response: We appreciate the comments submitted by the applicant in response to our concerns. After consideration of the public comments we received, which clarify the placebo group as having received conventional therapies and, therefore, the clinical trials did compare Stelara® to existing therapies, we believe Stelara® meets the substantial clinical improvement criterion because, according to the studies provided by the applicant, Stelara® produced a clinical response and remission in patients with moderate to severe Crohn's Disease who have failed conventional therapies, including antibiotics, mesalamines, corticosteroids, immunomodulators, and TNFα inhibitors as outlined in their label. Specifically, Stelara® targets cytokines IL–12 and IL–23 which are responsible for inflammation in CD, offering a treatment option, otherwise not available, for a specific patient population. Stelara® provides a treatment option for this difficult-to-treat patient population.

We have determined that Stelara® meets all of the criteria for approval of new technology add-on payments. Therefore, we are approving new technology add-on payments for Stelara® for FY 2018. We expect that Stelara® will be administered for the treatment of adult patients (18 years and older) diagnosed with moderately to severely active CD who have: (1) Failed or were intolerant to treatment using immunomodulators or corticosteroids, but never failed a tumor necrosis factor (TNF) blocker; or (2) failed or were intolerant to treatment using one or more TNF blockers. Cases involving Stelara® that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code XW033F3 (Introduction of other New Technology therapeutic substance into peripheral vein, percutaneous approach, New Technology Group 3). In its application, the applicant estimated that the average dose of Stelara® administered through IV infusion is 390 mg which would require 3 vials of Stelara IV at a hospital acquisition cost of $1,600 per vial (for a total of $4,800). Under 42 CFR 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment amount for a case involving the use of STELARA™ is $2,400 for FY 2018.

III. Changes to the Hospital Wage Index for Acute Care Hospitals

A. Background

1. Legislative Authority

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary adjust the standardized amounts for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. We currently define hospital labor market areas based on the delineations of statistical areas established by the Office of Management and Budget (OMB). A discussion of the FY 2018 hospital wage index based on the statistical areas appears under section III.A.2. of the preamble of this final rule.

Section 1886(d)(3)(E) of the Act requires the Secretary to update the wage index annually and to base the update on a survey of wages and wage-related costs of short-term, acute care hospitals. (CMS collects these data on the Medicare cost report, CMS Form 2552–10, Worksheet S–3, Parts II, III, and IV. The OMB control number for approved collection of this information is 0938–0050.) This provision also requires that any updates or adjustments to the wage index be made in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. The adjustment for FY 2018 is discussed in section II.B. of the Addendum to this final rule.

As discussed in section III.I. of the preamble of this final rule, we also take into account the geographic reclassification of hospitals in accordance with sections 1886(d)(8)(B) and 1886(d)(10) of the Act when calculating IPPS payment amounts. Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amounts so as to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B), 1886(d)(8)(C), and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. The budget neutrality adjustment for FY 2018 is discussed in section II.A.4.b. of the Addendum to this final rule.

Section 1886(d)(3)(E) of the Act also provides for the collection of data every 3 years on the occupational mix of employees for short-term, acute care hospitals participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index. A discussion of the occupational mix adjustment that we are applying to the FY 2018 wage index appears under sections III.E.3. and F. of the preamble of this final rule.

2. Core-Based Statistical Areas (CBSAs) for the FY 2018 Hospital Wage Index

The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on OMB-established Core-Based Statistical Areas (CBSAs). The current statistical areas (which were implemented beginning with FY 2015) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No. 13–01. OMB Bulletin No.

13–01 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico based on the 2010 Census, and provided guidance on the use of the delineations of these statistical areas using standards published on June 28, 2010 in the **Federal Register** (75 FR 37246 through 37252). We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963) for a full discussion of our implementation of the OMB labor market area delineations beginning with the FY 2015 wage index.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses through OMB Bulletins. On July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provides updates to and supersedes OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provides detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15–01 are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913), we adopted the updates set forth in OMB Bulletin No. 15–01 effective October 1, 2016, beginning with the FY 2017 wage index. For a complete discussion of the adoption of the updates set forth in OMB Bulletin No. 15–01, we refer readers to the FY 2017 IPPS/LTCH PPS final rule.

For FY 2018, we are continuing to use the OMB delineations that we adopted beginning with FY 2015 to calculate the area wage indexes, with updates as reflected in OMB Bulletin No. 15–01 specified in the FY 2017 IPPS/LTCH PPS final rule.

3. Codes for Constituent Counties in CBSAs

CBSAs are made up of one or more constituent counties. Each CBSA and constituent county has its own unique identifying codes. There are two different lists of codes associated with counties: Social Security Administration (SSA) codes and Federal Information Processing Standard (FIPS) codes. Historically, CMS has listed and used SSA and FIPS county codes to identify and crosswalk counties to CBSA codes for purposes of the hospital wage index. We have learned that SSA county codes are no longer being maintained and updated. However, the FIPS codes continue to be maintained by the U.S. Census Bureau. The Census Bureau's most current statistical area information is derived from ongoing census data received since 2010; the most recent data are from 2015. For the purposes of crosswalking counties to CBSAs, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19898 through 19899), we proposed to discontinue the use of SSA county codes and begin using only the FIPS county codes.

The Census Bureau maintains a complete list of changes to counties or county equivalent entities on the Web site at: *https://www.census.gov/geo/reference/county-changes.html*. In our proposed transition to using only FIPS codes for counties for the hospital wage index, we proposed to update the FIPS codes used for crosswalking counties to CBSAs for the hospital wage index to incorporate changes to the counties or county equivalent entities included in the Census Bureau's most recent list. Based on information included in the Census Bureau's Web site, since 2010, the Census Bureau has made the following updates to the FIPS codes for counties or county equivalent entities:

- Petersburg Borough, AK (FIPS State County Code 02–195), CBSA 02, was created from part of former Petersburg Census Area (02–195) and part of Hoonah-Angoon Census Area (02–105). The CBSA code remains 02.
- The name of La Salle Parish, LA (FIPS State County Code 22–059), CBSA 14, is now LaSalle Parish, LA (FIPS State County Code 22–059). The CBSA code remains as 14.
- The name of Shannon County, SD (FIPS State County Code 46–113), CBSA 43, is now Oglala Lakota County, SD (FIPS State County Code 46–102). The CBSA code remains as 43.

We believe that it is important to use the latest counties or county equivalent entities in order to properly crosswalk hospitals from a county to a CBSA for purposes of the hospital wage index used under the IPPS. In addition, we believe that using the latest FIPS codes will allow us to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19898 through 19899), we proposed to implement these FIPS code updates, effective October 1, 2017, beginning with the FY 2018 wage indexes. We proposed to use these update changes to calculate area wage indexes in a manner that is generally consistent with the CBSA-based methodologies finalized in the FY 2005 IPPS final rule and the FY 2015 IPPS/LTCH PPS final rule. We note that while the county update changes listed earlier changed the county names, the CBSAs to which these counties map did not change from the prior counties. Therefore, there is no impact or change to hospitals in these counties; they continue to be considered rural for the hospital wage index under these changes. We invited public comments on our proposals.

We did not receive any public comments on our proposals. Therefore, for the reasons discussed earlier, we are finalizing our proposal, without modification, to discontinue the use of the SSA county codes and begin using only the FIPS county codes for purposes of crosswalking counties to CBSAs. In addition, we are finalizing our proposal, without modification, to implement the latest FIPS code updates, as discussed earlier, effective October 1, 2017, beginning with the FY 2018 wage indexes. As we proposed, we will use these update changes to calculate the wage indexes in a manner that is generally consistent with the CBSA-based methodologies finalized in the FY 2005 IPPS final rule and the FY 2015 IPPS/LTCH PPS final rule. For FY 2018, Tables 2 and 3 associated with this final rule and the County to CBSA Crosswalk File and Urban CBSAs and Constituent Counties for Acute Care Hospitals File posted on the CMS Web site reflect these county changes.

B. Worksheet S–3 Wage Data for the FY 2018 Wage Index

The FY 2018 wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2014 (the FY 2017 wage indexes were based on data from cost reporting periods beginning during FY 2013).

1. Included Categories of Costs

The FY 2018 wage index includes all of the following categories of data associated with costs paid under the IPPS (as well as outpatient costs):

- Salaries and hours from short-term, acute care hospitals (including paid lunch hours and hours associated with military leave and jury duty);
- Home office costs and hours;
- Certain contract labor costs and hours, which include direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services, and certain contract indirect patient care services (as discussed in the FY 2008 final rule

with comment period (72 FR 47315 through 47317)); and

• Wage-related costs, including pension costs (based on policies adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51586 through 51590)) and other deferred compensation costs.

2. Excluded Categories of Costs

Consistent with the wage index methodology for FY 2017, the wage index for FY 2018 also excludes the direct and overhead salaries and hours for services not subject to IPPS payment, such as skilled nursing facility (SNF) services, home health services, costs related to GME (teaching physicians and residents) and certified registered nurse anesthetists (CRNAs), and other subprovider components that are not paid under the IPPS. The FY 2018 wage index also excludes the salaries, hours, and wage-related costs of hospital-based rural health clinics (RHCs), and Federally qualified health centers (FQHCs) because Medicare pays for these costs outside of the IPPS (68 FR 45395). In addition, salaries, hours, and wage-related costs of CAHs are excluded from the wage index for the reasons explained in the FY 2004 IPPS final rule (68 FR 45397 through 45398).

3. Use of Wage Index Data by Suppliers and Providers Other Than Acute Care Hospitals Under the IPPS

Data collected for the IPPS wage index also are currently used to calculate wage indexes applicable to suppliers and other providers, such as SNFs, home health agencies (HHAs), ambulatory surgical centers (ASCs), and hospices. In addition, they are used for prospective payments to IRFs, IPFs, and LTCHs, and for hospital outpatient services. We note that, in the IPPS rules, we do not address comments pertaining to the wage indexes of any supplier or provider except IPPS providers and LTCHs. Such comments should be made in response to separate proposed rules for those suppliers and providers.

C. Verification of Worksheet S–3 Wage Data

The wage data for the FY 2018 wage index were obtained from Worksheet S–3, Parts II and III of the Medicare cost report (Form CMS–2552–10) for cost reporting periods beginning on or after October 1, 2013, and before October 1, 2014. For wage index purposes, we refer to cost reports during this period as the ''FY 2014 cost report,'' the ''FY 2014 wage data,'' or the ''FY 2014 data.'' Instructions for completing the wage index sections of Worksheet S–3 are included in the Provider Reimbursement Manual (PRM), Part 2 (Pub.15–2), Chapter 40, Sections 4005.2 through 4005.4. The data file used to construct the FY 2018 wage index includes FY 2014 data submitted to us as of June 14, 2017. As in past years, we performed an extensive review of the wage data, mostly through the use of edits designed to identify aberrant data.

We asked our MACs to revise or verify data elements that result in specific edit failures. For the proposed FY 2018 wage index, we identified and excluded 51 providers with aberrant data that should not be included in the wage index, although we stated in the FY 2018 IPPS/LTCH PPS proposed rule that if data elements for some of these providers are corrected, we intend to include data from those providers in the final FY 2018 wage index (82 FR 19899). We note that of the 51 hospitals that we excluded from the proposed wage index, some hospitals had data that we did not expect to change or improve (for example, among the reasons these providers were excluded are: They are low Medicare utilization providers; they closed and failed edits for reasonableness; or they have extremely high or low average hourly wages that are atypical for their CBSAs). We also adjusted certain aberrant data and included these data in the proposed wage index. For example, in situations where a hospital did not have documentable salaries, wages, and hours for housekeeping and dietary services, we imputed estimates, in accordance with policies established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965 through 49967). We instructed MACs to complete their data verification of questionable data elements and to transmit any changes to the wage data no later than March 24, 2017. In addition, as a result of the April and May appeals processes, and posting of the April 28, 2017 PUF, we have made additional revisions to the FY 2018 wage data, as described further below. The revised data are reflected in this FY 2018 IPPS/LTCH PPS final rule.

In constructing the proposed FY 2018 wage index, we included the wage data for facilities that were IPPS hospitals in FY 2014, inclusive of those facilities that have since terminated their participation in the program as hospitals, as long as those data did not fail any of our edits for reasonableness. We believed that including the wage data for these hospitals is, in general, appropriate to reflect the economic conditions in the various labor market areas during the relevant past period and to ensure that the current wage index represents the labor market area's current wages as compared to the national average of wages. However, we excluded the wage data for CAHs as discussed in the FY 2004 IPPS final rule (68 FR 45397 through 45398). For the proposed rule, we removed 7 hospitals that converted to CAH status on or after January 22, 2016, the cut-off date for CAH exclusion from the FY 2017 wage index, and through and including January 23, 2017, the cut-off date for CAH exclusion from the FY 2018 wage index. After excluding CAHs and hospitals with aberrant data, we calculated the proposed wage index using the Worksheet S–3, Parts II and III wage data of 3,325 hospitals.

Since the development of the FY 2018 proposed wage index, as a result of further review by the MACs and the April and May appeals processes, we received improved data for 15 hospitals and are including the wage data of these 15 hospitals in the final wage index. However, during our review of the wage data in preparation of the April 28, 2017 PUF, we identified and deleted the data of 2 additional hospitals whose data we determined to be aberrant (unusually low average hourly wages) relative to their CBSAs, and there was insufficient documentation provided to explain their wage data. Finally, we learned that in the proposed wage index, we inadvertently deleted the data of one hospital when we should have deleted the data of a different hospital. We have corrected this error, although because we were including one hospital while deleting another, there was no effect on the number of hospitals in the wage index. With regard to CAHs, we have since learned of 2 additional hospitals that converted to CAH status on or after January 22, 2016, the cut-off date for CAH exclusion from the FY 2017 wage index, and through and including January 23, 2017, the cut-off date for CAH exclusion from the FY 2018 wage index. Accordingly, we have removed 9 hospitals that converted to CAH status from the FY 2018 wage index. The final FY 2018 wage index is based on the wage index of 3,336 hospitals (3,325 + 15 − 2 − 1 + 1 − 2 = 3,336).

For the final FY 2018 wage index, we allotted the wages and hours data for a multicampus hospital among the different labor market areas where its campuses are located in the same manner that we allotted such hospitals' data in the FY 2017 wage index (81 FR 56915). Table 2, which contains the final FY 2018 wage index associated with this final rule (available via the Internet on the CMS Web site), includes separate wage data for the campuses of 9 multicampus hospitals.

D. Method for Computing the FY 2018 Unadjusted Wage Index

1. Methodology for FY 2018

The method used to compute the FY 2018 wage index without an occupational mix adjustment follows the same methodology that we used to compute the wage indexes without an occupational mix adjustment since FY 2012 (76 FR 51591 through 51593).

Comment: One commenter requested that CMS consider developing a process for determining a wage index that would reward hospitals that invest in the workforce and raise the wages of the lowest paid workers, rather than relying primarily on the average hourly wages of the labor market area as a whole.

Response: Section 1886(d)(3)(E) of the Act requires the Secretary to adjust for area differences in hospital wage levels by a factor reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. The statute does not direct the Secretary to develop a wage index that rewards hospitals for workforce investment or other labor initiatives.

Comment: One commenter requested that CMS establish a floor wage index for providers in Puerto Rico that is not lower than the ratio of Puerto Rico nonhealth care wages to U.S. nonhealth care wages, using data from the Occupational Employment Statistics (OES) of the U.S. Bureau of Labor Statistics (BLS).

Response: We appreciate this comment. However, we consider it to be outside the scope of the FY 2018 IPPS/LTCH PPS proposed rule. Therefore, we are not responding to this comment at this time.

As discussed in the FY 2012 IPPS/LTCH PPS final rule, in ''Step 5,'' for each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2013, through April 15, 2015, for private industry hospital workers from the BLS' *Compensation and Working Conditions.* We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we did not propose any changes to the usage of the ECI for FY 2018. The factors used to adjust the hospital's data were based on the midpoint of the cost reporting period, as indicated in the following table.

MIDPOINT OF COST REPORTING PERIOD

After	Before	Adjustment factor
10/14/2013	11/15/2013	1.02310
11/14/2013	12/15/2013	1.02155
12/14/2013	01/15/2014	1.02004
01/14/2014	02/15/2014	1.01866
02/14/2014	03/15/2014	1.01740
03/14/2014	04/15/2014	1.01615
04/14/2014	05/15/2014	1.01482
05/14/2014	06/15/2014	1.01339
06/14/2014	07/15/2014	1.01193
07/14/2014	08/15/2014	1.01048
08/14/2014	09/15/2014	1.00905
09/14/2014	10/15/2014	1.00761
10/14/2014	11/15/2014	1.00614
11/14/2014	12/15/2014	1.00463
12/14/2014	01/15/2015	1.00309
01/14/2015	02/15/2015	1.00155
02/14/2015	03/15/2015	1.00000
03/14/2015	04/15/2015	0.99845

For example, the midpoint of a cost reporting period beginning January 1, 2014, and ending December 31, 2014, is June 30, 2014. An adjustment factor of 1.01193 would be applied to the wages of a hospital with such a cost reporting period. Using the data as previously described, the FY 2018 national average hourly wage (unadjusted for occupational mix) is $42.1027.

Previously, we also would provide a Puerto Rico overall average hourly wage. As discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56915), prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we calculated a Puerto Rico-specific wage index that was applied to the labor share of the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. As we stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56915 through 56916), because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act, as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need to calculate a Puerto Rico-specific average hourly wage and wage index. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national average hourly wage (unadjusted for occupational mix) (which is $42.1027 for this FY 2018 final rule) and the national wage index, which is applied to the national labor share of the national standardized amount. Therefore, for FY 2018, we did not propose a Puerto Rico-specific overall average hourly wage or wage index.

2. Clarification of Other Wage Related Costs in the Wage Index

Section 1886(d)(3)(E) of the Act requires the Secretary to update the wage index based on a survey of hospitals' costs that are attributable to wages and wage-related costs. In the September 1, 1994 IPPS final rule (59 FR 45356), we developed a list of ''core'' wage-related costs that hospitals may report on Worksheet S–3, Part II of the Medicare hospital cost report in order to include those costs in the wage index. Core wage-related costs include categories of retirement cost, plan administrative costs, health and insurance costs, taxes, and other specified costs such as tuition reimbursement. In addition to these categories of core wage-related costs, we allow hospitals to report wage-related costs other than those on the core list if the other wage-related costs meet certain criteria. The criteria for including other wage-related costs in the wage index are discussed in the September 1, 1994 IPPS final rule (59 FR 45357) and also are listed in the Provider Reimbursement Manual (PRM), Part II, Chapter 40, Sections 4005.2 through 4005.4, Line 18 of the Medicare cost report (Form CMS–2552–10, OMB control number 0938–0050). Specifically, ''other'' wage-related costs are allowable for the wage index if the cost for employees whose services are paid under the IPPS exceeds 1 percent of the total adjusted salaries net of excluded area salaries, is a fringe benefit as defined by the IRS and has been reported to the IRS (as income to the employees or contractors), is not being furnished for the convenience of the provider, and is not listed on Worksheet S–3, Part IV.

We note that other wage-related costs are not to include benefits already included in Line 1 salaries on Worksheet S–3, Part II (refer to the cost report instructions for Worksheet S–3, Part II, Line 18, which state, '' 'Other' wage-related costs do not include wage-related costs reported on line 1 of this worksheet.''). We also note that the 1-percent test is conducted by dividing each individual category of the other wage-related cost (that is, the

numerator) by the sum of the following lines on the Medicare hospital cost report (Form CMS–2552–10): Worksheet S–3, Part II, Lines 11, 12, 13, and 14, Column 4, and Worksheet S–3, Part III, Line 3, Column 4 (that is, the denominator). The other wage-related costs associated with contract labor and home office/related organization personnel are included in the numerator because these other wage-related costs are allowed in the wage index (in addition to other wage-related costs for direct employees), assuming the requirements for inclusion in the wage index are met. For example, if a hospital is trying to include a parking garage as an other-wage related cost that is reported on the W–2 or 1099 form, when running the 1-percent test, include in the numerator all the parking garage other wage-related cost for direct salary employees, contracted employees, and home office employees and divide by the sum of Worksheet S–3, Part II, Lines 11, 12, 13, and 14, Column 4, and Worksheet S–3, Part III, Line 3, Column 4. For the category of parking other wage-related costs, the 1-percent test would be run only one time, inclusive of other wage-related costs for employee salaries, contracted employees, and home office employees. We intend to clarify the hospital cost report instructions to reflect that contract labor and home office/related organization salaries should be added to the subtotal of salaries on Worksheet S–3, Part III, Line 3, Column 4 (Line 3 is the difference of net salaries minus excluded area salaries) for purposes of performing the 1-percent test. If a hospital has more than one other wage-related cost, the 1-percent test must be conducted separately for each other wage-related cost (for example, parking and cafeteria separately; do not sum all the different types of other wage-related costs together and then run the 1-percent test). If the 1-percent test is met for a particular type of other wage-related costs, and the other criteria listed earlier are met as well, the other wage-related cost may be reported on Worksheet S–3, Part II, Line 18 of the hospital cost report.

We originally allowed for the inclusion of wage-related costs other than those on the core list because we were concerned that individual hospitals might incur unusually large wage-related costs that are not reflected on the core list but that may represent a significant wage-related cost. However, as we discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19900 through 19902), we are reconsidering allowing other wage-related costs to be included in the wage index because recent internal reviews of the FY 2018 wage data show that only a small minority of hospitals are reporting other wage-related costs that meet the 1-percent test described earlier. In the calculation of the proposed FY 2018 wage index, for each hospital reporting other wage-related costs on Line 18 of Worksheet S–3, we performed the 1-percent test. We then made internal edits removing other wage-related costs on Line 18 where hospitals reported data that failed to meet the mathematical requirement that other wage-related costs must exceed 1 percent of total adjusted salaries net of excluded area salaries. After this review, only approximately 80 hospitals of approximately 3,320 hospitals had other wage-related costs on Line 18 meeting the 1-percent test. We believe that such a limited number of hospitals nationally reporting and meeting the 1-percent test may indicate that other wage-related costs might not constitute an appropriate part of a relative measure of wage costs in a particular labor market area, a longstanding tenet of the wage index. In other words, while other wage-related costs may represent costs that may have an impact on an individual hospital's average hourly wage, we do not believe that costs reported by only a very small minority of hospitals accurately reflect the economic conditions of the labor market areas in which those hospitals are located. Therefore, it is possible that inclusion of other wage-related costs in the wage index in such a limited manner may distort the average hourly wage of a particular labor market area so that its wage index does not accurately represent that labor market area's current wages relative to national wages.

Furthermore, the open-ended nature of the types of other wage-related costs that may be included on Line 18 of Worksheet S–3, in contrast to the concrete list of core wage-related costs, may hinder consistent and proper reporting of fringe benefits. Our internal review indicates widely divergent types of costs that hospitals are reporting as other wage-related costs on Line 18. We are concerned that inconsistent reporting of other wage-related costs on Line 18 further compromises the accuracy of the wage index as a representation of the relative average hourly wage for each labor market area. Our intent in creating a core list of wage-related costs in the September 1, 1994 IPPS final rule was to promote consistent reporting of fringe benefits, and we are increasingly concerned that inconsistent reporting of wage-related costs on Line 18 of Worksheet S–3 undermines this effort. Specifically, we expressed in the September 1, 1994 IPPS final rule that, since we began including fringe benefits in the wage index, we have been concerned with the inconsistent reporting of fringe benefits, whether because of a lack of provider proficiency in identifying fringe benefit costs or varying interpretations across fiscal intermediaries of the definition for fringe benefits in PRM–I, Section 2144.1 (59 FR 45356).

We believe that the limited and inconsistent use of Line 18 of Worksheet S–3 for reporting wage-related costs other than the core list might indicate that including other wage-related costs in the wage index compromises the accuracy of the wage index as a relative measure of wages in a given labor market area. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19901), we sought public comments on whether we should, in future rulemaking, propose to only include the wage-related costs on the core list in the calculation of the wage index and not to include any other wage-related costs in the calculation of the wage index.

Meanwhile, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19901 through 19902), we clarified that, under our current policy, an other wage-related cost (which we define as the value of a benefit) must be a fringe benefit as described by the IRS (refer to IRS Publication 15–B) and must be reported to the IRS on employees' or contractors' W–2 or 1099 forms as taxable income in order to be considered an other wage-related cost on Line 18 of Worksheet S–3 and for the wage index. That is, other wage-related costs that are not reported to the IRS on employees' or contractors' W–2 or 1099 forms as taxable income, *even if not required to be reported to the IRS according to IRS requirements,* will *not* be included in the wage index. This is consistent with current cost report instructions for Line 18 of Worksheet S–3, Part II of the Medicare cost report, Form 2552–10, which state that, to be considered an allowable other wage-related cost, the cost ''has been reported to the IRS.'' We will apply this policy to the process for calculating the wage index for FY 2019, including the FY 2019 desk reviews beginning in September 2017.

As we stated in the FY 2018 proposed rule, we believe this clarification is necessary because some hospitals have incorrectly interpreted prior manual and existing preamble language to mean that a cost could be considered an other wage-related cost if the provider's reporting (or not reporting) of the cost

was in accordance with IRS requirements, rather than if the cost was actually reported on an employee's or contractor's W–2 or 1099 form as taxable income. We believe that such an interpretation of our policy would require an analysis of whether the reporting or not reporting of the cost to the IRS was done properly in accordance with IRS regulations and guidance in order to allow the cost as an other wage-related cost. We believe that the determinations regarding the proper or improper reporting of certain other wage-related costs to the IRS for the purpose of inclusion in the Medicare wage index are impractical for CMS and the MACs because we do not have the expertise and fluency in IRS regulations and tax law sufficient to perform such technical reviews of hospital wage-related costs. In contrast, our current policy of including an amount as an other wage-related cost for wage index purposes only if the amount was actually reported to the IRS on employees' or contractors' W–2 or 1099 forms as taxable income is a straightforward policy that we believe provides clarity to all involved parties. The brightline test of allowing an other wage-related cost to be included in the wage index only if it has been reported on an employee's or contractor's W–2 or 1099 form as taxable income helps ensure consistent treatment of other wage-related costs for all hospitals. Considering the variety of types of costs that may be included on Line 18 of Worksheet S–3 of the cost report for other wage-related costs (assuming the 1-percent test is met and other criteria are met), we believe that a straightforward policy that is simple for hospitals and CMS to apply is particularly important.

In addition, we believe the policy we are clarifying that an other wage-related cost can be included in the wage index only if it was reported to the IRS as taxable income on the employee's or contractor's W–2 or 1099, is consistent with CMS' longstanding position that a fringe benefit is not furnished for the convenience of the employer or otherwise excludable from income as a fringe benefit (such as a working condition fringe) and that inappropriate types of costs may not be included in the wage index. In response to a comment when we finalized the criteria for other wage-related costs in the September 1, 1994 IPPS final rule (59 FR 45359), we stated that ''items such as the unrecovered cost of employee meals, tuition reimbursement, and auto allowances will only be allowed as a wage-related cost for purposes of the wage index if properly reported to the IRS on an employee's W–2 form as a fringe benefit.'' (We note that the September 1, 1994 IPPS final rule does not mention the 1099 form for contractors, as contract labor was not allowed at that time in the wage index. Consistent with our treatment of costs for contract labor similar to that of employees for the wage index, we are clarifying that the requirement that a cost be reported to the IRS to be allowed as a wage-related cost for the wage index also applies to contract labor, which must be reported on the contractor's 1099 to be allowed as a wage-related cost for the wage index.) We believe that requiring other wage-related costs to be reported on employees' or contractors' W–2 or 1099 forms to be allowable for Line 18 of Worksheet S–3 of the Medicare cost report is consistent with the requirement that the cost is not being furnished for the convenience of the employer. A cost reported on an employee's or contractor's W–2 or 1099 form as taxable income is clearly a wage-related cost that is provided solely for the benefit of the employee. We believe that the requirement that other wage-related costs be a benefit to the employee also guarantees that administrative costs such as overhead and capitalized costs are excluded from other wage-related costs in the wage index.

Therefore, for the reasons discussed above, as we discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19901 through 19902), we are clarifying that a cost must be a fringe benefit as described by the IRS and must be reported to the IRS on employees' or contractors' W–2 or 1099 forms as taxable income in order to be considered an other wage-related cost on Line 18 of Worksheet S–3 and for the wage index. In addition, as discussed earlier, in the proposed rule, we requested public comments on whether we should consider in future rulemaking removing other wage-related costs from the wage index.

Because some hospitals have incorrectly interpreted prior manual and existing preamble language, as stated earlier, in the proposed rule we restated the criteria from the September 1, 1994 IPPS final rule (59 FR 45357) for allowing other wage-related costs for the wage index, with clarifications. The criteria follow below, and as stated in the proposed rule, we intend to update the manual with these clarifications: *Other Wage-Related Costs.* A hospital may be able to report a wage-related cost (defined as the value of the benefit) that does not appear on the core list if it meets all of the following criteria:

- The wage-related cost is provided at a significant financial cost to the employer. To meet this test, the individual wage-related cost must be greater than 1 percent of total salaries after the direct excluded salaries are removed (the sum of Worksheet S–3, Part II, Lines 11, 12, 13, 14, column 4, and Worksheet S–3, Part III, Line 3, Column 4).
- The wage-related cost is a fringe benefit as described by the IRS and is reported to the IRS on an employee's or contractor's W–2 or 1099 form as taxable income.
- The wage-related cost is not furnished for the convenience of the provider or otherwise excludable from income as a fringe benefit (such as a working condition fringe).

We note that those wage-related costs *reported* as salaries on Line 1 (for example, loan forgiveness and sick pay accruals) should not be included as other wage-related costs on Line 18.

Comment: One commenter fully supported CMS proposing in future rulemaking to only include the wage-related costs on the core list in the calculation of the wage index and not to include any other wage-related costs in the calculation of the wage index. The commenter reiterated CMS' observation that only a small minority of hospitals benefit from the reporting of other wage-related costs, emphasizing that the inclusion of other wage-related costs in the wage index in such a limited manner distorts the average hourly wage of a particular labor market area so that its wage index does not accurately represent that labor market area's current wages relative to national wages. Several commenters did not oppose CMS proposing in future rulemaking to only include wage-related costs on the core list but requested that CMS first consider convening stakeholders for additional input prior to the removal of the item. Similarly, one commenter requested that CMS be as transparent as possible and provide complete information on the impact on the wage index for all areas of the country in future rulemaking if CMS proposes to exclude other wage-related costs from the wage index calculation.

Response: We appreciate the commenter's support for our proposing in future rulemaking to consider only including the wage-related costs on the core list in the calculation of the wage index and not to include any other wage-related costs in the calculation of the wage index. In response to the commenters who requested that CMS first consider convening stakeholders

for additional input prior to the removal of other wage-related costs (on Line 18 of Worksheet S–3) from the wage index, we are reassuring the commenters that we would engage in notice-and-comment rulemaking in order to solicit stakeholder input before removing Line 18 of Worksheet S–3 from the wage index calculation. Similarly, we endeavor to be as transparent as possible and, if appropriate, may consider providing information on the impact on the wage index for all areas of the country in future rulemaking if we propose to exclude other wage-related costs from the wage index calculation.

Comment: Two commenters applauded CMS' goals of achieving a more equitable and accurate wage index, but suggested that CMS address the inadequacies in the current reporting requirements for noncore other wage-related costs rather than consider eliminating Line 18 of Worksheet S–3 of the Medicare cost report from the wage index. These commenters asserted that all hospitals have noncore benefits. However, the commenters added, the limited guidance and ''significant threshold limitations'' in the current instructions prevent hospitals from capturing these noncore benefits. Furthermore, the commenters maintained that benefits are rapidly evolving into more nontraditional structures and, therefore, a mechanism to capture these evolving benefits is necessary for CMS to ensure an equitable survey. The commenters submitted several suggestions to ensure open and transparent reporting of other wage-related costs and to remove the onus from CMS and the MAC to make determinations regarding the acceptability of other wage-related costs. The commenters believed that clear and consistent reporting guidelines create an equitable playing field for all providers and stated that addressing the inadequacies in the current reporting requirements for Line 18 is prudent. However, the commenters suggested an approach different than CMS' clarifications of current policy to more accurately identify and capture other wage-related costs.

Response: We appreciate the feedback from commenters in favor of our improving the current reporting requirements for noncore other wage-related costs rather than considering eliminating Line 18 of Worksheet S–3 from the wage index calculation. We are not eliminating Line 18 from the wage index calculation at this time. Rather, in line with the commenters' recommendation, we are clarifying the requirements for Line 18 in this final rule to facilitate consistent and accurate reporting of other wage-related costs for the wage index. We share the commenters' interests in reporting guidelines that are clear, consistent, and equitable. The commenters' specific suggestions and our responses follow below:

Comment: Commenters suggested that CMS, with input from providers, define a specific list of noncore benefits commonly shared by a large number of providers for inclusion in the wage index, such as employee parking and transit costs, uniform costs, and meal allowances. The commenters suggested that CMS approach the identification of noncore benefits with the same specificity as it does with core benefits in order to ensure an equitable wage index, more easily address tax issues, and allow more direct application of the employer convenience test.

Response: We appreciate the commenters' suggestion and agree that defined lists of allowable costs are generally helpful to support consistent and equitable reporting. In fact, our intent in creating a core list of wage-related costs in the September 1, 1994 IPPS final rule was to promote ''more equitable and consistent reporting of wage-related costs for all hospitals'' (59 FR 45356). When developing the list of core wage-related costs, we stated that one or more of the following criteria must be met to be considered a core wage-related cost: The wage-related cost is provided at a significant financial cost to the employer; the wage-related cost is of a type and nature that would generally be offered as a fringe benefit by most employers; the perceived value of this wage-related cost is of such importance that it would influence an individual's employment decisions; and the wage-related cost is a mandatory requirement under Federal or State law (for example FICA, Federal and State unemployment, among others) (59 FR 45356).

If there are noncore benefits that are of a type and nature that would generally be offered as a fringe benefit by most employers, as the commenters suggested, we believe that perhaps these costs should be added to the core list rather than defined separately as a list of other wage-related costs. In future rulemaking, we may consider this suggestion in the form of seeking hospitals' input on expanding the core list of wage-related costs to include common wage-related costs (such as parking) that are currently considered other wage-related costs.

Comment: Commenters suggested that the taxable or nontaxable nature of the benefit should not be a determinant for inclusion as a noncore benefit. In the commenters' opinion, CMS made too broad a connection between taxable reporting and the employer convenience test; specifically, many employee benefits are not taxable due to dollar threshold exclusions and public policy considerations by Congress and the IRS. Furthermore, the commenters pointed out that evolving tax law could cause volatility in the wage index because what is considered a taxable benefit one year may not be taxable in the next year.

Rather, the commenters suggested that, in order for other wage-related costs to be included in the wage index, CMS require other wage-related costs to be reported to the IRS on the W–2, regardless of whether the benefit is taxable or not (the W–2 allows for reporting of both taxable and nontaxable benefits), and that CMS could then include other wage-related costs in the wage index as long as those costs, whether taxable or nontaxable, are reported on the W–2. The commenters maintained that it should not be the responsibility of CMS or the MACs to prove that the benefit has been handled appropriately for tax purposes, and this requirement to include all taxable and nontaxable costs on the W–2 in order to have those costs included in the wage index would ensure that the benefit has been handled correctly for tax purposes.

Response: In the proposed rule (82 FR 19902), we stated that requiring other wage-related costs to be reported on employees' or contractors' W–2 or 1099 forms to be allowable for Line 18 is consistent with the requirement that the cost is not being furnished for the convenience of the employer because, typically, a cost that is for the convenience of the employer is not taxable as income to the employee. This is not to say that all costs that are a benefit to the employee are taxable. Indeed, in our clarification of the criteria for allowing a cost as an other wage-related costs on Line 18 in the wage index, we specifically stated that ''The wage-related cost is not furnished for the convenience of the provider *or otherwise excludable* from income as a fringe benefit (such as a working condition fringe)'' (emphasis added). That is, we recognize that being furnished for the convenience of the provider is only one of many reasons that a cost may be excludable from income as a fringe benefit.

While we understand that many employee benefits are not taxable due to dollar threshold exclusions and public policy considerations by Congress and the IRS, and thereby excluded from Line 18, we continue to believe that a brightline test is necessary for consistent

treatment of other wage-related costs for all hospitals. Taken with the commenter's suggestion that CMS allow taxable and nontaxable other wage-related costs (assuming other criteria are met) as long as the costs are reported on W–2s or 1099s, we understand that the commenter is suggesting a different brightline test: That the cost be listed on the W–2, regardless of whether the cost is taxable or tax-exempt. We continue to believe that our clarification in the proposed rule is a more straightforward policy than the commenter's suggestion for two reasons. First, not all employers report nontaxable costs on an employee's W–2, nor are they required to do so. Therefore, to allow nontaxable costs so long as those costs are on an employee's W–2 would create an uneven playing field with inconsistent treatment of nontaxable costs. Second, a taxable benefit is typically income-related and a benefit to the employee. While we understand that there may be benefits to the employee that are tax-exempt due to a variety of public policy considerations, we believe that costs should be taxable in order to be incorporated as part of the wage index because the wage index is a relative measure of salaries and wages.

Furthermore, we agree with the commenters' assertion that it should not be the responsibility of CMS or the MACs to prove that the benefit has been handled appropriately for tax purposes. Indeed, it is for that reason that we clarified our current policy of allowing an amount as an other wage-related cost for wage index purposes only if the amount was actually reported to the IRS on employees' or contractors' W–2 or 1099 forms as taxable income. We stated in the proposed rule (82 FR 19901 through 19902) that other wage-related costs that are not reported to the IRS on employees' or contractors' W–2 or 1099 forms as taxable income, *even if not required to be reported to the IRS according to IRS requirements,* will *not* be included in the wage index. We explained that determinations regarding the proper or improper reporting of certain other wage-related costs to the IRS for the purpose of inclusion in the Medicare wage index are impractical for CMS and the MACs because we do not have the expertise and fluency in IRS regulations and tax law sufficient to perform such technical reviews of hospital wage-related costs.

Comment: Commenters suggested that CMS change the 1-percent test to a test in aggregate for the items on their recommended noncore list. For benefits not specifically listed by CMS as noncore, the commenters suggested that CMS continue using the current methodology, which requires each individual benefit to meet the 1-percent test.

Response: We appreciate the commenters' suggestion. However, as we stated earlier, if there are noncore benefits that are of a type and nature that would generally be offered as a fringe benefit by most employers, we believe that perhaps these costs should be added to the core list rather than defined separately as a list of other wage-related costs. In future rulemaking, we may consider this suggestion in the form of seeking hospitals' input on expanding the core list of wage-related costs to include common wage-related costs (such as parking) that are currently considered other wage-related costs.

We continue to believe that it is appropriate for the 1-percent test to be performed on individual, rather than aggregate, other wage-related costs. In response to a public comment, in the September 1, 1994 IPPS final rule (59 FR 45358), we stated that ''[t]he provision to include wage-related costs other than those reflected on the core list is intended to recognize only those limited circumstances where a hospital incurs any additional wage-related cost items that truly represent a significant financial burden to the hospital, but that also meet the current definition of a fringe benefit cost. We believe the 1-percent threshold is an appropriate measure of significance, and that the exclusion of any cost representing less than 1 percent of total salaries would not significantly affect the hospital's overall average hourly wage. We consider the 1-percent test critical in ensuring that providers only include other wage-related costs that contribute significantly to their wage costs and that are not accounted for in the core list.'' We continue to believe that the 1-percent test performed on individual costs ensures that the wage-related cost is provided at a significant financial cost to the employer.

Furthermore, we believe that allowing the 1-percent test to be performed on aggregate other wage-related costs (even on a limited list of other wage-related costs, as the commenter suggests) would lead to inequitable treatment of other wage-related costs. Hospitals with an other wage-related cost comprising an identical percentage of total adjusted salaries net of excluded area salaries could be treated differently, depending on the presence or absence of additional other wage-related costs to collectively ''pass'' the 1-percent test. For example, parking costs totaling .08 percent of total salaries for one hospital could be allowed (assuming the other criteria were met) if the hospital also has additional noncore wage-related costs that combine to exceed 1 percent, while another hospital with parking costs totaling the identical .08 percentage of total salaries could have those costs disallowed in absence of additional noncore wage-related costs to add to the parking costs to exceed 1 percent of salaries.

We appreciate all of the comments submitted on this issue. We will take these comments into consideration in determining whether to propose in future rulemaking to remove other wage-related costs from the wage index calculation. Meanwhile, as discussed earlier and in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19900 through 19902), we are again clarifying that a cost must be a fringe benefit as described by the IRS and must be reported to the IRS on employees' or contractors' W–2 or 1099 forms as taxable income in order to be considered an other wage-related cost on Line 18 of Worksheet S–3 and for the wage index.

E. Occupational Mix Adjustment to the FY 2018 Wage Index

As stated earlier, section 1886(d)(3)(E) of the Act provides for the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index, for application beginning October 1, 2004 (the FY 2005 wage index). The purpose of the occupational mix adjustment is to control for the effect of hospitals' employment choices on the wage index. For example, hospitals may choose to employ different combinations of registered nurses, licensed practical nurses, nursing aides, and medical assistants for the purpose of providing nursing care to their patients. The varying labor costs associated with these choices reflect hospital management decisions rather than geographic differences in the costs of labor.

1. Use of 2013 Occupational Mix Survey for the FY 2018 Wage Index

Section 304(c) of the Consolidated Appropriations Act, 2001 (Pub. L. 106–554) amended section 1886(d)(3)(E) of the Act to require CMS to collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. We collected data in 2013 to compute the occupational mix adjustment for the FY 2016, FY 2017, and FY 2018 wage indexes. A new

measurement of occupational mix is required for FY 2019.

The 2013 survey included the same data elements and definitions as the previous 2010 survey and provided for the collection of hospital-specific wages and hours data for nursing employees for calendar year 2013 (that is, payroll periods ending between January 1, 2013 and December 31, 2013). We published the 2013 survey in the **Federal Register** on February 28, 2013 (78 FR 13679 through 13680). This survey was approved by OMB on May 14, 2013, and is available on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/Medicare-Wage-Index-Occupational-Mix-Survey2013.html*. The 2013 Occupational Mix Survey Hospital Reporting Form CMS–10079 for the Wage Index Beginning FY 2016 (in Excel format) is available on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/Medicare-Wage-Index-Occupational-Mix-Survey2013.html*. Hospitals were required to submit their completed 2013 surveys to their MACs by July 1, 2014. The preliminary, unaudited 2013 survey data were posted on the CMS Web site on July 11, 2014. As with the Worksheet S–3, Parts II and III cost report wage data, we asked our MACs to revise or verify data elements in hospitals' occupational mix surveys that result in certain edit failures.

2. Use of the 2016 Medicare Wage Index Occupational Mix Survey for the FY 2019 Wage Index

As stated earlier, a new measurement of occupational mix is required for FY 2019. The FY 2019 occupational mix adjustment will be based on a new calendar year (CY) 2016 survey. The CY 2016 survey (CMS Form CMS–10079) received OMB approval on September 27, 2016. The final CY 2016 Occupational Mix Survey Hospital Reporting Form is available on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/2016-Occupational-Mix-Survey-Hospital-Reporting-Form-CMS-10079-for-the-Wage-Index-Beginning-FY-2019.html*. Hospitals were required to submit their completed 2016 surveys to their MACs by July 3, 2017. The preliminary, unaudited CY 2016 survey data were posted on the CMS Web site on July 12, 2017. As with the Worksheet S–3, Parts II and III cost report wage data, as part of the FY 2019 desk review process, the MACs will revise or verify data elements in hospitals' occupational mix surveys that result in certain edit failures.

3. Calculation of the Occupational Mix Adjustment for FY 2018

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19903), for FY 2018, we proposed to calculate the occupational mix adjustment factor using the same methodology that we have used since the FY 2012 wage index (76 FR 51582 through 51586) and to apply the occupational mix adjustment to 100 percent of the FY 2018 wage index. Because the statute requires that the Secretary measure the earnings and paid hours of employment by occupational category not less than once every 3 years, all hospitals that are subject to payments under the IPPS, or any hospital that would be subject to the IPPS if not granted a waiver, must complete the occupational mix survey, unless the hospital has no associated cost report wage data that are included in the FY 2018 wage index. For the proposed FY 2018 wage index, we used the Worksheet S–3, Parts II and III wage data of 3,325 hospitals, and we used the occupational mix surveys of 3,128 hospitals for which we also have Worksheet S–3 wage data, which represented a ''response'' rate of 94 percent (3,128/3,325). For the proposed FY 2018 wage index, we applied proxy data for noncompliant hospitals, new hospitals, or hospitals that submitted erroneous or aberrant data in the same manner that we applied proxy data for such hospitals in the FY 2012 wage index occupational mix adjustment (76 FR 51586).

Comment: One commenter stated that all hospitals should be obligated to submit the occupational mix survey because failure to complete the survey jeopardizes the accuracy of the wage index. The commenter suggested that a penalty be instituted for nonsubmitters. This commenter also requested that, pending CMS' analysis of the Commuting Based Wage Index and given the Institute of Medicine's study on geographic variation in hospital wage costs, CMS eliminate the occupational mix survey and the significant reporting burden it creates.

Response: We appreciate the commenter's concern about the accuracy of the wage index. We have continually requested that all hospitals complete and submit the occupational mix surveys. We did not establish a penalty for hospitals that did not submit the 2013 surveys. However, we are continuing to consider for future rulemaking various options for ensuring full compliance with future occupational mix surveys. Regarding the commenter's request that CMS eliminate the occupational mix survey, this survey is necessary to meet the provisions of section 1886(d)(3)(E) of the Act, which requires us to measure the earnings and paid hours of employment by occupational category.

After consideration of the public comments we received, for FY 2018, we are adopting as final our proposal to calculate the occupational mix adjustment factor using the same methodology that we have used since the FY 2012 wage index. For the final FY 2018 wage index, we are using the Worksheet S–3, Parts II and III wage data of 3,336 hospitals, and we are using the occupational mix surveys of 3,138 hospitals for which we also have Worksheet S–3 wage data, which represents a ''response rate'' of 94 percent (3,138/3,336). We note that, in the proposed rule (82 FR 19903), we stated that we used the occupational mix survey of 3,128 hospitals. The reason for the increase in the number of hospitals from 3,128 to 3,138 is that 10 hospitals that had been deleted from the proposed rule wage index and that are now included in the final rule wage index had acceptable occupational mix surveys to use for the final rule. Therefore, we have included the occupational mix surveys of these 10 additional hospitals to calculate the wage index for this final rule. For the final FY 2018 wage index, we applied proxy data for noncompliant hospitals, new hospitals, or hospitals that submitted erroneous or aberrant data in the same manner that we applied proxy data for such hospitals in the FY 2012 wage index occupational mix adjustment (76 FR 51586). As a result of applying this methodology, the FY 2018 occupational mix adjusted national average hourly wage is $42.0564.

F. Analysis and Implementation of the Occupational Mix Adjustment and the FY 2018 Occupational Mix Adjusted Wage Index

As discussed in section III.E. of the preamble of this final rule, for FY 2018, we are applying the occupational mix adjustment to 100 percent of the FY 2018 wage index. We calculated the occupational mix adjustment using data from the 2013 occupational mix survey data, using the methodology described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51582 through 51586). Using the occupational mix survey data and applying the occupational mix adjustment to 100 percent of the FY 2018 wage index results in a national average hourly wage of $42.0564.

The FY 2018 national average hourly wages for each occupational mix nursing subcategory as calculated in Step 2 of the occupational mix calculation are as follows:

Occupational mix nursing subcategory	Average hourly wage
National RN	$38.86637039
National LPN and Surgical Technician	22.73227683
National Nurse Aide, Orderly, and Attendant	15.95002569
National Medical Assistant	17.96799473
National Nurse Category	32.856948

The national average hourly wage for the entire nurse category as computed in Step 5 of the occupational mix calculation is $32.856948. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of greater than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of less than 1.0. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of less than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of greater than 1.0.

Based on the 2013 occupational mix survey data, we determined (in Step 7 of the occupational mix calculation) that the national percentage of hospital employees in the nurse category is 42.6 percent, and the national percentage of hospital employees in the all other occupations category is 57.4 percent. At the CBSA level, the percentage of hospital employees in the nurse category ranged from a low of 25.7 percent in one CBSA to a high of 73.5 percent in another CBSA.

We compared the FY 2018 occupational mix adjusted wage indexes for each CBSA to the unadjusted wage indexes for each CBSA. As a result of applying the occupational mix adjustment to the wage data, the final wage index values for 222 (54.4 percent) urban areas and 23 (48.9 percent) rural areas will increase. The final wage index values for 110 (27.0 percent) urban areas will increase by greater than or equal to 1 percent but less than 5 percent, and the final wage index values for 6 (1.5 percent) urban areas will increase by 5 percent or more. The final wage index values for 10 (21.3 percent) rural areas will increase by greater than or equal to 1 percent but less than 5 percent, and no rural areas' final wage index values will increase by 5 percent or more. However, the final wage index values for 184 (45.1 percent) urban areas and 24 (51.1 percent) rural areas will decrease. The final wage index values for 85 (20.8 percent) urban areas will decrease by greater than or equal to 1 percent but less than 5 percent, and no urban areas' final wage index value will decrease by 5 percent or more. The final wage index values of 8 (17.0 percent) rural areas will decrease by greater than or equal to 1 percent and less than 5 percent, and no rural areas' final wage index values will decrease by 5 percent or more. The largest final positive impacts will be 17.4 percent for an urban area and 2.9 percent for a rural area. The largest final negative impacts will be 4.9 percent for an urban area and 2.4 percent for a rural area. Two urban areas' final wage index, but no rural area wage indexes, will remain unchanged by application of the occupational mix adjustment. These results indicate that a larger percentage of urban areas (54.4 percent) will benefit from the occupational mix adjustment than will rural areas (48.9 percent).

G. Application of the Rural, Imputed, and Frontier Floors

1. Rural Floor

Section 4410(a) of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. This provision is referred to as the ''rural floor.'' Section 3141 of Public Law 111–148 also requires that a national budget neutrality adjustment be applied in implementing the rural floor. Based on the FY 2018 wage index associated with this final rule (which is available via the Internet on the CMS Web site), we estimate that 366 hospitals will receive an increase in their FY 2018 wage index due to the application of the rural floor.

2. Expiration of the Imputed Floor Policy

In the FY 2005 IPPS final rule (69 FR 49109 through 49111), we adopted the ''imputed floor'' policy as a temporary 3-year regulatory measure to address concerns from hospitals in all-urban States that have argued that they are disadvantaged by the absence of rural hospitals to set a wage index floor for those States. Since its initial implementation, we have extended the imputed floor policy seven times, the last of which was adopted in the FY 2017 IPPS/LTCH PPS final rule and is set to expire on September 30, 2017. (We refer readers to further discussions of the imputed floor in the FY 2014, FY 2015, FY 2016, and FY 2017 IPPS/LTCH PPS final rules (78 FR 50589 through 50590, 79 FR 49969 through 49970, 80 FR 49497 through 49498, and 81 FR 56921 through 56922, respectively) and to the regulations at 42 CFR 412.64(h)(4).) Currently, there are three all-urban States—Delaware, New Jersey, and Rhode Island—with a range of wage indexes assigned to hospitals in these States, including through reclassification or redesignation. (We refer readers to discussions of geographic reclassifications and redesignations in section III.I. of the preamble of this final rule.) In computing the imputed floor for an all-urban State under the original methodology, which was established beginning in FY 2005, we calculated the ratio of the lowest-to-highest CBSA wage index for each all-urban State as well as the average of the ratios of lowest-to-highest CBSA wage indexes of those all-urban States. We then compared the State's own ratio to the average ratio for all-urban States and whichever is higher is multiplied by the highest CBSA wage index value in the State—the product of which established the imputed floor for the State. As of FY 2012, there were only two all-urban States—New Jersey and Rhode Island—and only New Jersey benefitted under this methodology. Under the previous OMB labor market area delineations, Rhode Island had only one CBSA (Providence-New Bedford-Fall River, RI–MA) and New Jersey had 10 CBSAs. Therefore, under the original methodology, Rhode Island's own ratio equaled 1.0, and its imputed floor was equal to its original CBSA wage index value. However, because the average ratio of New Jersey and Rhode Island was higher than New Jersey's own ratio, this methodology provided a benefit for New Jersey, but not for Rhode Island.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53368 through 53369), we retained the imputed floor calculated under the original methodology as discussed above, and established an alternative methodology for computing the imputed floor wage index to address the concern that the original imputed floor methodology guaranteed a benefit for one all-urban State with multiple wage indexes (New Jersey) but could not benefit the other all-urban State (Rhode Island). The alternative methodology for calculating the imputed floor was established using data from the application of the rural floor policy for FY 2013. Under the alternative methodology, we first determined the average percentage difference between the post-reclassified, pre-floor area wage index and the post-reclassified, rural floor wage index (without rural floor

budget neutrality applied) for all CBSAs receiving the rural floor. (Table 4D associated with the FY 2013 IPPS/LTCH PPS final rule (which is available via the Internet on the CMS Web site) included the CBSAs receiving a State's rural floor wage index.) The lowest post-reclassified wage index assigned to a hospital in an all-urban State having a range of such values then is increased by this factor, the result of which establishes the State's alternative imputed floor. We amended § 412.64(h)(4) of the regulations to add new paragraphs to incorporate the finalized alternative methodology, and to make reference and date changes. In summary, for the FY 2013 wage index, we did not make any changes to the original imputed floor methodology at § 412.64(h)(4) and, therefore, made no changes to the New Jersey imputed floor computation for FY 2013. Instead, for FY 2013, we adopted a second, alternative methodology for use in cases where an all-urban State has a range of wage indexes assigned to its hospitals, but the State cannot benefit under the original methodology.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50589 through 50590), we extended the imputed floor policy (both the original methodology and the alternative methodology) for 1 additional year, through September 30, 2014, while we continued to explore potential wage index reforms.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49969 through 49970), for FY 2015, we adopted a policy to extend the imputed floor policy (both the original methodology and alternative methodology) for another year, through September 30, 2015, as we continued to explore potential wage index reforms. In that final rule, we revised the regulations at § 412.64(h)(4) and (h)(4)(vi) to reflect the 1-year extension of the imputed floor. As discussed in section III.B. of the preamble of that FY 2015 final rule, we adopted the new OMB labor market area delineations beginning in FY 2015. Under the new OMB delineations, Delaware became an all-urban State, along with New Jersey and Rhode Island. Under the new OMB delineations, Delaware has three CBSAs, New Jersey has seven CBSAs, and Rhode Island continues to have only one CBSA (Providence-Warwick, RI–MA). We refer readers to a detailed discussion of our adoption of the new OMB labor market area delineations in section III.B. of the preamble of the FY 2015 IPPS/LTCH PPS final rule. Therefore, under the adopted new OMB delineations discussed in section III.B. of the preamble of the FY 2015 IPPS/LTCH PPS final rule, Delaware became an all-urban State and was subject to an imputed floor as well for FY 2015.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49497 through 49498), for FY 2016, we extended the imputed floor policy (under both the original methodology and the alternative methodology) for 1 additional year, through September 30, 2016. In that final rule, we revised the regulations at § 412.64(h)(4) and (h)(4)(vi) to reflect this additional 1-year extension. Similarly, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56921 through 56922), for FY 2017, we extended the imputed floor policy (under both the original methodology and the alternative methodology) for 1 additional year, through September 30, 2017. In that final rule, we revised the regulations at § 412.64(h)(4) and (h)(4)(vi) to reflect this additional 1-year extension.

The imputed floor is set to expire effective October 1, 2017, and in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19905), we did not propose to extend the imputed floor policy. In the FY 2005 IPPS final rule (69 FR 49110), we adopted the imputed floor policy for all-urban States under the authority of section 1886(d)(3)(E) of the Act, which gives the Secretary broad authority to adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates for area differences in hospital wage levels by a factor (established by the Secretary). However, we have expressed reservations about establishment of an imputed floor, considering that the imputed rural floor methodology creates a disadvantage in the application of the wage index to hospitals in States with rural hospitals but no urban hospitals receiving the rural floor (72 FR 24786 and 72 FR 47322). As we discussed in the FY 2008 IPPS final rule (72 FR 47322), the application of the rural and imputed floors requires transfer of payments from hospitals in States with rural hospitals but where the rural floor is not applied to hospitals in States where the rural or imputed floor is applied. For this reason, in the FY 2018 IPPS/LTCH PPS proposed rule, we proposed not to apply an imputed floor to wage index calculations and payments for hospitals in all-urban States for FY 2018 and subsequent years. That is, we proposed that hospitals in New Jersey, Delaware, and Rhode Island (and in any other all-urban State) would receive a wage index that is calculated without applying an imputed floor for FY 2018 and subsequent years. Therefore, under our proposal, only States containing both rural areas and hospitals located in such areas (including any hospital reclassified as rural under the provisions of § 412.103 of the regulations) would benefit from the rural floor, in accordance with section 4410 of Public Law 105–33. In addition, we proposed to no longer include the imputed floor as a factor in the national budget neutrality adjustment. Therefore, the proposed wage index and impact tables associated with the FY 2018 IPPS/LTCH PPS proposed rule (which are available via the Internet on the CMS Web site) did not reflect the imputed floor policy, and there was no proposed national budget neutrality adjustment for the imputed floor for FY 2018. We invited public comments on our proposal not to extend the imputed floor for FY 2018 and subsequent years.

We are presenting below summaries of the public comments we received and our responses.

Comment: Several commenters supported CMS' proposal to allow the imputed floor policy to expire. One commenter stated that the imputed floor policy only benefited two States at the expense of other States due to national budget neutrality. Another commenter stated the imputed floor policy should only apply when required by statute.

Response: We appreciate the positions of commenters that support the proposal not to extend the imputed floor. In the FY 2005 IPPS final rule (69 FR 49110), we adopted the imputed floor policy for all-urban States under the authority of section 1886(d)(3)(E) of the Act, which gives the Secretary broad authority to adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs, of the DRG prospective payment rates for area differences in hospital wage levels by a factor (established by the Secretary). Therefore, we believe that we have the discretion to adopt a policy that would adjust wage indexes in the stated manner. We adopted the imputed floor policy to address concerns from hospitals in all-urban States and subsequently extended it through notice-and-comment rulemaking. While we understand the commenters' concerns that the application of the imputed floors requires transfer of payments from hospitals in States with rural hospitals but where the rural floor is not applied to hospitals in States where the rural or imputed floor is applied, we also received many comments expressing concern about discontinuing the imputed floor (as further discussed below). As explained further below, we have decided to

temporarily extend the imputed floor for 1 year while we continue to consider the comments we received and assess whether to continue or discontinue the imputed floor policy for the long term.

Comment: Several commenters disagreed with the proposal to allow the imputed floor to expire, and stated that CMS should maintain the status quo and continue to extend the imputed floor in 1-year increments until the entirety of Medicare wage index reform is complete. The commenters stated that, by eliminating the imputed floor wage index, CMS is alleviating only a fraction of the combined payment transfer from the application of the rural and imputed floors. The commenters pointed out that, combined, hospitals in the three all-urban States (New Jersey, Rhode Island, and Delaware) accounted for less than 10 percent of the 397 hospitals nationally that received either the rural or imputed floor last year. The commenters conveyed that CMS indicated in the FY 2014 and FY 2015 IPPS/LTCH PPS final rules, both of which extended the imputed floor for an additional year, that CMS would continue to explore potential wage index reform, and that, as of the FY 2018 IPPS/LTCH PPS proposed rule, such reform has not occurred.

Multiple commenters indicated that eliminating the imputed floor would create the same uneven playing field that existed prior to 2005, in response to which CMS initially established the policy. The commenters stated that the anomaly originally cited by CMS (that is, that hospitals in all-urban States with predominant labor market areas do not have any type of protection, or ''floor,'' from declines in their wage index) would exist again if the imputed floor policy were discontinued.

One commenter indicated that the imputed floor is an equitable measure established by CMS which provides relief to hospitals in all-urban States. The commenter stated that this longstanding policy has reduced volatility and increased the equitability of the wage index system. The commenter believed that CMS should not remove the imputed floor from all-urban States. Regarding CMS' concern with the payment impact of the existing imputed floor policy on States with rural hospitals that do not have urban hospitals that benefit from a rural floor, the commenter believed this should be reviewed as part of a comprehensive Medicare wage index reform. The commenter suggested that CMS consider all recommended changes to the imputed floor as part of wage index reform, and that the public have a chance to provide input to CMS prior to finalizing any decisions regarding elimination of the imputed rural floor. The commenter further suggested that if there is a decision made to eliminate the imputed rural floor, the decision should include a 2-year notification period to allow impacted hospitals appropriate planning time. The commenter stated that CMS has extended such advance notice, including changes concerning the wage index, for this purpose in the past.

Several commenters stated they would like to make the imputed floor wage index provision permanent in the FY 2018 IPPS/LTCH PPS final rule. The commenters pointed out that CMS has upheld the imputed floor for the past 12 years as a valuable method of maintaining equitable wage index protections for all-urban States, consistent with those that exist for States with rural areas. The commenters referenced CMS' explanation from the FY 2005 IPPS final rule (69 FR 49110) for adopting the imputed floor, such as: ''because there is no 'floor' to protect those hospitals not located in the predominant labor market area from facing continued declines in their wage index, it becomes increasingly difficult for those hospitals to continue to compete for labor.'' The commenters stated it is imperative that the imputed floor policy be made permanent to ensure that its State's hospitals are not artificially disadvantaged simply because of geography and population.

In addition, the commenters stated that there are many Medicare payment programs that redirect scarce Medicare funding to a class of unique hospitals. Not all States have hospitals that benefit from these programs. For example, the commenters stated that CMS makes payments to CAHs at a rate of 101 percent of their cost. The commenters noted that some States do not have any hospitals that qualify as a CAH and do not benefit from this program. The commenters further stated that while CAHs are paid outside the IPPS program, the dollars continue to come from a finite Medicare trust fund. The commenters believed that this represents a transfer of payments from hospitals in States without any CAHs, such as all-urban States, into States with CAHs, similar to the transfer of payments CMS cites as its rationale to discontinue the imputed floor. The commenters indicated that there is precedent for CMS to restore, in the final rule, policies or provisions that were scheduled for elimination or discontinuation in the proposed rule. The commenters pointed out that, in the FY 2012 IPPS/LTCH PPS proposed rule, CMS stated that the imputed floor would expire on September 30, 2011. However, in the final rule, CMS announced that the imputed floor provision was extended for 2 additional years, through FY 2013 (September 30, 2013).

One commenter supported the alternative methodology for calculating the imputed rural floor in Rhode Island. According to the commenter, the methodology has been used since FY 2013 and has been key for the State's hospitals and maintaining access to care for residents of Rhode Island. The commenter stated that the alternative methodology for calculating the imputed floor appropriately addresses a hospital wage index reclassification system that does not reflect Rhode Island's characteristics. The commenter further expressed that the alternative methodology for calculating the imputed rural floor protects its hospitals from falling to some of the lowest reimbursement rates in the country, at the same time while competing with some of the most highly reimbursed urban hospitals. The commenter referenced FY 2013, where a majority of hospitals in Rhode Island reported operating losses and a cumulative operating margin of negative 2.0 percent. The commenter pointed out that since implementing the alternative methodology for calculating the imputed floor, there has been improvement in the overall fiscal condition of Rhode Island's health care system. According to the commenter, the alternative methodology provided nearly $29 million to hospitals in Rhode Island last year. The commenter was concerned that any discontinuation of this policy would be devastating for a State still facing challenging economic conditions.

Response: While the commenters raised concerns that, if the imputed floor were discontinued, hospitals in all-urban States would again be disadvantaged by the absence of rural hospitals to set a wage index floor for those States, as well as concerns about the fiscal impacts of discontinuing the rural floor, we also have expressed concerns about continuing the imputed floor policy. As we discussed in the FY 2008 IPPS/LTCH PPS final rule (72 FR 47322), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51593), and the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19905), the application of the rural and imputed floors requires transfer of payments from hospitals in States with rural hospitals but where the rural floor is not applied to hospitals in States where the rural or imputed floor is applied. While the three all-urban States may count for a fraction of all States that

received the rural and imputed floor last year, the imputed rural floor methodology still creates a disadvantage in the application of the wage index to hospitals in States with rural hospitals but no urban hospitals receiving the rural floor. As discussed below, given the many comments we received both in support of and against our proposal to discontinue the imputed floor, we believe it would be appropriate to temporarily extend the imputed floor for an additional year, while we continue to consider these comments and further assess the effects of this policy and whether to continue or discontinue the policy for the long term.

In response to the comment suggesting that we maintain the status quo and continue to extend the imputed floor until wage index reform is complete, we note that section 3137(b) of the Affordable Care Act required the Secretary to submit to Congress a report that includes a plan to reform the Medicare wage index applied under the IPPS. We submitted the report to Congress on April 11, 2012, and have posted the report and other information regarding wage index reform on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Reform.html*. While in past years we have stated that we continue to explore wage index reforms while extending the imputed floor in increments (for example, 78 FR 50589 through 50590 and 79 FR 49969 through 49970), we note that it has already been many years since our Report to Congress was issued with no new legislation from Congress to comprehensively reform the wage index. Therefore, we do not agree with the commenter that the imputed floor should continue until such time as comprehensive wage index reform may be implemented.

In addition, we note that the imputed floor was originally authorized for only 3 years. In the FY 2005 IPPS final rule (69 FR 49110), we indicated that during the 3 years that the policy is in effect, we would determine whether to make additional changes to the policy or eliminate it. Given that we had indicated in the FY 2005 IPPS final rule that the provision was set to expire after 3 years, and that we have temporarily extended the provision in increments for several subsequent years due to the reasons discussed earlier, we believe that hospitals in all-urban States should not rely on the policy to continue permanently or until wage index reform is implemented. Furthermore, because the policy has been temporarily extended in increments for several years, we believe that hospitals have had ample notice that the policy could ultimately expire, and thus should not rely on a notification period as requested by the commenter. However, we would provide the public a chance to provide input to CMS through the rulemaking process prior to finalizing any decisions regarding elimination of the imputed rural floor.

Finally, regarding the comparison made by commenters between the CAH payment methodology and the imputed floor methodology with respect to the transfer of payments, we disagree with this comparison. Because there is no national budget neutrality requirement relating to CAH payments (as there is with the imputed floor methodology), there is no transfer of payments from hospitals in States without any CAHs to hospitals in States with CAHs, similar to that which exists as a result of the application of the imputed floor. Under sections 1814(l) and 1834(g) of the Act, payments made to CAHs for inpatient and outpatient services are generally based on 101 percent of the reasonable costs of the CAH in providing such services. Reasonable cost is defined in section 1861(v)(1)(A) of the Act and determined in accordance with the regulations under 42 CFR part 413.

Comment: One commenter stated that, in more recent years, the rural floor wage index adjustment has been a cause for concern nationally because urban hospitals in certain States have had their wage indexes set equal to the highest wage index of any rural hospital in their respective State. As a result, the commenter pointed out, hospitals in such States draw Medicare money away from hospitals in other States. The commenter reemphasized its previous recommendations, which were also included in the MedPAC's 2007 Report to Congress, that Congress repeal the existing hospital wage index. The commenter appeared to be requesting support for legislation which would include: Removing the more than 900 individual hospital reclassifications, and other exceptions that occur each year, which are either stipulated in law or implemented through regulation, and also giving the Secretary authority to establish a new wage index system, using compensation data from all employees, together with hospital industry-specific occupational weights, and adjusting at the county level to smooth large differences between counties; and a transition period to mitigate large changes in wage index values. The commenter indicated that the system it proposed is similar to recommendations made by the Institute of Medicine and that its sets of recommendations would eliminate the need for the system of geographic reclassification and exceptions that is currently in place.

Response: We thank the commenter for its comments and its recommendations regarding modifications to the hospital wage index. However, we note that we do not have authority to repeal or revise the existing wage index statutory provisions, including the rural floor statutory provisions at section 4410(b) of the BBA and section 3141 of the Affordable Care Act.

Comment: One commenter opposed the continued application of the nationwide rural floor budget neutrality adjustment as described in the proposed rule. The commenter recognized that the impetus for the policy is a Federal statute, not regulation. The commenter discussed section 3141 of the Affordable Care Act which established a policy of national budget neutrality for the application of the rural and imputed floors to the Medicare wage index. The commenter conveyed that, coupled with the orchestrated conversion of a single facility in Massachusetts—Nantucket Cottage Hospital—from a CAH to an IPPS hospital, section 3141 of the Affordable Care Act allows hospitals to unfairly manipulate the Medicare payment system and reward hospitals in Massachusetts and a few other States at the expense of most other hospitals across the nation. The commenter stated that the adverse consequences of nationwide rural floor budget neutrality have been recognized and commented upon by CMS, MedPAC, and many others over the past several years. Until this policy is corrected, the commenter stated that the Medicare wage index system cannot possibly accomplish its objective of ensuring that payments for the wage component of labor accurately reflect actual wage costs.

Other commenters stated ''that the current application of the rural floor is broken'' and referenced how a single hospital can shift such a large amount of payments and have it paid for by many other States in the nation. The commenters explained that section 4410 of the BBA established a rural floor. The commenters noted that, by careful selection of specific hospitals converting from CAHs to hospitals paid under the IPPS, States could game the system and exploit this provision, shifting millions of dollars into that State. These commenters stated that the most notable example of such gaming is a hospital located on Nantucket Island off the coast of Massachusetts. This single hospital sets the wage index for all hospitals in Massachusetts. The commenters stated that, according to

rural floor impact statements provided by CMS in the annual IPPS final rule from FY 2012 through FY 2017, this one hospital will bring a projected $1.3 billion into the commonwealth of Massachusetts. The commenter pointed out that the inequity of this provision recently was highlighted in a March 2017 Office of Inspector General (OIG) report showing how a single hospital overreported dollars and underreported hours, driving up the average hourly wage. According to the commenter, the OIG estimated that this error resulted in more than $133 million in Medicare overpayments to be paid to Massachusetts hospitals. The commenters ''urged CMS to establish a national wage index ceiling (for example, 1.33) that can be used to increase the national wage index floor to a reasonable level (for example, .874)''. In addition, the commenters opposed the application of a nationwide rural floor budget neutrality adjustment and requested that CMS overturn section 3141 of the Affordable Care Act and restore integrity to the hospital wage index system.

Response: We thank the commenters for their comments and suggestions. Because there is no national wage index floor, we are not clear what the commenter meant with respect to its request to establish a national wage index ceiling that can be used to increase the national wage index floor to a reasonable level. Therefore, we are unable to respond to this suggestion made by the commenter. As we stated earlier, section 4410 of the BBA requires the application of the rural floor and section 3141 of the Affordable Care Act requires a uniform, national budget neutrality adjustment for the rural floor. We do not have authority to repeal or revise these laws.

Comment: One commenter suggested that CMS use its authority to establish a temporary wage index floor for Puerto Rico in the interest of preventing a decrease in Medicare payments due to Puerto Rico's lower than national average wages.

Response: We appreciate the suggestions provided by the commenter regarding a temporary wage index floor for Puerto Rico. However, this comment is outside the scope of the proposed rule.

We appreciate the positions of commenters that both supported and opposed the proposal to allow the imputed floor policy to expire. After consideration of public comments we received, we believe extending the imputed floor policy for 1 more year through FY 2018 is appropriate while we continue to consider the many comments we received and whether to continue or discontinue the imputed floor for the long term. Therefore, we are extending the imputed floor policy under both the original methodology and the alternative methodology for an additional year, through September 30, 2018, and will address this issue again in our FY 2019 rulemaking. We also are revising the regulations at §§ 412.64(h)(4) and (h)(4)(vi) to reflect the 1-year extension of the imputed floor, through September 30, 2018.

The wage index and impact tables associated with this FY 2018 IPPS/LTCH PPS final rule (which are available on the Internet via the CMS Web site) reflect the continued application of the imputed floor policy at § 412.64(h)(4) and a national budget neutrality adjustment for the imputed floor for FY 2018. There are 17 hospitals in New Jersey that will receive an increase in their FY 2018 wage index due to the continued application of the imputed floor policy under the original methodology, and 10 hospitals in Rhode Island and 6 hospitals in Delaware that will benefit under the alternative methodology.

3. State Frontier Floor for FY 2018

Section 10324 of Public Law 111–148 requires that hospitals in frontier States cannot be assigned a wage index of less than 1.0000. (We refer readers to the regulations at 42 CFR 412.64(m) and to a discussion of the implementation of this provision in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 through 50161).) In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19905), we did not propose any changes to the frontier floor policy for FY 2018. We stated in the proposed rule that 52 hospitals would receive the frontier floor value of 1.0000 for their FY 2018 wage index. These hospitals are located in Montana, Nevada, North Dakota, South Dakota, and Wyoming.

We did not receive any public comments on the application of the State frontier floor for 2018. In this final rule, 49 hospitals will receive the frontier floor value of 1.0000 for their FY 2018 wage index. These hospitals are located in Montana, Nevada, North Dakota, South Dakota, and Wyoming.

The areas affected by the final rural and frontier floor policies for the FY 2018 wage index are identified in Table 2 associated with this final rule, which is available via the Internet on the CMS Web site.

H. FY 2018 Wage Index Tables

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49498 and 49807 through 49808), we finalized a proposal to streamline and consolidate the wage index tables associated with the IPPS proposed and final rules for FY 2016 and subsequent fiscal years. Prior to FY 2016, the wage index tables had consisted of 12 tables (Tables 2, 3A, 3B, 4A, 4B, 4C, 4D, 4E, 4F, 4J, 9A, and 9C) that were made available via the Internet on the CMS Web site. Effective beginning FY 2016, with the exception of Table 4E, we streamlined and consolidated 11 tables (Tables 2, 3A, 3B, 4A, 4B, 4C, 4D, 4F, 4J, 9A, and 9C) into 2 tables (Tables 2 and 3). We refer readers to section VI. of the Addendum to this final rule for a discussion of the final wage index tables for FY 2018.

I. Revisions to the Wage Index Based on Hospital Redesignations and Reclassifications

1. General Policies and Effects of Reclassification and Redesignation

Under section 1886(d)(10) of the Act, the Medicare Geographic Classification Review Board (MGCRB) considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. Hospitals must apply to the MGCRB to reclassify not later than 13 months prior to the start of the fiscal year for which reclassification is sought (usually by September 1). Generally, hospitals must be proximate to the labor market area to which they are seeking reclassification and must demonstrate characteristics similar to hospitals located in that area. The MGCRB issues its decisions by the end of February for reclassifications that become effective for the following fiscal year (beginning October 1). The regulations applicable to reclassifications by the MGCRB are located in 42 CFR 412.230 through 412.280. (We refer readers to a discussion in the FY 2002 IPPS final rule (66 FR 39874 and 39875) regarding how the MGCRB defines mileage for purposes of the proximity requirements.) The general policies for reclassifications and redesignations and the policies for the effects of hospitals' reclassifications and redesignations on the wage index are discussed in the FY 2012 IPPS/LTCH PPS final rule for the FY 2012 final wage index (76 FR 51595 and 51596). In addition, in the FY 2012 IPPS/LTCH PPS final rule, we discussed the effects on the wage index of urban hospitals reclassifying to rural areas under 42 CFR 412.103. Hospitals that are geographically located in States without any rural areas are ineligible to apply for rural reclassification in accordance with the provisions of 42 CFR 412.103.

On April 21, 2016, we published an interim final rule with comment period

(IFC) in the **Federal Register** (81 FR 23428 through 23438) that included provisions amending our regulations to allow hospitals nationwide to have simultaneous § 412.103 and MGCRB reclassifications. For reclassifications effective beginning FY 2018, a hospital may acquire rural status under § 412.103 and subsequently apply for a reclassification under the MGCRB using distance and average hourly wage criteria designated for rural hospitals. In addition, we provided that a hospital that has an active MGCRB reclassification and is then approved for redesignation under § 412.103 will not lose its MGCRB reclassification; such a hospital receives a reclassified urban wage index during the years of its active MGCRB reclassification and is still considered rural under section 1886(d) of the Act and for other purposes.

We discussed that when there is both a § 412.103 redesignation and an MGCRB reclassification, the MGCRB reclassification controls for wage index calculation and payment purposes. We exclude hospitals with § 412.103 redesignations from the calculation of the reclassified rural wage index if they also have an active MGCRB reclassification to another area. That is, if an application for urban reclassification through the MGCRB is approved, and is not withdrawn or terminated by the hospital within the established timelines, we consider the hospital's geographic CBSA and the urban CBSA to which the hospital is reclassified under the MGCRB for the wage index calculation. We refer readers to the April 21, 2016 IFC (81 FR 23428 through 23438) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 56922 through 56930) for a full discussion of the effect of simultaneous reclassifications under both the § 412.103 and the MGCRB processes on wage index calculations.

2. MGCRB Reclassification and Redesignation Issues for FY 2018

a. FY 2018 Reclassification Requirements and Approvals

As previously stated, under section 1886(d)(10) of the Act, the MGCRB considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. The specific procedures and rules that apply to the geographic reclassification process are outlined in regulations under 42 CFR 412.230 through 412.280.

At the time this final rule was constructed, the MGCRB had completed its review of FY 2018 reclassification requests. Based on such reviews, there are 374 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2018. Because MGCRB wage index reclassifications are effective for 3 years, for FY 2018, hospitals reclassified beginning in FY 2016 or FY 2017 are eligible to continue to be reclassified to a particular labor market area based on such prior reclassifications for the remainder of their 3-year period. There were 245 hospitals approved for wage index reclassifications in FY 2016 that will continue for FY 2018, and 246 hospitals approved for wage index reclassifications in FY 2017 that will continue for FY 2018. Of all the hospitals approved for reclassification for FY 2016, FY 2017, and FY 2018, based upon the review at the time of this final rule, 865 hospitals are in a MGCRB reclassification status for FY 2018.

Under the regulations at 42 CFR 412.273, hospitals that have been reclassified by the MGCRB are permitted to withdraw their applications if the request for withdrawal is received by the MGCRB within 45 days of the publication of CMS' annual notice of proposed rulemaking concerning changes to the inpatient hospital prospective payment system and proposed payment rates for the fiscal year for which the application has been filed. (We note that in section III.I.4. of the preamble of this final rule, we did not finalize our proposal to revise the above described regulation text to specify that written notice to the MGCRB must be provided within 45 days from the date of public display of the proposed rule at the Office of the Federal Register.) For information about withdrawing, terminating, or canceling a previous withdrawal or termination of a 3-year reclassification for wage index purposes, we refer readers to § 412.273, as well as the FY 2002 IPPS final rule (66 FR 39887 through 39888) and the FY 2003 IPPS final rule (67 FR 50065 through 50066). Additional discussion on withdrawals and terminations, and clarifications regarding reinstating reclassifications and ''fallback'' reclassifications were included in the FY 2008 IPPS final rule (72 FR 47333).

Changes to the wage index that result from withdrawals of requests for reclassification, terminations, wage index corrections, appeals, and the Administrator's review process for FY 2018 are incorporated into the wage index values published in this FY 2018 IPPS/LTCH PPS final rule. These changes affect not only the wage index value for specific geographic areas, but also the wage index value that redesignated/reclassified hospitals receive; that is, whether they receive the wage index that includes the data for both the hospitals already in the area and the redesignated/reclassified hospitals. Further, the wage index value for the area from which the hospitals are redesignated/reclassified may be affected.

Comment: MedPAC and other commenters stated that the increasing number of wage index reclassifications, along with other wage index exceptions, raises questions regarding whether the current wage index is equitably adjusting payments for local input costs of providing patient care. One commenter stated that the increasing number of hospitals that reclassify is a ''clear indication of the broken system'' that needs to be replaced; another commenter requested general wage index reform. MedPAC reiterated that recommendations included in the Commission's 2007 Report to Congress and similar recommendations made by the Institute of Medicine would eliminate the need for the system of geographic reclassification and exceptions that is currently in place. Specifically, MedPAC recommended that the Congress repeal the existing hospital wage index, remove the more than 900 individual hospital reclassifications and other exceptions that occur each year, and give the Secretary the authority to establish a new wage index system.

Response: We understand the commenters' concerns regarding the high volume of MGCRB reclassifications. We appreciate MedPAC's recommendation to repeal the current wage index statute. However, repealing the wage index statute would require legislative action by Congress. Specifically, section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary must adjust the standardized amounts for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. We also appreciate the other commenters' requests for wage index reform. We will take the requests into consideration and may address this issue again in future rulemaking.

Applications for FY 2019 reclassifications are due to the MGCRB by September 1, 2017 (the first working day of September 2017). We note that this is also the deadline for canceling a previous wage index reclassification, withdrawal, or termination under 42 CFR 412.273(d). Applications and other information about MGCRB

reclassifications may be obtained, beginning in mid-July 2017, via the Internet on the CMS Web site at: *https://www.cms.gov/Regulations-and-Guidance/Review-Boards/MGCRB/index.html*, or by calling the MGCRB at (410) 786–1174. The mailing address of the MGCRB is: 2520 Lord Baltimore Drive, Suite L, Baltimore, MD 21244–2670.

Under previous regulations at 42 CFR 412.256(a)(1), applications for reclassification were required to be mailed or delivered to the MGCRB, with a copy to CMS, and were not allowed to be submitted through the facsimile (FAX) process or by other electronic means. Because we believed this previous policy was outdated and overly restrictive and to promote ease of application for FY 2018 and subsequent years, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56928), we revised this policy to require applications and supporting documentation to be submitted via the method prescribed in instructions by the MGCRB, with an electronic copy to CMS. We revised § 412.256(a)(1) to specify that an application must be submitted to the MGCRB according to the method prescribed by the MGCRB, with an electronic copy of the application sent to CMS. We specified that CMS copies should be sent via email to *wageindex@cms.hhs.gov*.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56928), we reiterated that MGCRB application requirements will be published separately from the rulemaking process, and paper applications will likely still be required. The MGCRB makes all initial determinations for geographic reclassification requests, but CMS requests copies of all applications to assist in verifying a reclassification status during the wage index development process. We stated that we believed that requiring electronic versions would better aid CMS in this process, and would reduce the overall burden upon hospitals.

We did not receive any public comments on the requirements for applications for FY 2019 reclassifications.

b. Extension of PRA Information Collection Requirement Approval for MGCRB Applications

As stated earlier, under section 1886(d)(10) of the Act, the MGCRB considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. The specific procedures and rules that apply to the geographic reclassification process are outlined in the regulations under 42 CFR 412.230 through 412.280. The information collection requirements for the MGCRB procedures and criteria and supporting regulations in 42 CFR 412.256 subject to the Paperwork Reduction Act provisions were approved under OMB Control Number 0938–0573 and expired on February 28, 2017. As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19906 and 19907), an extension of the collection was required in time for applications due to the MGCRB by September 1, 2017 for FY 2019 reclassifications. A request for an extension of the information collection requirements for the MGCRB procedures and criteria and supporting regulations received approval by OMB on June 30, 2017, and can be accessed at: *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201612-0938-023*.

c. Deadline for Submittal of Documentation of Sole Community Hospital (SCH) and Rural Referral Center (RRC) Classification Status to the MGCRB

The regulations at 42 CFR 412.230(a)(3), consistent with section 1886(d)(10)(D)(i)(III) of the Act, set special rules for sole community hospitals (SCHs) and rural referral centers (RRCs) that are reclassifying under the MGCRB. Specifically, a hospital that is an RRC or an SCH, or both, does not have to demonstrate a close proximity to the area to which it seeks redesignation. If a hospital that is an RRC or an SCH, or both, qualifies for urban redesignation, it is redesignated to the urban area that is closest to the hospital. If the hospital is closer to another rural area than to any urban area, it may seek redesignation to either the closest rural or the closest urban area.

In addition, section 1886(d)(10)(D)(iii) of the Act, as implemented in the regulations at § 412.230(d)(3)(i), provides an exception to certain wage comparison criteria for RRCs and former RRCs reclassifying under the MGCRB. Under § 412.230(d)(3)(i), if a hospital was ever an RRC, it does not have to demonstrate that it meets the average hourly wage criterion at § 412.230(d)(1)(iii), which would require that the hospital's average hourly wage be at least 106 percent for rural hospitals and at least 108 percent for urban hospitals of the average hourly wage of all other hospitals in the area in which the hospital is located. Rather, as codified at § 412.230(d)(3)(ii), consistent with our authority under section 1886(d)(10)(D)(i) of the Act, if a hospital was ever an RRC, it is required to meet only the criterion for rural hospitals at § 412.230(d)(1)(iv), which requires that the hospital's average hourly wage is equal to at least 82 percent of the average hourly wage of hospitals in the area to which it seeks redesignation. The regulations at § 412.96 set forth the criteria that a hospital must meet in order to qualify as an RRC.

For a hospital to use the special rules at § 412.230(a)(3) for SCHs and RRCs, the existing regulation at § 412.230(a)(3) requires that the hospital be an active SCH or an RRC as of the date of the MGCRB's review. In addition, for a hospital to use the RRC exceptions at § 412.230(d)(3), a hospital must either be an RRC at the time of the MGCRB's review or have previously been classified as an RRC in the past. In other words, under the existing regulations, if a hospital is approved by CMS as an SCH or an RRC but the approval is not yet effective at the time of the MGCRB's review, the hospital's status as an SCH or an RRC would not be considered in the MGCRB's decision, unless the hospital was a former RRC, in which case it would be able to use the RRC exceptions at § 412.230(d)(3).

The MGCRB currently accepts supporting documentation of SCH and RRC classification (including, but not limited to, the CMS approval letter) up until the date of MGCRB's review, which varies annually. A hospital may apply at any time for classification as an SCH, and the classification is effective 30 days after the date of CMS' written notification of approval, in accordance with § 412.92. Considering that the MGCRB usually meets in early February, hospitals typically seek to obtain SCH approval letters no later than early January (30 days prior to the date of MGCRB review) for the SCH status to be effective as of the date of the MGCRB's review. However, consistent with section 1886(d)(5)(C)(i) of the Act, a hospital must submit its application for RRC status during the quarter before the first quarter of the hospital's cost reporting period, to be effective at the beginning of the next cost reporting period. The existing regulation at § 412.230(a)(3), combined with the statutory timeframe for RRC classification, require that a hospital's cost reporting period as an RRC begin on or before the date of the MGCRB's review in order to be considered an RRC by the MGCRB for purposes of the special rules under § 412.230(a)(3). Similarly, in order to use the RRC exceptions under § 412.230(d)(3), a hospital's RRC status must be effective on the date of the MGCRB's review, or (unlike § 412.230(a)(3)) the hospital must have had RRC status in the past. For example, a hospital with a cost

reporting period beginning in March would obtain RRC approval, in accordance with the statutory timeframe, during the December through February quarter (potentially before the MGCRB's decision), but would not be considered an RRC by the MGCRB because the approval would not be effective until the next cost reporting period begins in March, after the MGCRB's decision (unless, for purposes of § 412.230(d)(3), the hospital had previously been classified as an RRC in the past).

As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19907 through 19908), the current practice of accepting documentation of SCH and RRC approvals up until the date of MGCRB review does not ensure adequate time for the MGCRB to include SCH and RRC approvals in its review. We noted in the proposed rule that many hospitals now obtain SCH or RRC status based on a § 412.103 reclassification in order to reclassify using the special rules and exceptions under the MGCRB following the April 21, 2016 IFC (81 FR 23428), which revised the regulations to allow hospitals nationwide to reclassify based on acquired rural status. We stated in the proposed rule that we believe the additional volume of SCH and RRC approvals submitted to the MGCRB increases the need for an earlier deadline for documentation of SCH and RRC classifications to be submitted to the MGCRB for purposes of the special rules at § 412.230(a)(3) and the exception for RRCs at § 412.230(d)(3). In addition, because the date of the MGCRB's review varies annually, we stated in the proposed rule that we believe hospitals would benefit from the certainty of a set date by which documentation of RRC or SCH status must be submitted in order to have that status considered by the MGCRB under § 412.230(a)(3) and § 412.230(d)(3).

Therefore, to ensure sufficient time for the MGCRB to include SCH and RRC status approvals in its review and increase clarity for hospitals, while allowing as much time and flexibility as possible for hospitals applying for RRC status to be considered RRCs by the MGCRB, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19907 through 19908), we proposed to revise the regulations at § 412.230(a)(3) and § 412.230(d)(3). We proposed to revise the regulations at § 412.230(a)(3) in two ways. First, we proposed to establish a deadline of the first business day after January 1 for hospitals to submit to the MGCRB documentation of SCH or RRC status approval (the CMS approval letter) in order to take advantage of the special rules under § 412.230(a)(3) when reclassifying under the MGCRB. We stated that we believe that this date of the first business day after January 1 would provide sufficient time for the MGCRB to consider documentation of SCH or RRC status approval in its review, without negatively affecting hospitals seeking to obtain SCH or RRC status, as explained below. Second, we proposed to revise § 412.230(a)(3) to require hospitals to submit documentation of SCH or RRC status approval (the CMS approval letter) by the deadline above, rather than to have SCH or RRC classification that is effective as of the date of MGCRB review, in order to use the special rules for SCHs and RRCs under § 412.230(a)(3). Likewise, we proposed to revise the regulations at § 412.230(d)(3) so that a hospital qualifies for these RRC exceptions if it was ever *approved* as a RRC. In other words, the exceptions at § 412.230(d)(3) would continue to apply to hospitals that were ever classified as RRCs, but consistent with our authority under section 1886(d)(10)(D)(i) of the Act to publish guidelines to be utilized by the MGCRB, we proposed to also extend these exceptions to hospitals that were ever approved as RRCs. Similar to § 412.230(a)(3), we also proposed to establish a deadline of the first business day after January 1 for hospitals to submit documentation of RRC status approval (the CMS approval letter) in order to take advantage of the exception under § 412.230(d)(3) when reclassifying under the MGCRB. We stated in the proposed rule that these proposed revisions would more appropriately allow the MGCRB to prepare for its review and would allow hospitals obtaining SCH or RRC status approval as late as the first business day after January 1 to have these classifications considered by the MGCRB under § 412.230(a)(3) and (d)(3), irrespective of the effective date of these classifications. We stated that these proposals would not substantially affect hospitals seeking SCH classification for purposes of reclassifying under the MGCRB because a hospital must obtain SCH status approval by early January under the existing regulation in order to have that classification effective 30 days later by the time the Board usually meets in early February. For hospitals seeking RRC classification for purposes of reclassifying under the MGCRB, however, the proposed deadline of no later than the first business day after January 1, in concert with our proposal to accept documentation of approval (the CMS approval letter) instead of requiring the hospital to be an active RRC at the time of the MGCRB review in order to take advantage of the special rules and exceptions under § 412.230(a)(3) and (d)(3), is beneficial. We stated that the proposed revisions to the regulations at § 412.230(a)(3) and (d)(3) would accommodate more hospitals with various cost reporting year ends by allowing hospitals with cost reporting periods beginning soon after the MGCRB's decision to have RRC status approvals included in the MGCRB's review. Under the proposals, the MGCRB would consider an RRC status approval obtained as late as the first business day after January 1 instead of requiring the RRC classification to be effective by the time the Board meets, which has been in February in past years. For example, under our proposal, a hospital with a cost reporting period beginning as late as March, which could apply for RRC status approval in accordance with the statutory timeframe starting in December, would be considered an RRC by the MGCRB if it submits documentation of approval of RRC status no later than the first business day after January 1, even though the approval would not be effective until after the MGCRB's decision.

For the reasons discussed earlier, consistent with our authority under section 1886(d)(10)(D)(i) of the Act to publish guidelines to be utilized by the MGCRB, we proposed to revise the regulations at § 412.230(a)(3) to specify that, to be redesignated under the special rules in that paragraph, the hospital must submit documentation of the approval of SCH or RRC status to the MGCRB no later than the first business day after January 1. In addition, we proposed conforming revisions to paragraphs (a)(3)(i) and (ii) of § 412.230 to reflect that these paragraphs apply to hospitals with SCH and RRC approval as specified above (and not only effective status). Specifically, we proposed to revise § 412.230(a)(3)(i) to specify that a hospital that is approved as an RRC or SCH, or both, does not have to demonstrate a close proximity to the area to which it seeks redesignation; and to revise § 412.230(a)(3)(ii) to specify that this paragraph applies if a hospital that is approved as an RRC or SCH, or both, qualifies for urban redesignation. We note that we proposed additional revisions to § 412.230(a)(3)(ii) as discussed in section III.I.2.d. of the preamble of the proposed rule and this final rule.

In addition, for the reasons discussed above, consistent with our authority under section 1886(d)(10)(D)(i) of the

Act to publish guidelines to be utilized by the MGCRB, we proposed to revise the regulations at § 412.230(d)(3). Specifically, we proposed to add introductory language to § 412.230(d)(3) to specify that for the exceptions in this paragraph to apply, the hospital must submit documentation of the approval of RRC status (current or past) to the MGCRB no later than the first business day after January 1. In addition, we proposed to revise § 412.230(d)(3)(i) to specify that if a hospital was ever approved as an RRC, it does not have to demonstrate that it meets the average hourly wage criterion set forth in § 412.230(d)(1)(iii); and to revise § 412.230(d)(3)(ii) to specify that if a hospital was ever approved as an RRC, it is required to meet only the criterion that applies to rural hospitals under § 412.230(d)(1)(iv), regardless of its actual location in an urban or rural area.

We invited public comments on these proposals.

Comment: One commenter did not disagree with the establishment of a deadline for submitting documentation of SCH and RRC status to the MGCRB because the commenter believed that the proposed deadline will provide clarity to hospitals, the MGCRB, and CMS in this process and will ensure adequate time for the MGCRB to include SCH and RRC approvals in its review. However, the commenter urged CMS to also establish a deadline of 30 days from receipt of request for SCH or RRC status for CMS to respond. The commenter pointed out that while the regulations specify effective dates for SCH and RRC status, the regulations do not set a timeframe by which CMS must rule on an SCH or RRC request. Therefore, the commenter stated, a hospital may face uncertainty that CMS will respond to its request for SCH or RRC status by the first business day in January, in time to submit to the MGCRB. According to the commenter, absent a defined timeframe within which CMS must respond to hospitals' requests for SCH and RRC status, hospitals face a disadvantage in complying with the deadline of the first business day in January for submitting documentation of SCH and RRC status to the MGCRB.

Response: We appreciate the commenter's support for our effort to provide clarity to all parties. The commenter is correct that the regulations do not set a timeframe by which CMS must rule on an SCH or RRC request. However, under section 1886(d)(5)(C)(i) of the Act, CMS must make a final determination on a request for RRC status within 60 days after the date the request was submitted. We agree with the commenter that, depending on the timeframe within which SCH and RRC status approvals are issued, hospitals may face a disadvantage in complying with the proposed deadline to submit SCH and RRC documentation to the MGCRB. Thus, we believe that further consideration is needed regarding the appropriate timeframe for such approvals to avoid the disadvantage cited by the commenter. Accordingly, for FY 2018, we are *not* finalizing the proposed deadline of the first business day after January 1 for hospitals to submit documentation of SCH and RRC status to the MGCRB. We may revisit the deadline for submitting documentation to the MGCRB in future rulemaking to give us the opportunity to further consider the timeframe for CMS to respond to applications for SCH and RRC status.

However, we believe that the proposal to require that a hospital must be approved for SCH or RRC status, rather than have active RRC or SCH status, in order to use the special rules for SCHs and RRCs and exceptions for RRCs under §§ 412.230(a)(3) and (d)(3), remains beneficial for hospitals. While we are still concerned with providing the MGCRB sufficient time to include SCH and RRC status approval in its review, we believe finalizing our proposal to require that a hospital be approved for SCH or RRC status, rather than have active RRC or SCH status, in order to use the special rules for SCHs and RRCs and exceptions for RRCs under §§ 412.230(a)(3) and (d)(3) is appropriate because it provides flexibility and accommodates more hospitals. Therefore, as discussed further below, we are finalizing our proposed changes to the regulations to specify that a hospital must be approved as an SCH or RRC at the date of the MGCRB's review, irrespective of effective date of SCH or RRC status. While documentation of SCH and RRC status approval may include the CMS approval letter, we are clarifying that other documents could also serve this purpose as determined by the MGCRB, and that documentation in addition to the CMS approval letter may be required. Questions about acceptable supporting documentation should be directed to the MGCRB at 410–786–1174.

After consideration of the public comment we received, for the reasons discussed earlier, we are not finalizing our proposed revisions to the regulations at §§ 412.230(a)(3) and (d)(3) to establish a deadline of the first business day after January 1 for hospitals to submit documentation of SCH and RRC status approval to the MGCRB. However, consistent with our authority under section 1886(d)(10)(D)(i) to publish guidelines to be used by the MGCRB, for the reasons discussed earlier and in the FY 2018 IPPS/LTCH PPS proposed rule, we are finalizing our proposal that a hospital must be approved for SCH or RRC status, rather than have active SCH or RRC status in order to use the special rules for SCHs and RRCs and exceptions for RRCs under §§ 412.230(a)(3) and (d)(3). Specifically, we are revising the regulation at § 412.230(a)(3) to specify that, to be redesignated under the special rules in this paragraph, a hospital must be approved as an SCH or RRC as of the date of the MGCRB's review. In addition, we are finalizing, without modification, our proposed revisions to paragraphs (a)(3)(i) and (ii) of § 412.230 to reflect that these paragraphs apply to hospitals with SCH and RRC approval (and not only effective status). Specifically, we are revising § 412.230(a)(3)(i) to specify that a hospital that is approved as an RRC or SCH, or both, does not have to demonstrate a close proximity to the area to which it seeks redesignation; and revising § 412.230(a)(3)(ii) to specify that this paragraph applies if a hospital that is approved as an RRC or SCH, or both, qualifies for urban redesignation. (We note that we are making additional revisions to § 412.230(a)(3)(ii) as discussed in section III.I.2.d. of the preamble of this final rule).

In addition, for the reasons discussed earlier, while we are not finalizing our proposed introductory language at § 412.230(d)(3), we are finalizing our proposed revisions to paragraphs (d)(3)(i) and (ii) of § 412.230, without modification, to reflect that these paragraphs apply to hospitals with RRC approval (and not only effective status). Specifically, we are revising § 412.230(d)(3)(i) to specify that if a hospital was ever approved as an RRC, it does not have to demonstrate that it meets the average hourly wage criterion set forth in § 412.230(d)(1)(iii); and revising § 412.230(d)(3)(ii) to specify that if a hospital was ever approved as an RRC, it is required to meet only the criterion that applies to rural hospitals under § 412.230(d)(1)(iv), regardless of its actual location in an urban or rural area.

d. Clarification of Special Rules for SCHs and RRCs Reclassifying to Geographic Home Area

Following issuance of the April 21, 2016 IFC (81 FR 23428), hospitals may simultaneously be redesignated as rural under § 412.103 and reclassified under the MGCRB. An urban hospital seeking

benefits of rural status, such as rural payments for disproportionate share hospitals (DSH) and eligibility for the 340B Drug Pricing Program administered by HRSA, without the associated rural wage index may be redesignated as rural under § 412.103 (if it meets the applicable requirements) and also reclassify under the MGCRB to an urban area (again, if it meets the applicable requirements). As discussed earlier and in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56922 through 56927), a hospital with simultaneous § 412.103 redesignation and MGCRB reclassification receives the wage index of the CBSA to which it is reclassified under the MGCRB while still maintaining § 412.103 reclassified rural status for other purposes.

Hospitals that are redesignated under § 412.103 may seek MGCRB reclassification to their geographic home area. Such hospitals automatically meet the criteria for proximity, but must still demonstrate that they meet the wage comparison requirements using the criteria for rural hospitals at § 412.230(d). Specifically, a hospital with a § 412.103 redesignation seeking reclassification under the MGCRB must demonstrate that its average hourly wage is at least 106 percent of the average hourly wage of all other hospitals in the area in which the hospital is located in accordance with § 412.230(d)(1)(iii), and the hospital's average hourly wage is equal to at least 82 percent of the average hourly wage of hospitals in the area to which it seeks redesignation, in accordance with § 412.230(d)(1)(iv). In this case, both the area in which the hospital is located and the area to which it seeks redesignation are the geographic home area. If a hospital with a § 412.103 rural redesignation also has SCH or RRC status based on its acquired rural status, the hospital may use the exception at § 412.230(d)(3) for RRCs seeking reclassification under the MGCRB and the special reclassification rules at § 412.230(a)(3) for SCHs and RRCs. Specifically, under § 412.230(d)(3)(ii), an RRC or former RRC must only demonstrate that its average hourly wage is equal to at least 82 percent of the average hourly wage of hospitals in the area to which it seeks redesignation. In other words, a hospital with RRC status based on a § 412.103 rural redesignation that is seeking additional reclassification under the MGCRB to its geographic home area must only demonstrate that its average hourly wage is equal to at least 82 percent of the average hourly wage of hospitals in its geographic home area. The proximity requirement is waived under § 412.230(a)(3) for SCHs and RRCs, and SCHs and RRCs are redesignated to the urban area that is closest to the hospital (or if the hospital is closer to another rural area than to any urban area, it may seek redesignation to either the closest rural area or the closest urban area).

As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19908 through 19909), the existing regulation at § 412.230(a)(3)(ii) states that if an SCH or RRC qualifies for urban redesignation, it is redesignated to the urban area that is closest to the hospital. As currently worded, we believe it is unclear how this provision would apply to a hospital with a § 412.103 rural redesignation and SCH or RRC status. If the urban area that is closest to the hospital is interpreted to mean the hospital's geographic home area, a hospital with a § 412.103 rural redesignation and SCH or RRC status would not be able to reclassify to any closest area outside of the hospital's geographic home area, but would only be allowed to reclassify to the geographic home area. Alternatively, if the urban area that is closest to the hospital is interpreted to mean the closest urban area to the hospital's geographic home area, the hospital would seem to be precluded from reclassifying under the MGCRB to its geographic home area. In other words, under the existing language of this regulation, the urban area that is closest to the hospital can either be interpreted to mean the hospital's geographic home area, or the closest area outside of the hospital's geographic home area.

In the FY 2018 IPS/LTCH PPS proposed rule (82 FR 19909), we stated that we believe it would be appropriate to revise § 412.230(a)(3)(ii) to clarify that it allows for redesignation to either the hospital's geographic home area or to the closest area outside of the hospital's geographic home area. Prior to the April 21, 2016 interim final rule with comment period (IFC) (81 FR 23428), it was not possible for a hospital with § 412.103 rural redesignation to seek reclassification to its geographic home area or to the closest area outside its geographic home area under the MGCRB because dual reclassification under § 412.103 and under the MGCRB was not permitted. However, the IFC allowed dual § 412.103 and MGCRB reclassifications, so a hospital may now reclassify to a rural area under § 412.103 and then reclassify back to its geographic home area or another area under the MGCRB for wage index purposes (if it meets all criteria). Thus, depending on the circumstances, a hospital may seek to reclassify to either its geographic home area or the closest area outside of its geographic home area.

Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19909), we proposed to revise the regulations at § 412.230(a)(3)(ii) to clarify that a hospital with a § 412.103 rural redesignation and SCH or RRC approval may reclassify under the MGCRB to its geographic home area *or* to the closest area outside of its geographic home area. Specifically, we proposed to revise § 412.230(a)(3)(ii) to state that if a hospital that is approved as an RRC or an SCH, or both, qualifies for urban redesignation, it is redesignated to the urban area that is closest to the hospital or to the hospital's geographic home area. If the hospital is closer to another rural area than to any urban area, it may seek redesignation to either the closest rural or the closest urban area.

Comment: Two commenters supported the clarification in the proposed rule and stated that it provides clarity with respect to SCHs and RRCs with § 412.103 rural redesignation applying for MGCRB reclassification based on special access rules. In addition, the commenters stated that the proposed regulatory revision is consistent with the regulations, past administrative decisions, and CMS' policy of allowing a hospital with § 412.103 rural redesignation to reclassify under the MGCRB.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, for the reasons discussed earlier and in the FY 2018 IPPS/LTCH PPS proposed rule, we are finalizing, without modification, our proposed revision of § 412.230(a)(3)(ii) to clarify that a hospital with a § 412.103 rural redesignation and SCH or RRC approval may reclassify under the MGCRB to its geographic home area *or* to the closest area outside of its geographic home area.

3. Redesignations Under Section 1886(d)(8)(B) of the Act

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600), we adopted the policy that, beginning with FY 2012, an eligible hospital that waives its Lugar status in order to receive the out-migration adjustment has effectively waived its deemed urban status and, thus, is rural for all purposes under the IPPS effective for the fiscal year in which the hospital receives the out-migration adjustment. In addition, we adopted a minor procedural change that would allow a Lugar hospital that qualifies for and accepts the out-migration adjustment (through written notification to CMS within 45 days from

the publication of the proposed rule) to waive its urban status for the full 3-year period for which its out-migration adjustment is effective. (We note that, in section III.I.4. of the preamble of this final rule, we finalized a policy revision to require a Lugar hospital that qualifies for and accepts the out-migration adjustment, or that no longer wishes to accept the out-migration adjustment and instead elects to return to its deemed urban status, to notify CMS within 45 days from the date of public display of the proposed rule at the Office of the Federal Register.) By doing so, such a Lugar hospital would no longer be required during the second and third years of eligibility for the out-migration adjustment to advise us annually that it prefers to continue being treated as rural and receive the out-migration adjustment. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56930), we again clarified that such a request to waive Lugar status, received within 45 days of the publication of the proposed rule, is valid for the full 3-year period for which the hospital's out-migration adjustment is effective. We further clarified that if a hospital wishes to reinstate its urban status for any fiscal year within this 3-year period, it must send a request to CMS within 45 days of publication of the proposed rule for that particular fiscal year. We indicated that such reinstatement requests may be sent electronically to *wageindex@cms.hhs.gov*. We wish to further clarify that both requests to waive and to reinstate ''Lugar'' status may be sent to this mailbox. To ensure proper accounting, we request hospitals to include their CCN, and either ''waive Lugar'' or ''reinstate Lugar'', in the subject line of these requests. As noted earlier, and discussed further in section III.I.4. of this final rule, we are finalizing our proposal to revise these notification timeframes, effective October 1, 2017, to 45 days from the date of public display of the annual proposed rule.

We did not receive any public comments on this subject area in the proposed rule.

4. Changes to the 45-Day Notification Rules

Certain Medicare regulations specify that hospitals have 45 days from the publication of the annual proposed rule for the hospital inpatient prospective payment system to inform CMS or the MGCRB of certain requested reclassification/redesignation and out-migration adjustment changes relating to the development of the hospital wage index. Specifically, 42 CFR 412.64(i)(3)(iii), which provides for adjusting the wage index to account for commuting patterns of hospital workers, and 42 CFR 412.211(f)(3)(iii), which provides for the same adjustment for hospitals in Puerto Rico, state that a hospital may waive the application of this wage index adjustment by notifying CMS in writing within 45 days after the publication of the annual notice of proposed rulemaking for the hospital inpatient prospective payment system. The regulations at § 412.273(c) concerning withdrawing an MGCRB application, terminating an approved 3-year reclassification, or canceling a previous withdrawal or termination, also state (specifically § 412.273(c)(1)(ii) and (2)) that a request for withdrawal or termination must be received by the MGCRB within 45 days of publication of CMS' annual notice of proposed rulemaking concerning changes to the inpatient hospital prospective payment system and proposed payment rates. Similarly, the policy outlined in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600) allows a Lugar hospital that qualifies for and accepts the out-migration adjustment, or that no longer wishes to accept the out-migration adjustment and instead elects to return to its deemed urban status to notify CMS within 45 days from the publication of the proposed rule.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19910), we proposed to revise the above described regulation text and policies as follows to specify that written notification to CMS or the MGCRB (as applicable) must be provided within 45 days from the date of public display of the annual proposed rule for the hospital inpatient prospective payment system at the Office of the Federal Register. We stated that we believe that the public has access to the necessary information from the date of public display of the proposed rule at the Office of the Federal Register and on its Web site in order to make the decisions at issue. Specifically, we proposed to revise the regulations at § 412.64(i)(3)(iii) and § 412.211(f)(3)(iii) to provide that a hospital may waive the application of the wage index adjustment by notifying CMS within 45 days of the date of public display of the annual notice of proposed rulemaking for the hospital inpatient prospective payment system at the Office of the Federal Register. In addition, we proposed to revise the regulations at § 412.273(c)(1)(ii) and (c)(2) to provide that a request for withdrawal or termination of an MGCRB reclassification must be received by the MGCRB within 45 days of the date of public display at the Office of the Federal Register of the annual notice of proposed rulemaking concerning changes to the inpatient hospital prospective payment system and proposed payment rates for the fiscal year for which the application has been filed (in the case of a withdrawal under § 412.273(c)(1)(ii)), or for the fiscal year for which the termination is to apply (under § 412.273(c)(2)). We also proposed to revise our policy outlined in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600) (as described above) to require a Lugar hospital that qualifies for and accepts the out-migration adjustment, or that no longer wishes to accept the out-migration adjustment and instead elects to return to its deemed urban status to notify CMS within 45 days from the date of public display of the IPPS proposed rule at the Office of the Federal Register. We invited public comments on these proposals.

We did not receive any public comments on the proposed revisions to § 412.64(i)(3)(iii) or § 412.211(f)(3)(iii) with regard to the time period for hospitals to notify CMS of decisions about the out-migration adjustment, or with regard to the proposed revision to the policy outlined in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600) concerning the time period for notifications by Lugar hospitals regarding acceptance or nonacceptance of the out-migration adjustment. However, we did receive public comments on our proposed revisions to § 412.273(c)(1)(ii) and (c)(2) regarding the time period to request withdrawal or termination of an MGCRB reclassification. These comments are summarized below.

Comment: Several commenters disagreed with the proposal to change the 45-day notification requirement for MGCRB withdrawals and terminations. They stated that 45 days from the date of public display at the Office of the Federal Register would not give hospitals adequate time to review the applicable data. The commenters pointed out that the proposal would decrease the time period for providers to act by approximately 14 days, which they claimed would ''unnecessarily disadvantage'' hospitals in making the most beneficial reclassification determinations for their wage index. In addition, a few commenters presented scenarios whereby the proposal may require hospitals to submit withdrawal or termination requests to the MGCRB prior to the Administrator's decisions on MGCRB appeals. The commenters recommended that CMS maintain its existing policy of 45 days after the proposed rule is issued in the **Federal Register** for hospitals to request

withdrawal and termination of MGCRB reclassifications. One commenter suggested that CMS also allow for an extension of the current deadline to ensure providers have at least 15 days from the issuance of a CMS Administrator decision to make withdrawal and termination requests.

Response: While the commenters are correct that requiring hospitals to submit withdrawal or termination requests to the MGCRB within 45 days from the date of public display, rather than the date the proposed rule is issued in the **Federal Register**, reduces the time for hospitals to make such determinations, we do not agree that hospitals generally would have inadequate time to review the applicable data. As discussed in the proposed rule (82 FR 19910), we believe that the public has access to the necessary information from the date of public display of the proposed rule at the Office of the Federal Register and on its Web site in order to make the decisions at issue under our proposals. However, while we believe that hospitals generally would have adequate time to make reclassification determinations under the proposal, we acknowledge that hospitals may be disadvantaged if the Administrator's decision on a hospital's appeal of an MGCRB decision has not been issued prior to the proposed deadline for submitting withdrawal or termination requests to the MGCRB. Specifically, the regulations at §§ 412.278(a) and (b)(1) provide that a hospital may request the Administrator to review the MGCRB decision, and that such request must be received by the Administrator within 15 days after the date the MGCRB issues its decision. Under § 412.278(f)(2)(i), the Administrator issues a decision not later than 90 days following receipt of the party's request for review (except that the Administrator may, it his or her discretion, for good cause shown, toll such 90 days). Considering the usual dates of the MGCRB's decisions (generally early February) and of the public display of the IPPS proposed rule, the maximum amount of time for an Administrator's decision to be issued may potentially extend beyond the proposed deadline of 45 days from the date of public display. Therefore, in order to further consider whether our proposed revisions to § 412.273(c) may require hospitals to submit withdrawal or termination requests to the MGCRB before the Administrator's decision on an appeal is issued, we are not finalizing at this time our proposed change to the 45-day notification rule at § 412.273(c)(1)(ii) and (c)(2) for requesting withdrawals and terminations of MGCRB reclassifications. However, after consideration of these comments, we are revising our regulations at §§ 412.273(c)(1)(ii) and (c)(2) to ensure that our current policy under those regulations is clear. Specifically, we are revising §§ 412.273(c)(1)(ii) and (c)(2) to clarify that, under these regulations, a hospital's request to withdraw or terminate an MGCRB reclassification must be received by the MGCRB within 45 days of the date the annual notice of proposed rulemaking is issued in the **Federal Register**. We believe that these revisions will provide for greater clarification regarding how these provisions are applied. We note that we are not providing for an extension of the current deadline as one commenter suggested to allow providers to have at least 15 days from the issuance of a CMS Administrator decision to withdraw or terminate an MGCRB reclassification because we do not believe that an extension is necessary under the current deadline under §§ 412.273(c)(1)(ii) and (c)(2). Under the current deadline, a hospital can plan its withdrawal or termination decisions for both potential alternatives of the Administrator's decision on its appeal, and then act immediately within the current 45-day timeframe as soon as the Administrator's decision either to affirm or reverse the MGCRB's decision is issued.

Comment: One commenter stated that CMS' policy that hospitals must request to withdraw or terminate MGCRB reclassifications within 45 days of the proposed rule is problematic because a hospital could terminate a reclassification based on information in the proposed rule and, with the publication of the final rule, discover that its original reclassified status was more desirable. The commenter stated that hospitals cannot make informed decisions concerning their reclassification status based on values in a proposed rule that are likely to change and, therefore, recommended that CMS revise its existing policy to permit hospitals to withdraw or terminate their reclassification status within 45 days after the publication of the final rule.

Response: We maintain that information provided in the proposed rule constitutes the best available data to assist hospitals in making reclassification decisions. In addition, section 1886(d)(8)(D) of the Act requires the Secretary to adjust the standardized amounts to ensure that aggregate payments under the IPPS after implementation of the provisions of certain sections of the Act, including section 1886(d)(10) of the Act for geographic reclassifications by the MGCRB, are equal to the aggregate prospective payments that would have been made absent these provisions. If hospitals were to withdraw or terminate reclassification statuses after the final rule, as the commenter suggested CMS permit, any resulting changes in the wage index would not have been taken into account when calculating the IPPS standardized amounts in the final rule in accordance with the statutory budget neutrality requirement. Therefore, the values published in the final rule represent the final wage index values reflective of reclassification decisions.

While we are not finalizing, for the reasons discussed earlier, the proposed changes to § 412.273(c)(1)(ii) and (c)(2) concerning the time period for requesting withdrawals and terminations of MGCRB reclassifications, we are finalizing, without modification, our proposed changes to § 412.64(i)(3)(iii) and § 412.211(f)(3)(iii) regarding the 45-day requirement for notifying CMS of decisions to waive application of the out-migration adjustment, and our proposed change to the policy outlined in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600) concerning the time period for notifications by Lugar hospitals regarding acceptance or nonacceptance of the out-migration adjustment. Unlike MGCRB decisions under § 412.278, out-migration adjustment and Lugar status decisions are not subject to Administrator's review. Therefore, hospitals deciding to waive the out-migration adjustment under § 412.64(i)(3)(iii) or § 412.211(f)(3)(iii) or Lugar hospitals deciding to accept or decline the out-migration adjustment would not experience the same potential disadvantage from implementation of the proposed revisions to the 45-day notification rules. For decisions regarding the out-migration adjustment and Lugar status, we continue to believe that the public has access to the necessary information from the date of public display of the proposed rule at the Office of the Federal Register and on its Web site in order to make decisions. Therefore, we believe that it is appropriate to finalize without modification our proposed changes to § 412.64(i)(3)(iii) and § 412.211(f)(3)(iii) and our proposed change to the policy outlined in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600) as discussed earlier.

In addition, as a courtesy, we will post on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-*

for-Service-Payment/AcuteInpatient PPS/wageindex.html the calendar closing dates of the 45-day notification deadlines for waiving the out-migration adjustment, for Lugar hospitals to notify CMS regarding acceptance or nonacceptance of the out-migration adjustment, and for requesting withdrawal or termination of an MGCRB reclassification. We note that the MGCRB is independent of CMS and that the deadline for withdrawals and terminations of MGCRB reclassifications posted on CMS' Web site will be posted as a courtesy only. The MGCRB makes the final decision regarding the date of the deadline and whether a request for withdrawal or termination is timely. The public should confirm the deadline for withdrawals and terminations of MGCRB reclassifications with the MGCRB.

After consideration of the public comments we received, for the reasons discussed earlier and in the FY 2018 IPPS/LTCH PPS proposed rule, we are finalizing, without modification, the proposed changes to the regulations at § 412.64(i)(3)(iii) and § 412.211(f)(3)(iii) to provide that hospitals may waive the application of the out-migration wage index adjustment within 45 days of the date of public display of the annual notice of proposed rulemaking for the hospital inpatient prospective payment system at the Office of the Federal Register. We also are finalizing, without modification, the proposed changes to the policy outlined in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600), so that a Lugar hospital that qualifies for and accepts the out-migration adjustment, or that no longer wishes to accept the out-migration adjustment and instead elects to return to its deemed urban status, must notify CMS within 45 days from the date of public display of the IPPS proposed rule at the Office of the Federal Register. For the reasons discussed earlier, we are *not* finalizing, as proposed, the changes to the regulations at § 412.273(c)(1)(ii) and (c)(2) concerning the timeframe for submitting a request to the MGCRB to withdraw or terminate an MGCRB reclassification. Rather, we are revising the regulations at § 412.273(c)(1)(ii) and § 412.273(c)(2) to clarify our current policy under these regulations that a request for withdrawal or termination of an MGCRB reclassification must be received by the MGCRB within 45 days of the date the annual notice of proposed rulemaking is issued in the **Federal Register**. Accordingly, a request for withdrawal or termination of an MGCRB reclassification must still be received by the MGCRB within 45 days of issuance in the **Federal Register** of CMS' annual notice of proposed rulemaking concerning changes to the inpatient hospital prospective payment system and proposed payment rates. Finally, as discussed earlier, as a courtesy (and independent of the MGCRB), we will begin posting on the CMS Web site the annual calendar dates of the 45-day notification deadlines for (1) hospitals to notify CMS that they are waiving the out-migration adjustment; (2) Lugar hospitals to notify CMS that they qualify for and accept the out-migration adjustment or no longer wish to accept the outmigration adjustment and elect instead to return to deemed urban status; and (3) hospitals to request from the MGCRB withdrawal or termination of an MGCRB reclassification.

J. Out-Migration Adjustment Based on Commuting Patterns of Hospital Employees

In accordance with section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, beginning with FY 2005, we established a process to make adjustments to the hospital wage index based on commuting patterns of hospital employees (the ''out-migration'' adjustment). The process, outlined in the FY 2005 IPPS final rule (69 FR 49061), provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county (or counties) with a higher wage index. Section 1886(d)(13)(B) of the Act requires the Secretary to use data the Secretary determines to be appropriate to establish the qualifying counties. When the provision of section 1886(d)(13) of the Act was implemented for the FY 2005 wage index, we analyzed commuting data compiled by the U.S. Census Bureau that were derived from a special tabulation of the 2000 Census journey-to-work data for all industries (CMS extracted data applicable to hospitals). These data were compiled from responses to the ''long-form'' survey, which the Census Bureau used at the time and which contained questions on where residents in each county worked (69 FR 49062). However, the 2010 Census was ''short form'' only; information on where residents in each county worked was not collected as part of the 2010 Census. The Census Bureau worked with CMS to provide an alternative dataset based on the latest available data on where residents in each county worked in 2010, for use in developing a new out-migration adjustment based on new commuting patterns developed from the 2010 Census data beginning with FY 2016. To determine the out-migration adjustments and applicable counties for FY 2016, we analyzed commuting data compiled by the Census Bureau that were derived from a custom tabulation of the American Community Survey (ACS), an official Census Bureau survey, utilizing 2008 through 2012 (5-Year) Microdata. The data were compiled from responses to the ACS questions regarding the county where workers reside and the county to which workers commute. As we discussed in the FY 2016 and FY 2017 IPPS/LTCH PPS final rules (80 FR 49501 and 81 FR 56930, respectively), the same policies, procedures, and computation that were used for the FY 2012 out-migration adjustment were applicable for FY 2016 and FY 2017, and in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19910), we proposed to use them again for FY 2018. We have applied the same policies, procedures, and computations since FY 2012, and we believe they continue to be appropriate for FY 2018. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49500 through 49502) for a full explanation of the revised data source.

For FY 2018, until such time that CMS finalizes out-migration adjustments based on the next Census, the out-migration adjustment continues to be based on the data derived from the custom tabulation of the ACS utilizing 2008 through 2012 (5-Year) Microdata. For FY 2018, we did not propose any changes to the methodology or data source that we used for FY 2016 (81 FR 25071). (We refer readers to a full discussion of the out-migration adjustment, including rules on deeming hospitals reclassified under section 1886(d)(8) or section 1886(d)(10) of the Act to have waived the out-migration adjustment, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51601 through 51602).) We did not receive any public comments regarding the FY 2018 out-migration adjustment. Thus, for the reasons discussed earlier and in the FY 2018 IPPS/LTCH PPS proposed rule, we are finalizing, without modification, our proposed policies, procedures, methodology, and computation for the out-migration adjustment. Table 2 associated with this final rule (which is available via the Internet on the CMS Web site) includes the final out-migration adjustments for the FY 2018 wage index.

K. Reclassification From Urban to Rural Under Section 1886(d)(8)(E) of the Act, Implemented at 42 CFR 412.103

Under section 1886(d)(8)(E) of the Act, a qualifying prospective payment hospital located in an urban area may apply for rural status for payment purposes separate from reclassification through the MGCRB. Specifically, section 1886(d)(8)(E) of the Act provides that, not later than 60 days after the receipt of an application (in a form and manner determined by the Secretary) from a subsection (d) hospital that satisfies certain criteria, the Secretary shall treat the hospital as being located in the rural area (as defined in paragraph (2)(D)) of the State in which the hospital is located. We refer readers to the regulations at 42 CFR 412.103 for the general criteria and application requirements for a subsection (d) hospital to reclassify from urban to rural status in accordance with section 1886(d)(8)(E) of the Act. The FY 2012 IPPS/LTCH PPS final rule (76 FR 51595 through 51596) includes our policies regarding the effect of wage data from reclassified or redesignated hospitals.

Hospitals must meet the criteria to be reclassified from urban to rural status under § 412.103, as well as fulfill the requirements for the application process. There may be one or more reasons that a hospital applies for the urban to rural reclassification, and the timeframe that a hospital submits an application is often dependent on those reason(s). Because the wage index is part of the methodology for determining the prospective payments to hospitals for each fiscal year, we believe there should be a definitive timeframe within which a hospital should apply for rural status in order for the reclassification to be reflected in the next Federal fiscal year's wage data used for setting payment rates.

Therefore, after notice of proposed rulemaking and consideration of public comments, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56931 through 56932), we revised § 412.103(b) by adding paragraph (6) to specify that, in order for a hospital to be treated as rural in the wage index and budget neutrality calculations under §§ 412.64(e)(1)(ii), (e)(2), (e)(4), and (h) for payment rates for the next Federal fiscal year, the hospital's filing date must be no later than 70 days prior to the second Monday in June of the current Federal fiscal year and the application must be approved by the CMS Regional Office in accordance with the requirements of § 412.103. We refer readers to the FY 2017 IPPS/LTCH PPS final rule for a full discussion of this policy. We clarified that the lock-in date does not affect the timing of payment changes occurring at the hospital-specific level as a result of reclassification from urban to rural under § 412.103. This lock-in date also does not change the current regulation that allows hospitals that qualify under § 412.103(a) to request, at any time during a cost reporting period, to reclassify from urban to rural. A hospital's rural status and claims payment reflecting its rural status continue to be effective on the filing date of its reclassification application, which is the date the CMS Regional Office receives the application, in accordance with § 412.103(d). The hospital's IPPS claims will be paid reflecting its rural status on the filing date (the effective date) of the reclassification, regardless of when the hospital applies.

Comment: One commenter suggested that CMS' current policy that the effective date of an urban to rural reclassification under § 412.103 is the date the application is received by CMS be revised to allow flexibility for a later date. Specifically, the commenter requested that CMS allow hospitals to ask for an effective date anytime from the date the application is received until up to 60 days after the receipt of the application, to help hospitals that experience a short-term reduction in payment from obtaining rural status before becoming eligible for increased payment at a later time. The commenter stated that amending the regulation in this way would accommodate the various reasons why hospitals request rural status and will be more consistent with the statutory language at section 1886(d)(8)(E) of the Act which provides that the Secretary shall treat a hospital as rural ''not later than 60 days after the receipt of an application.''

Response: We did not propose any such revisions to the policy at § 412.103 in the FY 2018 IPPS/LTCH PPS proposed rule, but instead explained and clarified our existing policy. We appreciate the comments and may consider the commenter's request in future rulemaking.

L. Clarification of Application Deadline for Rural Referral Center (RRC) Classification

Section 1886(d)(5)(C)(i) of the Act, implemented at 42 CFR 412.96, provides for the classification and special treatment of rural referral centers (RRCs). The regulations at § 412.96 set forth the criteria that a hospital must meet in order to qualify as an RRC. Under § 412.96(b)(1)(ii), a hospital may qualify as an RRC if it is located in a rural area and has 275 or more beds during its most recently completed cost reporting period. The hospital also can obtain RRC status by showing that at least 50 percent of its Medicare patients are referred from other hospitals or from physicians not on the staff of the hospital, and at least 60 percent of the hospital's Medicare patients live more than 25 miles from the hospital, and at least 60 percent of all the services that the hospital furnishes to Medicare beneficiaries are furnished to beneficiaries who live more than 25 miles from the hospital (§ 412.96(b)(2)), or by showing that the hospital meets the alternative criteria at § 412.96(c). We refer readers to 42 CFR 412.96 for a full description of the criteria for classification as an RRC.

Consistent with section 1886(d)(5)(C)(i) of the Act, the hospital must submit its application for RRC status during the last quarter of the hospital's cost reporting period, to be effective with the beginning of the next cost reporting period. Specifically, section 1886(d)(5)(C)(i) of the Act provides that an appeal allowed under this paragraph must be submitted to the Secretary (in such form and manner as the Secretary may prescribe) during the quarter before the first quarter of the hospital's cost reporting period (or, in the case of a cost reporting period beginning during October 1984, during the first quarter of that period), and the Secretary must make a final determination with respect to such appeal within 60 days after the date the appeal was submitted. Any payment adjustments necessitated by a reclassification based upon the appeal will be effective at the beginning of such cost reporting period. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19911), we clarified that applications for RRC status must be submitted during this timeframe. That is, applications for RRC status must be submitted during the last quarter of the cost reporting period before the first quarter of a hospital's cost reporting year. If approved, the RRC status is effective with the beginning of the hospital's cost reporting period occurring after the last quarter of the cost reporting period in which the hospital submits an application.

We also clarified in the proposed rule that, while RRC applications must be submitted only within the timeframe described above, applications for urban-to-rural reclassification under § 412.103 may be submitted at any time for the hospital to be approved for rural reclassification. This includes hospitals seeking rural reclassification under § 412.103(a)(3), which states that a hospital meets criteria for urban-to-rural

reclassification if the hospital would qualify as a RRC as set forth in § 412.96, or as an SCH as set forth in § 412.92, if the hospital were located in a rural area. A hospital seeking RRC status based on a rural reclassification under § 412.103, including § 412.103(a)(3), must still submit an application for RRC status during the last quarter of its cost reporting year before the next cost reporting period in accordance with section 1886(d)(5)(C)(i) of the Act. While the § 412.103 rural redesignation would be effective as of the date of filing the application, in accordance with § 412.103(d), the RRC status would be effective beginning with the hospital's cost reporting period occurring after the last quarter of the cost reporting period in which the hospital submits an application. Because a hospital may only apply for RRC status during the last quarter of its cost reporting year in accordance with section 1886(d)(5)(C)(i) of the Act, hospitals seeking RRC status, in order to reclassify through the MGCRB using the special rules for SCHs and RRCs at § 412.230(a)(3) and the exceptions at § 412.230(d)(3) for RRCs, may be disadvantaged due to their cost reporting year end. As discussed in section III.I.2. of the preamble of the proposed rule, we proposed to revise the regulations at § 412.230(a)(3) and (d)(3) to allow hospitals to submit documentation of the approval of SCH or RRC status (as applicable) to the MGCRB no later than the first business day after January 1. We stated in the proposed rule that we believe our proposal to accept documentation of approval of RRC classification, instead of requiring that the hospital be classified as a RRC at the time of Board review, would accommodate more hospitals with various cost reporting period endings. We refer readers to section III.I.2. of the preamble of the proposed rule for further discussion of this proposal. We note that, as discussed in section III.I.2. of the preamble of this final rule, while we are finalizing our proposal that a hospital must be approved for SCH or RRC status, rather than have active SCH or RRC status, in order to use the special rules for SCHs and RRCs and the exceptions for RRCs under § 412.230(a)(3) and (d)(3), we are not finalizing our proposal to establish a deadline of the first business day after January 1 for hospitals to submit documentation of SCH and RRC status approval to the MGCRB.

Comment: One commenter agreed that the specific timing is required by the statutory language, but argued that CMS is applying a ''restrictive interpretation'' of the RRC application timing requirements so that there is not a level playing field based solely on cost report year-ends. The commenter suggested an interpretation of the statute that it believes could allow hospitals seeking to obtain RRC status for the purposes of an MGCRB application to be considered RRCs even outside of the statutory timeframe. Specifically, the commenter pointed to section 1886(d)(10)(D)(iii) of the Act, which states that, in the case of a hospital that has ever been classified by the Secretary as rural referral center, the MGCRB may not reject the application on the basis of any comparison between the average hourly wage of the hospital and the average hourly wage of hospitals in the area in which it is located. According to the commenter, CMS' determination that a hospital meets the rural redesignation requirements under § 412.103(a)(3) (that is, the hospital would qualify as an RRC if it were located in a rural area) could be considered sufficient classification to trigger the exemption from the home area wage test and application of the special access rules.

Response: As discussed earlier, and as noted by the commenter, the timeframe for applying for RRC status is set forth in the statute. We recognize that certain hospitals may be disadvantaged due to their cost reporting year end, and for that reason we proposed, and are finalizing (as discussed in section III.I.2. of the preamble of this final rule) revisions to the regulations at § 412.230(a)(3) and (d)(3) to reflect that these paragraphs apply to hospitals with RRC approval (and not only effective status).

We do not agree with the commenter that CMS' determination under § 412.103(a)(3) that a hospital would qualify for RRC status if the hospital were located in a rural area (which is one condition under which a hospital can qualify for § 412.103 rural redesignation) is considered RRC classification. In fact, hospitals may obtain rural reclassification under § 412.103(a)(3), but not subsequently obtain RRC status. Therefore, we do not believe that such a determination under § 412.103(a)(3) is sufficient to satisfy the requirements at section 1886(d)(10)(D)(iii) of the Act.

M. Process for Requests for Wage Index Data Corrections

1. Process for Hospitals To Request Wage Index Data Corrections

The preliminary, unaudited Worksheet S–3 wage data files for the proposed FY 2018 wage index were made available on May 16, 2016, and the preliminary CY 2013 occupational mix data files on May 16, 2016, through the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2018-Wage-Index-Home-Page.html*.

On January 30, 2017, we posted a public use file (PUF) at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2018-Wage-Index-Home-Page.html* containing FY 2018 wage index data available as of January 29, 2017. This PUF contains a tab with the Worksheet S–3 wage data (which includes Worksheet S–3, Parts II and III wage data from cost reporting periods beginning on or after October l, 2013 through September 30, 2014; that is, FY 2014 wage data), a tab with the occupational mix data (which includes data from the CY 2013 occupational mix survey, Form CMS–10079), a tab containing the Worksheet S–3 wage data of hospitals deleted from the January 30, 2017 wage data PUF, and a tab containing the CY 2013 occupational mix data (if any) of the hospitals deleted from the January 30, 2017 wage data PUF. In a memorandum dated January 27, 2017, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the January 30, 2017 wage index data PUFs, and the process and timeframe for requesting revisions in accordance with the FY 2018 Wage Index Timetable.

In the interest of meeting the data needs of the public, beginning with the proposed FY 2009 wage index, we post an additional PUF on our Web site that reflects the actual data that are used in computing the proposed wage index. The release of this file does not alter the current wage index process or schedule. We notify the hospital community of the availability of these data as we do with the current public use wage data files through our Hospital Open Door Forum. We encourage hospitals to sign up for automatic notifications of information about hospital issues and about the dates of the Hospital Open Door Forums at the CMS Web site at: *http://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/index.html*.

In a memorandum dated May 16, 2016, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the wage index data files and the process and timeframe for requesting revisions. We also instructed the MACs to advise hospitals that these data were also made available directly through their representative hospital organizations.

If a hospital wished to request a change to its data as shown in the May

16, 2016 wage data files and the May 16, 2016 occupational mix data files, the hospital had to submit corrections along with complete, detailed supporting documentation to its MAC by September 2, 2016. Hospitals were notified of this deadline and of all other deadlines and requirements, including the requirement to review and verify their data as posted in the preliminary wage index data files on the Internet, through the letters sent to them by their MACs.

November 4, 2016 was the date by when MACs notified State hospital associations regarding hospitals that failed to respond to issues raised during the desk reviews. The MACs notified the hospitals by mid-January 2017 of any changes to the wage index data as a result of the desk reviews and the resolution of the hospitals' revision requests. The MACs also submitted the revised data to CMS by January 20, 2017. CMS published the wage index PUFs that included hospitals' revised wage index data on January 30, 2017. Hospitals had until February 17, 2017, to submit requests to the MACs for reconsideration of adjustments made by the MACs as a result of the desk review, and to correct errors due to CMS' or the MAC's mishandling of the wage index data. Hospitals also were required to submit sufficient documentation to support their requests.

After reviewing requested changes submitted by hospitals, MACs were required to transmit to CMS any additional revisions resulting from the hospitals' reconsideration requests by March 24, 2017. Under our current policy, the deadline for a hospital to request CMS intervention in cases where a hospital disagreed with a MAC's policy interpretation was April 5, 2017. As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19912), beginning next year (that is, April 2018 for wage data revisions for the FY 2019 wage index), we proposed to require that a hospital that seeks to challenge the MAC's handling of wage data on any basis (including a policy, factual, or any other dispute) must request CMS to intervene by the date in April that is specified as the deadline for hospitals to appeal MAC determinations and request CMS' intervention in cases where the hospital disagrees with the MAC's determination (the wage index timetable would be updated to reflect the specified date). We note that, as we did for the FY 2017 wage index, for the FY 2018 wage index, in accordance with the FY 2018 wage index timeline posted on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2018-Wage-Index-Home-Page.html*, the April appeals have to be sent via mail and email. We refer readers to the wage index timeline for complete details.

We did not receive any public comments regarding our proposal discussed above. Therefore, we are finalizing our proposal, without modification, to require that, beginning next year (that is, April 2018 for wage data revisions for the FY 2019 wage index), a hospital that seeks to challenge the MAC's handling of wage data on any basis (including a policy, factual, or any other dispute) must request CMS to intervene by the date in April that is specified as the deadline for hospitals to appeal MAC determinations and request CMS' intervention in cases where the hospital disagrees with the MAC's determination (as we stated above and in the proposed rule, the wage index timetable will be updated to reflect the specified date).

Hospitals were given the opportunity to examine Table 2, which was listed in section VI. of the Addendum to the proposed rule and available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2018-Wage-Index-Home-Page.html*. Table 2 associated with the proposed rule contained each hospital's proposed adjusted average hourly wage used to construct the wage index values for the past 3 years, including the FY 2014 data used to construct the proposed FY 2018 wage index. We noted in the proposed rule (82 FR 19912) that the proposed hospital average hourly wages shown in Table 2 only reflect changes made to a hospital's data that were transmitted to CMS by early February 2017.

We posted the final wage index data PUFs on April 28, 2017 on the Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2018-Wage-Index-Home-Page.html*. The April 2017 PUFs were made available solely for the limited purpose of identifying any potential errors made by CMS or the MAC in the entry of the final wage index data that resulted from the correction process previously described (revisions submitted to CMS by the MACs by March 24, 2017).

After the release of the April 2017 wage index data PUFs, changes to the wage and occupational mix data could only be made in those very limited situations involving an error by the MAC or CMS that the hospital could not have known about before its review of the final wage index data files. Specifically, neither the MAC nor CMS will approve the following types of requests:

- Requests for wage index data corrections that were submitted too late to be included in the data transmitted to CMS by the MACs on or before March 24, 2017.
- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the January 30, 2017 wage index PUFs.
- Requests to revisit factual determinations or policy interpretations made by the MAC or CMS during the wage index data correction process.

If, after reviewing the April 2017 final wage index data PUFs, a hospital believed that its wage or occupational mix data were incorrect due to a MAC or CMS error in the entry or tabulation of the final data, the hospital was given the opportunity to notify both its MAC and CMS regarding why the hospital believed an error exists and provide all supporting information, including relevant dates (for example, when it first became aware of the error). The hospital was required to send its request to CMS and to the MAC no later than May 30, 2017. Similar to the April appeals, beginning with the FY 2015 wage index, in accordance with the FY 2018 wage index timeline posted on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2018-Wage-Index-Home-Page.html*, the May appeals were required to be sent via mail and email to CMS and the MACs. We refer readers to the wage index timeline for complete details.

Verified corrections to the wage index data received timely by CMS and the MACs (that is, by May 30, 2017) were incorporated into the final FY 2018 wage index in this FY 2018 IPPS/LTCH PPS final rule, which is effective October 1, 2017.

We created the processes previously described to resolve all substantive wage index data correction disputes before we finalize the wage and occupational mix data for the FY 2018 payment rates. Accordingly, hospitals that did not meet the procedural deadlines set forth above will not be afforded a later opportunity to submit wage index data corrections or to dispute the MAC's decision with respect to requested changes. Specifically, our policy is that hospitals that do not meet the procedural deadlines set forth earlier (requiring requests to MACs by the specified date in February and, where such requests are unsuccessful,

requests for intervention by CMS by the specified date in April) will not be permitted to challenge later, before the PRRB, the failure of CMS to make a requested data revision. We refer readers also to the FY 2000 IPPS final rule (64 FR 41513) for a discussion of the parameters for appeals to the PRRB for wage index data corrections.

Again, we believe the wage index data correction process described earlier provides hospitals with sufficient opportunity to bring errors in their wage and occupational mix data to the MAC's attention. Moreover, because hospitals had access to the final wage index data PUFs by late April 2017, they had the opportunity to detect any data entry or tabulation errors made by the MAC or CMS before the development and publication of the final FY 2018 wage index by August 2017, and the implementation of the FY 2018 wage index on October 1, 2017. Given these processes, the wage index implemented on October 1 should be accurate. Nevertheless, in the event that errors are identified by hospitals and brought to our attention after May 30, 2017, we retain the right to make midyear changes to the wage index under very limited circumstances.

Specifically, in accordance with 42 CFR 412.64(k)(1) of our regulations, we make midyear corrections to the wage index for an area only if a hospital can show that: (1) The MAC or CMS made an error in tabulating its data; and (2) the requesting hospital could not have known about the error or did not have an opportunity to correct the error, before the beginning of the fiscal year. For purposes of this provision, ''before the beginning of the fiscal year'' means by the May deadline for making corrections to the wage data for the following fiscal year's wage index (for example, May 30, 2017 for the FY 2018 wage index). This provision is not available to a hospital seeking to revise another hospital's data that may be affecting the requesting hospital's wage index for the labor market area. As indicated earlier, because CMS makes the wage index data available to hospitals on the CMS Web site prior to publishing both the proposed and final IPPS rules, and the MACs notify hospitals directly of any wage index data changes after completing their desk reviews, we do not expect that midyear corrections will be necessary. However, under our current policy, if the correction of a data error changes the wage index value for an area, the revised wage index value will be effective prospectively from the date the correction is made.

In the FY 2006 IPPS final rule (70 FR 47385 through 47387 and 47485), we revised 42 CFR 412.64(k)(2) to specify that, effective on October 1, 2005, that is, beginning with the FY 2006 wage index, a change to the wage index can be made retroactive to the beginning of the Federal fiscal year only when CMS determines all of the following: (1) The MAC or CMS made an error in tabulating data used for the wage index calculation; (2) the hospital knew about the error and requested that the MAC and CMS correct the error using the established process and within the established schedule for requesting corrections to the wage index data, before the beginning of the fiscal year for the applicable IPPS update (that is, by the May 30, 2017 deadline for the FY 2018 wage index); and (3) CMS agreed before October 1 that the MAC or CMS made an error in tabulating the hospital's wage index data and the wage index should be corrected.

In those circumstances where a hospital requested a correction to its wage index data before CMS calculated the final wage index (that is, by the May 30, 2017 deadline for the FY 2018 wage index), and CMS acknowledges that the error in the hospital's wage index data was caused by CMS' or the MAC's mishandling of the data, we believe that the hospital should not be penalized by our delay in publishing or implementing the correction. As with our current policy, we indicated that the provision is not available to a hospital seeking to revise another hospital's data. In addition, the provision cannot be used to correct prior years' wage index data; and it can only be used for the current Federal fiscal year. In situations where our policies would allow midyear corrections other than those specified in 42 CFR 412.64(k)(2)(ii), we continue to believe that it is appropriate to make prospective-only corrections to the wage index.

We note that, as with prospective changes to the wage index, the final retroactive correction will be made irrespective of whether the change increases or decreases a hospital's payment rate. In addition, we note that the policy of retroactive adjustment will still apply in those instances where a final judicial decision reverses a CMS denial of a hospital's wage index data revision request.

2. Process for Data Corrections by CMS After the January Public Use File (PUF)

The process set forth with the wage index timeline discussed in section III.M.1. of the preamble of this final rule allows hospitals to request corrections to their wage index data within prescribed timeframes. In addition to hospitals' opportunity to request corrections of wage index data errors or MACs' mishandling of data, CMS has the authority under section 1886(d)(3)(E) of the Act to make corrections to hospital wage index and occupational mix data in order to ensure the accuracy of the wage index. As we explained in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49490 through 49491) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 56914), section 1886(d)(3)(E) of the Act requires the Secretary to adjust the proportion of hospitals' costs attributable to wages and wage-related costs for area differences reflecting the relative hospital wage level in the geographic areas of the hospital compared to the national average hospital wage level. As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19913 through 19915), we believe that, under section 1886(d)(3)(E) of the Act, we have discretion to make corrections to hospitals' data to help ensure that the costs attributable to wages and wage-related costs in fact accurately reflect the relative hospital wage level in the hospitals' geographic areas.

We have an established multistep, 15-month process for the review and correction of the hospital wage data that is used to create the IPPS wage index for the upcoming fiscal year. Since the origin of the IPPS, the wage index has been subject to its own annual review process, first by the MACs, and then by CMS. As a standard practice, after each annual desk review, CMS reviews the results of the MACs' desk reviews and focuses on items flagged during the desk review, requiring that, if necessary, hospitals provide additional documentation, adjustments, or corrections to the data. This ongoing communication with hospitals about their wage data may result in the discovery by CMS of additional items that were reported incorrectly or other data errors, even after the posting of the January PUF, and throughout the remainder of the wage index development process. In addition, the fact that CMS analyzes the data from a regional and even national level, unlike the review performed by the MACs that review a limited subset of hospitals, can facilitate additional editing of the data that may not be readily apparent to the MACs. In these occasional instances, an error may be of sufficient magnitude that the wage index of an entire CBSA is affected. Accordingly, CMS uses its authority to ensure that the wage index accurately reflects the relative hospital wage level in the geographic area of the

hospital compared to the national average hospital wage level, by continuing to make corrections to hospital wage data upon discovering incorrect wage data, distinct from instances in which hospitals request data revisions.

We note that CMS corrects errors to hospital wage data as appropriate, regardless of whether that correction will raise or lower a hospital's average hourly wage. For example, as discussed in section III.D.2. of the preamble of the proposed rule (82 FR 19900 through 19902), in the calculation of the proposed FY 2018 wage index, upon discovering that hospitals reported other wage-related costs on Line 18 of Worksheet S–3, despite those other wage-related costs failing to meet the requirement that other wage related costs must exceed 1 percent of total adjusted salaries net of excluded area salaries, CMS made internal edits to remove those other wage-related costs from Line 18. Conversely, if CMS discovers after conclusion of the desk review, for example, that a MAC inadvertently failed to incorporate positive adjustments resulting from a prior year's wage index appeal to a hospital's wage related costs such as pension, CMS would correct that data error and the hospital's average hourly wage would likely increase as a result.

While we maintain CMS' authority to conduct additional review and make resulting corrections at any time during the wage index development process, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19914), we proposed a process for hospitals to request further review of a correction made by CMS starting with the FY 2019 wage index. In order to allow opportunity for input from hospitals concerning corrections made by CMS after the posting of the January PUF, we proposed a process similar to the existing process in which hospitals may request corrections to wage index data displayed in the January PUF. We stated in the proposed rule that instances where CMS makes a correction to a hospital's data after the January PUF based on a different understanding than the hospital about certain reported costs, for example, could potentially be resolved using this proposed process before the final wage index is calculated. We stated that we believe this proposed process and timeline (as described below) would bring additional transparency to instances where CMS makes data corrections after the January PUF, and would provide opportunities for hospitals to request further review of CMS changes in time for the most accurate data to be reflected in the final wage index calculations.

Effective beginning with the FY 2019 wage index development cycle, we proposed to use existing appeal deadlines (in place for hospitals to appeal determinations made by the MAC during the desk review process) for hospitals to dispute corrections made by CMS after posting of the January PUF that do not arise from a hospital request for a wage data revision. Starting with the April appeal deadline, hospitals would use the soonest approaching appeal deadline to dispute any adjustments made by CMS. However, if a hospital was notified of an adjustment within 14 days of an appeal deadline, the hospital would have until the next appeal deadline to dispute any adjustments. We believe this would give hospitals sufficient time to prepare an appeal of adjustments made by CMS after the January PUF. Specifically, for any adjustments made by CMS between the date the January PUF is posted and at least 14 calendar days before the April appeals deadline, we proposed that hospitals would have until the April appeals deadline (which, for example, is April 5 in the FY 2018 Wage Index Timetable) to dispute the adjustments. For any adjustments made by CMS between 13 calendar days before the April appeals deadline and 14 calendar days before the May appeals deadline, we proposed that hospitals would have until the May appeals deadline (which, for example, is May 30 in the FY 2018 Wage Index Timetable) to dispute the adjustments. In cases where hospitals disagree with CMS adjustments of which they were notified 13 calendar days before the May appeals deadline or later, the hospitals could appeal to the PRRB with no need for further review by CMS before such appeal.

We are using dates from the FY 2018 Wage Index Timetable in the following example which was included in the proposed rule at 82 FR 19914 (we reiterate that this appeals process would be effective beginning with the FY 2019 wage index cycle, but for illustrative purposes, we are using dates from the FY 2018 Wage Index Timetable, the most recently published wage index timetable): A hospital that is notified by the MAC or CMS of an adjustment to its wage data after the release of the January 30, 2017 PUF could use the April 5, 2017 appeals deadline to dispute the adjustment. If the hospital is notified of an adjustment by CMS or the MAC to its wage data after March 22, 2017 (that is, less than 14 days prior to the April 5 appeals deadline), it could use the May 30, 2017 appeals deadline to dispute the adjustment. If the hospital is first notified about the adjustment after May 16, 2017 (that is, less than 14 days prior to the May 30 deadline), and disagrees with the adjustment, the hospital could appeal directly to the PRRB.

As with the existing process for requesting wage data corrections, we proposed that a hospital disputing an adjustment made by CMS after the posting of the January PUF would be required to request a correction by the first applicable deadline. For example, using the FY 2018 Wage Index Timetable for illustrative purposes only, if a hospital was notified on March 20 of an adjustment to its data by CMS and did not appeal by April 5, the hospital would not be able to appeal by May 30 or bring the case before the PRRB. That is, hospitals that do not meet the procedural deadlines set forth earlier would not be afforded a later opportunity to submit wage index data corrections or to dispute CMS' decision with respect to requested changes. As with the existing process for hospitals to request wage data corrections, our policy is that hospitals that do not meet the procedural deadlines set forth earlier would not be permitted to challenge later, before the PRRB, the failure of CMS to make a requested data revision.

In summary, under the statute, CMS has discretion to make corrections and revisions to hospitals' wage data throughout the multistep wage index development process, and we proposed a pathway for hospitals to request additional review of corrections to their wage data made by CMS. Beginning with the development of the FY 2019 wage index, we proposed a process whereby CMS could continue to correct data after the posting of the January PUF, while allowing hospitals to appeal changes made by CMS using existing deadlines from the process for hospitals to request wage data corrections. As with the existing process, a hospital would be required to appeal by the first applicable deadline, if relevant, to maintain the right to appeal to the PRRB to dispute a correction to its wage data made by CMS.

We invited public comments on our proposals.

Comment: Several commenters stated that CMS is proposing to limit the time a provider has to dispute an adjustment once the January PUF is posted. The commenters stated that, currently, hospitals have 1 month to request corrections for errors in the April 28 PUF. They maintained that the reduced timelines will require hospitals to review the posted PUF immediately to

ensure that the data are correct and take any necessary action to correct. The commenters also noted that CMS has taken a more active role in recent years in performing additional data analysis that results in follow-up questions or requests to hospitals for supporting data, which require time for hospitals to develop a response. One commenter stated that, by reducing time, CMS will be placing an administrative hardship on hospitals while they attempt to respond to detailed audit requests. Some of the commenters were ''deeply concerned'' that the short timeline CMS proposed to respond to detailed requests will not allow for comprehensive analysis and a thorough response. One commenter specifically requested that the dispute process be expanded to 28 days prior to the appeal deadline, instead of the proposed 14 days, to give hospitals enough time to collect data and respond in a timely manner.

Response: We believe that the commenters misunderstood our proposal as a change to the current process for hospitals to request wage data corrections, rather than an additional process for disputing corrections made by CMS after the January PUF that do not arise from a hospital's request for wage data revisions. Under our proposal, hospitals would still have approximately 1 month to request corrections for errors in the April 28 PUF, in accordance with the wage index timetable. Our proposal would create an additional process for hospitals to appeal adjustments or corrections made by CMS or the MAC after the normal desk review timeframe that do not arise from a hospital's request for wage data revisions. Therefore, we do not agree that this proposal requires hospitals to review the posted PUF any earlier than hospitals would do so under the current policy, or that it constitutes administrative hardship. Furthermore, we believe that, rather than limiting hospitals, our proposal would provide additional transparency and opportunities for hospitals to request further review of CMS changes made after the January PUF where there is currently no such established process.

Regarding the concerns that the proposed timeline is too short and the suggestion that CMS expand the 14-day timeline to 28 days, we continue to believe that our proposed timeline would give hospitals sufficient time to prepare an appeal of adjustments made by CMS after the January PUF. We believe that a hospital that was notified of an adjustment at least 2 weeks before the upcoming deadline has enough time to prepare an appeal by the upcoming deadline. Specifically, starting with the April appeal deadline, hospitals would use the soonest approaching appeal deadline to dispute any adjustments made by CMS. However, if a hospital was notified of an adjustment within 14 days of an appeal deadline, the hospital would have until the next appeal deadline to dispute any adjustments.

Comment: One commenter did not state a position on the proposal but expressed the following concerns: First, that CMS should add the particulars of this appeal process to the existing FY 2019 Wage Index Timeline that is published and made available online each year by CMS; second, that most adjustments to the wage data made by CMS on a routine basis be performed much earlier in the process than these April and May appeal deadlines, so that the proposed appeal process would be reserved for ''rare and unusual circumstances requiring CMS' intervention and adjustment to the data.'' Specifically, this commenter stated that it would oppose a policy that gives CMS the latitude to indiscriminately make adjustments to the hospital wage data this late in the process where that adjustment was known of far ahead of time and/or could have easily been made earlier in the process.

Response: We appreciate the commenter's concerns and suggestions. In response to the commenter's first suggestion, we intend to add the particulars of this appeal process to the existing Wage Index Timeline that is published and made available online each year by CMS. Second, while we maintain CMS' authority under section 1886(d)(3)(E) of the Act to make corrections to hospitals' data to help ensure the accuracy of the wage index, we note that routine adjustments to the wage data that are known of far ahead of time and/or could easily be made earlier in the process will continue to be performed earlier in the process than these April and May appeal deadlines.

After consideration of the public comments we received, for the reasons discussed earlier and in the FY 2018 IPPS/LTCH PPS proposed rule, we are finalizing, without modification, our proposed process for hospitals to dispute data corrections made by CMS after the January PUF that do not arise from a hospital's request for wage data revisions. Effective beginning with the FY 2019 wage index development cycle, we will use existing appeal deadlines (in place for hospitals to appeal determinations made by the MAC during the desk review process) for hospitals to dispute corrections made by CMS after posting of the January PUF that do not arise from a hospital request for a wage data revisions. Starting with the April appeal deadline, hospitals must use the soonest approaching appeal deadline to dispute any adjustments made by CMS. However, if a hospital is notified of an adjustment within 14 days of an appeal deadline, the hospital has until the next appeal deadline to dispute any adjustments, as discussed earlier. As with the existing process for requesting wage data corrections, a hospital disputing an adjustment made by CMS after the posting of the January PUF will be required to request a correction by the first applicable deadline. For example, using the FY 2018 Wage Index Timetable for illustrative purposes only, if a hospital was notified on March 20 of an adjustment to its data by CMS and did not appeal by April 5, the hospital would not be able to appeal by May 30 or bring the case before the PRRB. That is, hospitals that do not meet the procedural deadlines set forth above will not be afforded a later opportunity to submit wage index data corrections or to dispute CMS' decision with respect to requested changes. Our policy is that hospitals that do not meet the procedural deadlines set forth earlier will not be permitted to challenge later, before the PRRB, the failure of CMS to make a requested data revision.

N. Labor-Market Share for the FY 2018 Wage Index

Section 1886(d)(3)(E) of the Act directs the Secretary to adjust the proportion of the national prospective payment system base payment rates that are attributable to wages and wage-related costs by a factor that reflects the relative differences in labor costs among geographic areas. It also directs the Secretary to estimate from time to time the proportion of hospital costs that are labor-related and to adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates. We refer to the portion of hospital costs attributable to wages and wage-related costs as the labor-related share. The labor-related share of the prospective payment rate is adjusted by an index of relative labor costs, which is referred to as the wage index.

Section 403 of Public Law 108–173 amended section 1886(d)(3)(E) of the Act to provide that the Secretary must employ 62 percent as the labor-related share unless this would result in lower payments to a hospital than would otherwise be made. However, this provision of Public Law 108–173 did

not change the legal requirement that the Secretary estimate from time to time the proportion of hospitals' costs that are attributable to wages and wage-related costs. Thus, hospitals receive payment based on either a 62-percent labor-related share, or the labor-related share estimated from time to time by the Secretary, depending on which labor-related share resulted in a higher payment.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50596 through 50607), we rebased and revised the hospital market basket. We established a FY 2010-based IPPS hospital market basket to replace the FY 2006-based IPPS hospital market basket, effective October 1, 2013. In that final rule, we presented our analysis and conclusions regarding the frequency and methodology for updating the labor-related share for FY 2014. Using the FY 2010-based IPPS market basket, we finalized a labor-related share for FY 2014, FY 2015, FY 2016, and FY 2017 of 69.6 percent. In addition, in FY 2014, we implemented this rebased and revised labor-related share in a budget neutral manner (78 FR 51016). However, consistent with section 1886(d)(3)(E) of the Act, we did not take into account the additional payments that would be made as a result of hospitals with a wage index less than or equal to 1.0000 being paid using a labor-related share lower than the labor-related share of hospitals with a wage index greater than 1.0000.

For FY 2018, as described in section IV. of the preamble of the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19916 through 19929), we proposed to rebase and revise the IPPS market basket reflecting 2014 data. We also proposed to recalculate the labor-related share for discharges occurring on or after October 1, 2017 using the proposed 2014-based IPPS market basket. As discussed in Appendix A of the proposed rule, we proposed this rebased and revised labor-related share in a budget neutral manner. However, consistent with section 1886(d)(3)(E) of the Act, we did not take into account the additional payments that would be made as a result of hospitals with a wage index less than or equal to 1.0000 being paid using a labor-related share lower than the labor-related share of hospitals with a wage index greater than 1.0000. We refer readers to section IV. of the preamble of this final rule and Appendix A for our finalized policies for the 2014-based IPPS market basket.

The labor-related share is used to determine the proportion of the national IPPS base payment rate to which the area wage index is applied. We include a cost category in the labor-related share if the costs are labor intensive and vary with the local labor market. As described in section IV. of the preamble of the proposed rule, we proposed to include in the labor-related share the national average proportion of operating costs that are attributable to Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Facilities Support Services, Installation, Maintenance, and Repair Services, and All Other: Labor-Related Services as measured in the proposed 2014-based IPPS market basket. Therefore, for FY 2018, we proposed to use a labor-related share of 68.3 percent for discharges occurring on or after October 1, 2017.

We refer readers to section IV.B.3. of the preamble of this final rule for a discussion of our recalculation of the labor-related share for discharges occurring on or after October 1, 2017 using the 2014-based IPPS market basket.

Prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we applied the Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage to the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need for us to calculate a Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage for application to the Puerto Rico-specific standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national labor-related share and nonlabor-related share percentages that are applied to the national standardized amount. Accordingly, for FY 2018, we did not propose a Puerto Rico-specific labor-related share percentage or a nonlabor-related share percentage in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19915).

Comment: Commenters suggested that CMS consider an approach that will mitigate significant decreases in inpatient payments to hospitals as a result of the proposed decrease in the labor-related share for FY 2018.

Response: As noted earlier, section 1886(d)(3)(E) of the Act directs the Secretary to adjust the proportion of the national prospective payment system base payment rates that are attributable to wages and wage-related costs by a factor that reflects the relative differences in labor costs among geographic areas. It also directs the Secretary to estimate from time to time the proportion of hospital costs that are labor-related and to adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates. In section IV.B.3. of the preamble of this final rule, we discuss our recalculation of the labor-related share for discharges occurring on or after October 1, 2017, using the 2014-based IPPS market basket. We believe that the labor-related share calculated for FY 2018 accurately and appropriately reflects the proportion of hospitals' costs that are attributable to wages and wage-related costs. Therefore, we do not believe it is necessary or appropriate to mitigate the effects of the labor-related share percentage finalized in this rule.

After consideration of the public comments we received, for the reasons discussed in section IV.B.3. of the preamble of this final rule and in the FY 2018 IPPS/LTCH PPS proposed rule, we are finalizing our proposal to use a labor-related share of 68.3 percent for discharges occurring on or after October 1, 2017, for all hospitals (including Puerto Rico hospitals) whose wage indexes are greater than 1.0000.

Tables 1A and 1B, which are published in section VI. of the Addendum to this FY 2018 IPPS/LTCH PPS final rule and available via the Internet on the CMS Web site, reflect the national labor-related share, which is also applicable to Puerto Rico hospitals. For FY 2018, for all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are less than or equal to 1.0000, we are applying the wage index to a labor-related share of 62 percent of the national standardized amount. For all hospitals (including Puerto Rico hospitals) whose wage indexes are greater than 1.0000, for FY 2018, we are applying the wage index to a labor-related share of 68.3 percent of the national standardized amount.

IV. Rebasing and Revising of the Hospital Market Baskets for Acute Care Hospitals

A. Background

Effective for cost reporting periods beginning on or after July 1, 1979, we developed and adopted a hospital input price index (that is, the hospital market basket for operating costs). Although ''market basket'' technically describes the mix of goods and services used in providing hospital care, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies combined) derived from that market basket. Accordingly, the term ''market basket'' as used in this document refers to the hospital input price index.

The percentage change in the market basket reflects the average change in the price of goods and services hospitals purchase in order to provide inpatient care. We first used the market basket to adjust hospital cost limits by an amount that reflected the average increase in the prices of the goods and services used to provide hospital inpatient care. This approach linked the increase in the cost limits to the efficient utilization of resources.

Since the inception of the IPPS, the projected change in the hospital market basket has been the integral component of the update factor by which the prospective payment rates are updated every year. An explanation of the hospital market basket used to develop the prospective payment rates was published in the **Federal Register** on September 1, 1983 (48 FR 39764). We also refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50596) in which we discussed the most recent previous rebasing of the hospital input price index.

The hospital market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres-type price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time are not measured.

The index itself is constructed in three steps, which are discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19916 through 19929) and in this final rule. First, a base period is selected (in the proposed rule, we proposed to use 2014 as the base period) and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories, with the proportion of total costs that each category represents being calculated. These proportions are called ''cost weights'' or ''expenditure weights.'' Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a ''price proxy.'' In almost every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the expenditure weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the expenditure weights multiplied by their price index levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe.

As noted above, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to provide hospital services. The effects on total expenditures resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, a hospital hiring more nurses to accommodate the needs of patients would increase the volume of goods and services purchased by the hospital, but would not be factored into the price change measured by a fixed-weight hospital market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so that the cost weights reflect recent changes in the mix of goods and services that hospitals purchase (hospital inputs) to furnish inpatient care between base periods.

We last rebased the hospital market basket cost weights effective for FY 2014 (78 FR 50596), with FY 2010 data used as the base period for the construction of the market basket cost weights. For the FY 2018 IPPS/LTCH PPS proposed rule, we proposed to rebase the cost structure for the IPPS hospital index from FY 2010 to 2014, as discussed in the proposed rule (82 FR 19916 through 19929) and below in this final rule.

B. Rebasing and Revising the IPPS Market Basket

The terms ''rebasing'' and ''revising,'' while often used interchangeably, actually denote different activities. ''Rebasing'' means moving the base year for the structure of costs of an input price index (for example, in the proposed rule, we proposed to shift the base year cost structure for the IPPS hospital index from FY 2010 to 2014). We note that we proposed to no longer refer to the market basket as a ''FY 2014-based'' market basket and instead referred to the proposed market basket as simply ''2014-based''. We proposed this change in naming convention for the market basket because the base year cost weight data for the proposed market basket does not reflect only fiscal year data. For example, the proposed 2014-based IPPS market basket uses Medicare cost report data and other government data that reflect 2014 fiscal year, 2014 calendar year, and 2014 State fiscal year expenses to determine the base year cost weights. Given that it is based on a mix of classifications of 2014 data, we proposed to refer to the market basket as ''2014-based'' instead of ''FY 2014-based'' or ''CY 2014-based''.

''Revising'' means changing data sources or price proxies used in the input price index. As published in the FY 2006 IPPS final rule (70 FR 47387), in accordance with section 404 of Public Law 108–173, CMS determined a new frequency for rebasing the hospital market basket. We established a rebasing frequency of every 4 years and, therefore, for the FY 2018 IPPS update, we proposed to rebase and revise the IPPS market basket from FY 2010 to 2014. We invited public comments on our proposed methodology. A summary of the public comments we received and our responses are included below under the appropriate subject area.

1. Development of Cost Categories and Weights

a. Use of Medicare Cost Report Data

The major source of expenditure data for developing the proposed hospital market basket cost weights is the 2014 Medicare cost reports. These 2014 Medicare cost reports are for cost reporting periods beginning on and after October 1, 2013 and before October 1, 2014. We note that while these dates appear to reflect fiscal year data, in order to be classified as a ''2014 cost report,'' a hospital's cost reporting period must begin between these dates. For example, we found that of the 2014 Medicare cost reports for IPPS hospitals, approximately 40 percent of the reports had a begin date on January 1, 2014, approximately 30 percent had a begin date on July 1, 2014, and approximately 18 percent had a begin date on October 1, 2013. For this reason, we are defining the base year of the market basket as ''2014-based'' instead of ''FY 2014-

based''. We proposed to use 2014 as the base year because we believe that the 2014 Medicare cost reports represent the most recent, complete set of Medicare cost report data available to develop cost weights for IPPS hospitals at the time of rulemaking. As was done in previous rebasings, these cost reports are from IPPS hospitals only (hospitals excluded from the IPPS and CAHs are not included) and are based on IPPS Medicare-allowable operating costs. IPPS Medicare-allowable operating costs are costs that are eligible to be paid under the IPPS. For example, the IPPS market basket excludes home health agency (HHA) costs as these costs would be paid under the HHA PPS and, therefore, these costs are not IPPS Medicare-allowable costs.

We proposed to derive costs for eight major expenditures or cost categories for the 2014-based IPPS market basket from the CMS Medicare cost reports (Form 2552–10, OMB Control Number 0938–0050): Wages and Salaries, Employee Benefits, Contract Labor, Pharmaceuticals, Professional Liability Insurance (Malpractice), Blood and Blood Products, Home Office Contract Labor, and a residual ''All Other'' category. The residual ''All Other'' category reflects all remaining costs that are not captured in the other seven cost categories. We proposed that, for the 2014-based IPPS market basket, we obtain costs for one additional major cost category from the Medicare cost reports compared to the FY 2010-based IPPS market basket—Home Office Contract Labor Costs. We describe below the detailed methodology for obtaining costs for each of the seven cost categories directly determined from the Medicare cost reports. We received one specific comment on the detailed methodology of the major cost weights, specifically for the Home Office Contract Labor cost weight. We address this comment below.

(1) Wages and Salaries Costs

To derive wages and salaries costs for the Medicare allowable cost centers, we proposed to first calculate total unadjusted wages and salaries costs as reported on Worksheet S–3, part II. We then proposed to remove the wages and salaries attributable to non-Medicare allowable cost centers (that is, excluded areas) as well as a portion of overhead wages and salaries attributable to these excluded areas. Specifically, wages and salaries costs were equal to total wages and salaries as reported on Worksheet S–3, Part II, Column 4, Line 1, less excluded area wages and salaries (reported on Worksheet S–3, Part II, Column 4, Lines 3 and 5 through 10) and less overhead wages and salaries attributable to the excluded areas.

Overhead wages and salaries are attributable to the entire IPPS facility. Therefore, we proposed to only include the proportion attributable to the Medicare allowable cost centers. We proposed to estimate the proportion of overhead wages and salaries that are not attributable to Medicare allowable costs centers (that is, excluded areas) by multiplying the ratio of excluded area wages and salaries (as defined earlier) to total wages and salaries (Worksheet S–3, part II, Column 4, Line 1) by total overhead wages and salaries (Worksheet A, Column 1, Lines 4 through 18). A similar methodology was used to derive wages and salaries costs in the FY 2010-based IPPS market basket.

(2) Employee Benefits Costs

We proposed to derive employee benefits costs using a similar methodology as the wages and salaries costs; that is, reflecting employee benefits costs attributable to the Medicare allowable cost centers. First, we calculated total unadjusted employee benefits costs as the sum of Worksheet S–3, Part II, Column 4, Lines 17, 18, 20, and 22. We then excluded those employee benefits attributable to the overhead wages and salaries for the non-Medicare allowable cost centers (that is, excluded areas). Employee benefits attributable to the non-Medicare allowable cost centers were derived by multiplying the ratio of total employee benefits (equal to the sum of Worksheet S–3, Part II, Column 4, Lines 17 through 25) to total wages and salaries (Worksheet S–3, Part II, Column 4, Line 1) by excluded overhead wages and salaries (as derived above for wages and salaries costs). A similar methodology was used in the FY 2010-based IPPS market basket.

(3) Contract Labor Costs

Contract labor costs are primarily associated with direct patient care services. Contract labor costs for services such as accounting, billing, and legal are estimated using other government data sources as described below. We proposed to derive contract labor costs for the 2014-based IPPS market basket as the sum of Worksheet S–3, Part II, Column 4, Lines 11, 13 and 15. A similar methodology was used in the FY 2010-based IPPS market basket.

(4) Professional Liability Insurance Costs

We proposed that professional liability insurance (PLI) costs (often referred to as malpractice costs) be equal to premiums, paid losses, and self-insurance costs reported on Worksheet S–2, Part I, Columns 1 through 3, Line 118.01. A similar methodology was used for the FY 2010-based IPPS market basket.

(5) Pharmaceuticals Costs

We proposed to calculate pharmaceuticals costs using nonsalary costs reported for the Pharmacy cost center (Worksheet A, Column 2, Line 15) and Drugs Charged to Patients cost center (Worksheet A, Column 2, Line 73) less estimated employee benefits attributable to these two cost centers. We proposed to estimate these employee benefits costs by multiplying the ratio of total employee benefits (equal to the sum of Worksheet S–3, Part II, Column 4, Lines 17 through 25) to total wages and salaries (Worksheet S–3, Part II, Column 4, Line 1) by total wages and salaries costs for the Pharmacy and Drugs Charged to Patients cost centers (equal to the sum of Worksheet A, Column 1, Lines 15 and 73). A similar methodology was used for the FY 2010-based IPPS market basket.

(6) Blood and Blood Products Costs

We proposed to calculate blood and blood products costs using nonsalary costs reported for the Whole Blood & Packed Red Blood Cells cost center (Worksheet A, Column 2, Line 62) and the Blood Storing, Processing, & Transfusing cost center (Worksheet A, Column 2, Line 63) less estimated employee benefits attributable to these two cost centers. We estimated these employee benefits costs by multiplying the ratio of total employee benefits (equal to the sum of Worksheet S–3, Part II, Column 4, Lines 17 through 25) to total wages and salaries (Worksheet S3, Part II, Column 4, Line 1) by total wages and salaries for the Whole Blood & Packed Red Blood Cells and Blood Storing, Processing, & Transfusing cost centers (equal to the sum of Worksheet A, Column 1, Lines 62 and 63). A similar methodology was used for the FY 2010-based IPPS market basket.

(7) Home Office Contract Labor Costs

We proposed to determine home office contract labor costs using data reported on Worksheet S–3, Part II, Column 4, line 14. Specifically, we proposed to determine the Medicare allowable portion of these costs by multiplying them by the ratio of total Medicare allowable operating costs (as defined in section IV.B.1.b. of the preamble to the proposed rule and in section IV.B.1.b. of the preamble of this final rule) to total operating costs (calculated as Worksheet B, Part I, Column 26, Line 202, less Worksheet B,

Part I, Column 0, Lines 1 through 3). Home office contract labor costs in the FY 2010-based IPPS market basket were calculated using the U.S. Census Bureau's Bureau of Economic Analysis (BEA) Benchmark Input-Output (I–O) data, as described in section IV.B.1.c. of the preamble to the proposed rule and in section IV.B.1.c. of the preamble of this final rule.

Comment: One commenter stated that the data reported on Worksheet S–3, Part II, Column 4, Line 14 is not specific to home office costs but can include costs to other related organizations. The commenter recommended that if the intent is to only capture home office costs, CMS use a different data source. However, if the intent is to capture home office and other related organization costs, the commenter recommended that the label applied to the major cost category be altered to reflect the actual cost being utilized (for example, Home Office/Related Party Contract Labor Costs).

Response: We agree with the commenter's suggestion to alter the label for this cost category. The instructions for the Medicare cost report (CMS form 2552–10) in the CMS Provider Reimbursement Manual, Part 2 state that the costs included on this line represent salaries and wage-related costs paid to personnel who are affiliated with a home office and/or related organization, who provide services to the hospital, and whose salaries are not included on Worksheet A, Column 1 (CMS Pub. 15–2, Section 4005.2). According to the CMS Provider Reimbursement Manual, Part 1, an organization is defined as being related to the provider when the provider to a significant extent is associated or affiliated with, or has control of, or is controlled by, the organization furnishing the services, facilities, or supplies (CMS Pub 15–1, Section 1002.1).

As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19923), the costs included in this proposed category for the 2014-based IPPS market basket were previously obtained from the BEA Benchmark I–O data using the costs from the NAICS 55 sector (Management of Companies or Enterprises). The definition of the NAICS 55 sector from the BLS Web site is: (1) Establishments that hold the securities of (or other equity interests in) companies and enterprises for the purpose of owning a controlling interest or influencing management decisions or (2) establishments (except government establishments) that administer, oversee, and manage establishments of the company or enterprise and that normally undertake the strategic or organizational planning and decision-making role of the company or enterprise. Establishments that administer, oversee, and manage may hold the securities of the company or enterprise. (*https://www.bls.gov/iag/tgs/iag55.htm*).

As was done for the FY 2010-based IPPS market basket when we used the Benchmark I–O data, to calculate home office contract labor costs using the Medicare cost reports, our intent is to capture both home office and related organization compensation costs. Our proposed methodology of using the Medicare cost report data meets our intention and reflects the most current data on these expenses. We appreciate the commenter's suggestion and will incorporate this suggestion by finalizing the cost category label to be ''Home Office/Related Organization Contract Labor'' so it is more consistent with the scope of costs included in this category.

b. Final Major Cost Category Computation

After we derived costs for the seven major cost categories for each provider using the Medicare cost report data as previously described, we proposed to address data outliers using the following steps. First, we divided the costs for each of the seven categories by total Medicare allowable operating costs calculated for the provider to obtain cost weights for each PPS hospital. We proposed that total Medicare allowable operating costs were equal to noncapital costs (Worksheet B, part I, Column 26 less Worksheet B, part II, Column 26) that are attributable to the Medicare allowable cost centers of the hospital. Medicare allowable cost centers were defined as Lines 30 through 35, 50, 51, 53 through 60, 62 through 76, 90, 91, 92.01 and 93.

For all of the major cost weights except the Home Office Contract Labor cost weight, we then removed those providers whose derived cost weights fall in the top and bottom 5 percent of provider-specific cost weights to ensure the removal of outliers. After the outliers were removed, we summed the costs for each category across all remaining providers. We then divided this by the sum of total Medicare allowable operating costs across all remaining providers to obtain a cost weight for the proposed 2014-based IPPS market basket for the given category.

We note that, in the FY 2018 IPPS/LTCH PPS proposed rule, we mistakenly referenced that we used the same trimming methodology for the Home Office Contract Labor cost weight that we used for the other major cost weights (a top and bottom 5 percent trimming methodology).

For the Home Office Contract Labor cost weight, we applied a 1-percent top-only trimming methodology. This allowed all providers' Medicare allowable costs to be included, even if their home office contract labor costs were zero. We believe, as the Medicare cost report data (Worksheet S–2, Part 1, Line 140) indicate, that not all IPPS hospitals have a home office. IPPS hospitals without a home office can incur these expenses directly by having their own staff, for which the costs would be included in the Wages and Salaries and Employee Benefits cost weights. Alternatively, IPPS hospitals without a home office could also purchase related services from external contractors for which these expenses would be captured in the residual ''All-Other'' cost weight. We believe this 1-percent top-only trimming methodology is appropriate as it addresses outliers while allowing providers with zero Home Office Contract Labor costs to be included in the Home Office Contract Labor cost weight calculation. If we applied both the top and bottom 5 percent trimming methodology, we would exclude providers who have zero Home Office Contract Labor costs. Finally, we proposed to calculate the residual ''All Other'' cost weight that reflects all remaining costs that are not captured in the seven cost categories listed.

Table IV–01 in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19918) shows the major cost categories and their respective cost weights as derived from the Medicare cost reports for the proposed rule. Table IV–01 below provides these same major cost categories and respective cost weights, with the change made to the Home Office Contract Labor Cost category name as discussed earlier in our response to public comments.

TABLE IV–01—MAJOR COST CATEGORIES AS DERIVED FROM THE MEDICARE COST REPORTS

Major cost categories	FY 2010	Proposed and final 2014
Wages and Salaries	45.8	42.1
Employee Benefits	12.7	12.0
Contract Labor	1.8	1.8
Professional Liability Insurance (Malpractice)	1.3	1.2
Pharmaceuticals	5.4	5.9
Blood and Blood Products	1.1	0.8
Home Office/Related Organization Contract Labor*	-	4.2
''All Other'' Residual	31.9	32.0

*Home Office/Related Organization Contract Labor costs were included in the ''All Other'' residual cost weight of the FY 2010-based IPPS market basket.

From FY 2010 to 2014, the Wages and Salaries and Employee Benefits cost weights as calculated directly from the Medicare cost reports decreased by approximately 3.7 and 0.7 percentage points, respectively, while the Contract Labor cost weight was unchanged. The decrease in the Wages and Salaries cost weight occurred among most cost centers and in aggregate for the General Service (overhead), Inpatient Routine Service, Ancillary Service, and Outpatient Service cost centers.

Comment: One commenter expressed concerns that several of the updated payment rates based on the proposed market basket do not accurately account for the realities facing hospitals and health systems. For example, the commenter believed the proposed market basket cost weights for certain categories are too low. Specifically, the weight for employee benefits that decreased from 12.7 percent to 12.0 percent, and the weight for pharmaceuticals that increased from 5.4 percent to 5.9 percent. The commenter further stated that hospitals, similar to other employers, are experiencing significant increases in costs for providing health care to their employees. The commenter claimed that, in 2017 alone, employer-sponsored premiums increased by 3 percent nationally. The commenter further cited a study conducted for the American Hospital Association and the Federation of American Hospitals, which found that between FY 2013 and FY 2015, average annual inpatient drug spending at community hospitals increased by 23.4 percent and average spending per admission increased 38.7 percent. The commenter stated that Virginia hospitals saw a 9.6-percent increase in spending on pharmaceuticals between 2014 and 2015 and a 41-percent increase in the last 6 years. The commenter further stated that it is important that CMS ensures any rebasing of the market basket adequately accounts for these increased costs.

Response: As stated in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19916), the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to provide hospital services. The effects on total expenditures resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. Only when the index is rebased and updated cost weights determined would changes in the quantity and intensity be captured. Therefore, we rebase the market basket periodically so that the cost weights reflect recent changes in the mix of goods and services that hospitals purchase (hospital inputs) to furnish inpatient care between base periods.

We used a similar methodology for calculating the Employee Benefits and Pharmaceuticals cost weights as we used to derive the FY 2010-based IPPS market basket. These data are obtained directly from the Medicare cost reports completed by IPPS hospitals. In addition, in the FY 2018 IPPS/LTCH PPS proposed rule, we provided the specific fields from the Medicare cost report that we were proposing to use to calculate the cost weights. We did not receive any technical public comments on these specific methodologies we proposed.

The change in the cost weight of a specific category from the current index (FY 2010) to the rebased index (2014) is a function of the growth rate of those specific expenses relative to other components of the market basket. For pharmaceuticals, costs increased faster than other components of the market basket between FY 2010 and 2014, which is why the Pharmaceuticals cost weight increased from 5.4 to 5.9 percent. As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19917), the Pharmaceuticals cost weight does not include compensation costs associated with hospital pharmacy employees; rather, these costs are included in the compensation cost weight. The increase in pharmaceutical costs over this period reflects changes in both the price of prescription drugs, proxied by the Producer Price Index for Prescription Drugs, as well the quantity and intensity of prescriptions.

We note that, for the FY 2018 IPPS market basket update, pharmaceuticals price growth contributes approximately 0.4 percentage point to the FY 2018 IPPS market basket update of 2.7 percent, or nearly 15 percent of the update. This large contribution (relative to the base year cost weight) reflects not only a projected FY 2018 prescription drug price increase that is approximately 80 percent faster than the weighted average price associated with the other remaining market basket cost categories, but also that over the FY 2014 to FY 2017 time period, the pharmaceuticals prices are projected to increase over 25 percent compared to the price increases of the other market basket categories combined at approximately 5 percent. Thus, we believe that the market basket is adequately reflecting the recent trends in prescription drug price growth.

For employee benefits, costs increased over the FY 2010 to FY 2014 period but at a slower rate than other components of the market basket, which resulted in a slight decrease in the proposed Employee Benefits cost weight from 12.7 to 12.0 percent. The changes in employee benefit costs over this period reflect not only the price changes associated with employee benefits, which are proxied by the Employment Cost Index for All Civilian Workers in Hospitals, but also any changes in the mix of workers. For FY 2018, the price change in the benefits component for the ECI for hospital workers is projected to be 2.6 percent.

After consideration of public comments we received, in this final rule, we are finalizing our calculation of the major cost weights of the 2014-based IPPS market basket as proposed. As

discussed above, we are making one revision to change the label of the proposed ''Home Office Contract Labor'' category to ''Home Office/Related Organization Contract Labor''. However, there is no effect on the calculation of the major cost weight for this category or in how it is apportioned between Professional Fees: Labor-Related and Professional Fees: Nonlabor Related as described in detail in section IV.B.3 of the preamble of this final rule.

As we did for the FY 2010-based IPPS market basket (78 FR 50597), we proposed to allocate contract labor costs to the Wages and Salaries and Employee Benefits cost weights based on their relative proportions for employed labor under the assumption that contract labor costs are comprised of both wages and salaries and employee benefits. The contract labor allocation proportion for wages and salaries was equal to the Wages and Salaries cost weight as a percent of the sum of the Wages and Salaries cost weight and the Employee Benefits cost weight. Using the 2014 Medicare cost report data, this percentage was 78 percent. Therefore, we proposed to allocate approximately 78 percent of the Contract Labor cost weight to the Wages and Salaries cost weight and 22 percent to the Employee Benefits cost weight. The FY 2010-based IPPS market basket also allocated 78 percent of the Contract Labor cost weight to the Wages and Salaries cost weight.

Table IV–02 in the proposed rule (82 FR 19918) shows the Wages and Salaries and Employee Benefits cost weights after contract labor allocation for the FY 2010-based IPPS market basket and the proposed 2014-based IPPS market basket. This table is also included below to reflect the final 2014-based IPPS market basket.

TABLE IV–02—WAGES AND SALARIES AND EMPLOYEE BENEFITS COST WEIGHTS AFTER CONTRACT LABOR ALLOCATION

Major cost categories	FY 2010-based IPPS market basket	Proposed and final 2014-based IPPS market basket
Wages and Salaries	47.2	43.4
Employee Benefits	13.1	12.4

We did not receive any specific public comments regarding the allocation of the Contract Labor cost weight to the Wages and Salaries and Employee Benefits cost weights. In this final rule, we are finalizing our methodology of allocating the Contract Labor cost weight as we proposed.

c. Derivation of the Detailed Cost Weights

To further divide the ''All Other'' residual cost weight estimated from the 2014 Medicare cost report data into more detailed cost categories, we proposed to use the 2007 Benchmark I–O ''Use Tables/Before Redefinitions/Purchaser Value'' for NAICS 622000, Hospitals, published by the BEA. These data are publicly available at the following Web site: *http://www.bea.gov/industry/io_annual.htm.* The BEA Benchmark I–O data are generally scheduled for publication every 5 years on a lagged basis, with the most recent data available for 2007. The 2007 Benchmark I–O data are derived from the 2007 Economic Census and are the building blocks for BEA's economic accounts. Therefore, they represent the most comprehensive and complete set of data on the economic processes or mechanisms by which output is produced and distributed.[22] BEA also produces Annual I–O estimates. However, while based on a similar methodology, these estimates reflect less comprehensive and less detailed data sources and are subject to revision when benchmark data become available. Instead of using the less detailed Annual I–O data, we proposed to inflate the detailed 2007 Benchmark I–O data forward to 2014 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories that are obtained from the 2007 Benchmark I–O data. In our calculations for the proposed rule, we repeated this practice for each year.

We then calculated the cost shares that each cost category represents of the 2007 data inflated to 2014. These resulting 2014 cost shares were applied to the ''All Other'' residual cost weight to obtain the detailed cost weights for the proposed 2014-based IPPS market basket. For example, the cost for Food: Direct Purchases represented 7.3 percent of the sum of the ''All Other'' 2007 Benchmark I–O Hospital Expenditures inflated to 2014. Therefore, the Food: Direct Purchases cost weight represented 7.3 percent of the proposed 2014-based IPPS market basket's ''All Other'' cost category (32.0 percent), yielding a Food: Direct Purchases proposed cost weight of 2.3 percent in the proposed 2014-based IPPS market basket (0.073×32.0 percent = 2.3 percent). For the FY 2010-based IPPS market basket (78 FR 50597), we used the same methodology utilizing the 2002 Benchmark I–O data (aged to FY 2010).

Using this methodology, we proposed to derive 18 detailed cost categories from the proposed 2014-based IPPS market basket residual cost weight (32.0 percent). These categories were: (1) Fuel: Oil and Gas; (2) Electricity; (3) Water and Sewerage; (4) Food: Direct Purchases; (5) Food: Contract Services; (6) Chemicals; (7) Medical Instruments; (8) Rubber and Plastics; (9) Paper and Printing Products; (10) Miscellaneous Products; (11) Professional Fees: Labor-Related; (12) Administrative and Facilities Support Services; (13) Installation, Maintenance, and Repair Services; (14) All Other: Labor-Related Services; (15) Professional Fees: Nonlabor-Related; (16) Financial Services; (17) Telephone Services; and (18) All Other: Nonlabor-Related Services.

Similar to the 2013-based LTCH market basket, the proposed 2014-based IPPS market basket does not include separate cost categories for Apparel, Machinery and Equipment, and Postage. Due to the small weights associated with these detailed categories and relatively stable price growth in the applicable price proxy, we believed that consolidating these smaller cost category weights with other cost categories in the proposed market basket that experience similar price increases eliminates unnecessary complexity to the market basket without having a material impact on the total market basket increase. Therefore, we proposed to include Apparel and Machinery and Equipment in the Miscellaneous Products cost category and Postage in the All-Other: Nonlabor-Related Services cost category. We note that the

[22] *http://www.bea.gov/papers/pdf/IOmanual_092906.pdf.*

machinery and equipment expenses are for equipment that is paid for in a given year and not depreciated over the asset's useful life. Depreciation expenses for movable equipment are reflected in the proposed 2014-based Capital Input Price Index (described in section IV.D. of the preamble of this final rule). For the proposed 2014-based IPPS market basket, we also proposed to include a separate cost category for Installation, Maintenance, and Repair Services in order to proxy these costs by a price index that better reflects the price changes of labor associated with maintenance-related services.

We did not receive any specific public comments on the derivation of the detailed cost weights. In this final rule, we are finalizing our methodology for deriving the detailed cost weights as we proposed.

2. Selection of Proposed Price Proxies

After computing the proposed 2014 cost weights for the IPPS market basket, it was necessary to select appropriate wage and price proxies to reflect the rate of price change for each expenditure category. With the exception of the proxy for professional liability insurance (PLI), all the proxies we proposed are based on Bureau of Labor Statistics (BLS) data and are grouped into one of the following BLS categories:

- Producer Price Indexes—Producer Price Indexes (PPIs) measure price changes for goods sold in markets other than the retail market. PPIs are preferable price proxies for goods and services that hospitals purchase as inputs because PPIs better reflect the actual price changes encountered by hospitals. For example, we proposed to use a PPI for prescription drugs, rather than the Consumer Price Index (CPI) for prescription drugs, because hospitals generally purchase drugs directly from a wholesaler. The PPIs that we proposed to use measure price changes at the final stage of production.
- Consumer Price Indexes—Consumer Price Indexes (CPIs) measure change in the prices of final goods and services bought by the typical consumer. Because they may not represent the price faced by a producer, we proposed to use CPIs only if an appropriate PPI is not available, or if the expenditures are more like those faced by retail consumers in general rather than by purchasers of goods at the wholesale level. For example, the CPI for food purchased away from home was proposed to be used as a proxy for contracted food services.
- Employment Cost Indexes—Employment Cost Indexes (ECIs) measure the rate of change in employee wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. Appropriately, they are not affected by shifts in employment mix.

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance. Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Timeliness implies that the proxy is published regularly, preferably at least once a quarter. Availability means that the proxy is publicly available. Finally, relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. We stated in the proposed rule that we believe the proposed PPIs, CPIs, and ECIs selected meet these criteria.

a. Price Proxies for Each Cost Category

Below we present a detailed explanation of the price proxies that we proposed for each cost category weight and a statement of our finalized policies. We note that many of the proxies that we proposed to use for the 2014-based IPPS market basket are the same as those used for the FY 2010-based IPPS market basket.

(1) Wages and Salaries

We proposed to use the ECI for Wages and Salaries for All Civilian Workers in Hospitals (BLS series code CIU1026220000000I) to measure the price growth of this cost category. This is the same price proxy used in the FY 2010-based IPPS market basket.

(2) Employee Benefits

We proposed to use the ECI for Total Benefits for All Civilian Workers in Hospitals to measure the price growth of this cost category. This ECI is calculated using the ECI for Total Compensation for All Civilian Workers in Hospitals (BLS series code CIU1016220000000I) and the relative importance of wages and salaries within total compensation. This is the same price proxy used in the FY 2010-based IPPS market basket.

(3) Fuel: Oil and Gas

We proposed to change the proxy used for the Fuel: Oil and Gas cost category. The FY 2010-based IPPS market basket uses the PPI Industry for Petroleum Refineries (BLS series code PCU32411–32411–) to proxy these expenses.

For the proposed 2014-based IPPS market basket, we proposed to use a blend of the PPI Industry for Petroleum Refineries (BLS series code PCU32411–32411–) and the PPI Commodity for Natural Gas (BLS series code WPU0531). Our analysis of the BEA 2007 Benchmark I–O data (use table before redefinitions, purchaser's value for NAICS 622000 [Hospitals]) shows that petroleum refineries expenses account for approximately 70 percent and Natural Gas expenses account for approximately 30 percent of the Fuel: Oil and Gas expenses. Therefore, we proposed a blended proxy of 70 percent of the PPI Industry for Petroleum Refineries (BLS series code PCU32411–32411–) and 30 percent of the PPI Commodity for Natural Gas (BLS series code WPU0531). We stated in the proposed rule that we believe that these two price proxies are the most technically appropriate indices available to measure the price growth of the Fuel: Oil and Gas cost category in the proposed 2014-based IPPS market basket.

(4) Electricity

We proposed to use the PPI Commodity for Commercial Electric Power (BLS series code WPU0542) to measure the price growth of this cost category. This is the same price proxy used in the FY 2010-based IPPS market basket.

(5) Water and Sewerage

We proposed to use the CPI for Water and Sewerage Maintenance (All Urban Consumers) (BLS series code CUUR0000SEHG01) to measure the price growth of this cost category. This is the same price proxy used in the FY 2010-based IPPS market basket.

(6) Professional Liability Insurance

We proposed to proxy price changes in hospital professional liability insurance premiums (PLI) using percentage changes as estimated by the CMS Hospital Professional Liability Index. To generate these estimates, we collected commercial insurance premiums for a fixed level of coverage while holding nonprice factors constant (such as a change in the level of coverage). This is the same price proxy used in the FY 2010-based IPPS market basket.

(7) Pharmaceuticals

We proposed to use the PPI Commodity for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) to measure the price growth of this cost category. This is the same price proxy used in the FY 2010-based IPPS market basket.

(8) Food: Direct Purchases

We proposed to use the PPI Commodity for Processed Foods and Feeds (BLS series code WPU02) to measure the price growth of this cost category. This is the same price proxy used in the FY 2010-based IPPS market basket.

(9) Food: Contract Services

We proposed to use the CPI for Food Away From Home (All Urban Consumers) (BLS series code CUUR0000SEFV) to measure the price growth of this cost category. This is the same price proxy used in the FY 2010-based IPPS market basket.

(10) Chemicals

We proposed to continue to use a four-part blended index composed of the PPI Industry for Industrial Gas Manufacturing (BLS series code PCU325120325120P), the PPI Industry for Other Basic Inorganic Chemical Manufacturing (BLS series code PCU32518–32518–), the PPI Industry for Other Basic Organic Chemical Manufacturing (BLS series code PCU32519–32519–), and the PPI Industry for Soap and Cleaning Compound Manufacturing (BLS series code PCU32561–32561–). We proposed to update the blended weights using 2007 Benchmark I–O data, which we also proposed to use for the proposed 2014-based IPPS market basket. The FY 2010-based IPPS market basket included the same blended chemical price proxy, but used the 2002 Benchmark I–O data to determine the weights of the blended chemical price index. The 2007 Benchmark I–O data have a higher weight for organic chemical products and a lower weight for the other chemical products compared to the 2002 Benchmark I–O data.

Table IV–03 in the proposed rule (82 FR 19920) shows the proposed weights for each of the four PPIs used to create the blended index compared to those used for the FY 2010-based IPPS market basket. This table is also included below and reflects the final 2014-based IPPS weights.

TABLE IV–03—BLENDED CHEMICAL WEIGHTS

Name	FY 2010-based IPPS weights (%)	Proposed and final 2014-Based IPPS weights (%)	NAICS
PPI for Industrial Gas Manufacturing	35	32	325120
PPI for Other Basic Inorganic Chemical Manufacturing	25	17	325180
PPI for Other Basic Organic Chemical Manufacturing	30	45	325190
PPI for Soap and Cleaning Compound Manufacturing	10	6	325610

(11) Blood and Blood Products

We proposed to use the PPI Industry for Blood and Organ Banks (BLS series code PCU621991621991) to measure the price growth of this cost category. This is the same price proxy used in the FY 2010-based IPPS market basket.

(12) Medical Instruments

We proposed to use a blended price proxy for the Medical Instruments cost category. The 2007 Benchmark Input-Output data show an approximate 50/50 split between Surgical and Medical Instruments and Medical and Surgical Appliances and Supplies for this cost category. Therefore, we proposed a blend composed of 50 percent of the PPI Commodity for Surgical and Medical Instruments (BLS series code WPU1562) and 50 percent of the PPI Commodity for Medical and Surgical Appliances and Supplies (BLS series code WPU1563). The FY 2010-based IPPS market basket used the single, higher level PPI Commodity for Medical, Surgical, and Personal Aid Devices (BLS series code WPU156). We stated in the proposed rule that we believe that the proposed price proxy better reflects the mix of expenses for this cost category as obtained from the 2007 Benchmark I–O data.

(13) Rubber and Plastics

We proposed to use the PPI Commodity for Rubber and Plastic Products (BLS series code WPU07) to measure the price growth of this cost category. This is the same price proxy used in the FY 2010-based IPPS market basket.

(14) Paper and Printing Products

We proposed to use the PPI Commodity for Converted Paper and Paperboard Products (BLS series code WPU0915) to measure the price growth of this cost category. This is the same price proxy used in the FY 2010-based IPPS market basket.

(15) Miscellaneous Products

We proposed to use the PPI Commodity for Finished Goods Less Food and Energy (BLS series code WPUFD4131) to measure the price growth of this cost category. This is the same price proxy used in the FY 2010-based IPPS market basket.

(16) Professional Fees: Labor-Related

We proposed to use the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this category. It includes occupations such as legal, accounting, and engineering services. This is the same price proxy used in the FY 2010-based IPPS market basket.

(17) Administrative and Facilities Support Services

We proposed to use the ECI for Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code CIU2010000220000I) to measure the price growth of this category. This is the same price proxy used in the FY 2010-based IPPS market basket.

(18) Installation, Maintenance, and Repair Services

We proposed to use the ECI for Total Compensation for All Civilian Workers in Installation, Maintenance, and Repair (BLS series code CIU1010000430000I) to measure the price growth of this new cost category. Previously these costs were included in the All Other: Labor-Related Services category and were proxied by the ECI for Total Compensation for Private Industry Workers in Service Occupations (BLS series code CIU2010000300000I). We believe that this index better reflects the price changes of labor associated with maintenance-related services and its incorporation represents a technical improvement to the market basket.

(19) All Other: Labor-Related Services

We proposed to use the ECI for Total Compensation for Private Industry Workers in Service Occupations (BLS series code CIU2010000300000I) to measure the price growth of this cost category. This is the same price proxy used in the FY 2010-based IPPS market basket.

(20) Professional Fees: Nonlabor-Related

We proposed to use the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this category. This is the same price proxy that we proposed to use for the Professional Fees: Labor-Related cost category and the same price proxy used in the FY 2010-based IPPS market basket.

(21) Financial Services

We proposed to use the ECI for Total Compensation for Private Industry Workers in Financial Activities (BLS series code CIU201520A000000I) to measure the price growth of this cost category. This is the same price proxy used in the FY 2010-based IPPS market basket.

(22) Telephone Services

We proposed to use the CPI for Telephone Services (BLS series code CUUR0000SEED) to measure the price growth of this cost category. This is the same price proxy used in the FY 2010-based IPPS market basket.

(23) All Other: Nonlabor-Related Services

We proposed to use the CPI for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category. We believe that using the CPI for All Items Less Food and Energy avoids double counting of changes in food and energy prices as they are already captured elsewhere in the market basket. This is the same price proxy used in the FY 2010-based IPPS market basket. We did not receive any specific public comments on the price proxies we proposed to use for the 2014-based IPPS market basket. In this final rule, we are finalizing the use of these price proxies as we proposed.

After consideration of the public comments we received, we are finalizing the 2014-based IPPS market basket as proposed.

Table IV–04 in the proposed rule (82 FR 19921) set forth the proposed 2014-based IPPS market basket, including the cost categories and their respective weights and price proxies. For comparison purposes, the corresponding FY 2010-based IPPS market basket cost weights also were listed. This table is also included below and reflects the final 2014-based IPPS market basket.

TABLE IV–04—PROPOSED AND FINAL 2014-BASED IPPS MARKET BASKET COST CATEGORIES, COST WEIGHTS, AND PRICE PROXIES COMPARED TO FY 2010-BASED IPPS MARKET BASKET COST WEIGHTS

Cost categories	FY 2010-based IPPS market basket cost weights	Proposed and final 2014-based IPPS market basket cost weights	Proposed and final 2014-based IPPS market basket price proxies
1. Compensation	60.3	55.8	
A. Wages and Salaries [1]	47.2	43.4	ECI for Wages and Salaries for All Civilian Workers in Hospitals.
B. Employee Benefits [1]	13.1	12.4	ECI for Total Benefits for All Civilian Workers in Hospitals.
2. Utilities	2.2	2.5	
A. Fuel: Oil and Gas	0.4	1.3	Blend of PPIs for Petroleum Refineries and Natural Gas.
B. Electricity	1.7	1.0	PPI Commodity for Commercial Electric Power.
C. Water and Sewerage	0.1	0.1	CPI for Water and Sewerage Maintenance (All Urban Consumers).
3. Professional Liability Insurance	1.3	1.2	CMS Hospital Professional Liability Insurance Premium Index.
4. All Other	36.1	40.5	
A. All Other Products	19.5	17.4	
(1) Pharmaceuticals	5.4	5.9	PPI Commodity for Pharmaceuticals for Human Use, Prescription.
(2) Food: Direct Purchases	4.2	2.3	PPI Commodity for Processed Foods and Feeds.
(3) Food: Contract Services	0.6	1.3	CPI for Food Away From Home (All Urban Consumers).
(4) Chemicals	1.5	0.9	Blend of Chemical PPIs.
(5) Blood and Blood Products	1.1	0.8	PPI Industry for Blood and Organ Banks.
(6) Medical Instruments	2.6	2.9	Blend of PPI for Surgical and Medical Instruments and PPI for Medical and Surgical Appliances and Supplies.
(7) Rubber and Plastics	1.6	0.8	PPI Commodity for Rubber and Plastic Products.
(8) Paper and Printing Products	1.5	1.5	PPI Commodity for Converted Paper and Paperboard Products.
(9) Miscellaneous Products [2]	1.0	1.1	PPI Commodity for Finished Goods less Food and Energy.
B. Labor-Related Services	9.2	12.5	
(1) Professional Fees: Labor-Related	5.5	6.8	ECI for Total Compensation for Private Industry Workers in Professional and Related.
(2) Administrative and Facilities Support Services.	0.6	1.0	ECI for Total Compensation for Private Industry Workers in Office and Administrative Support.

TABLE IV–04—PROPOSED AND FINAL 2014-BASED IPPS MARKET BASKET COST CATEGORIES, COST WEIGHTS, AND PRICE PROXIES COMPARED TO FY 2010-BASED IPPS MARKET BASKET COST WEIGHTS—Continued

Cost categories	FY 2010-based IPPS market basket cost weights	Proposed and final 2014-based IPPS market basket cost weights	Proposed and final 2014-based IPPS market basket price proxies
(3) Installation, Maintenance and Repair Services.		2.4	ECI for Total Compensation for Civilian Workers in Installation, Maintenance, and Repair.
(4) All Other: Labor-Related Services	3.1	2.3	ECI for Total Compensation for Private Industry Workers in Service Occupations.
C. Nonlabor-Related Services	7.4	10.7	
(1) Professional Fees: Nonlabor-Related	3.7	5.1	ECI for Total Compensation for Private Industry Workers in Professional and Related.
(2) Financial Services	1.2	3.0	ECI for Total Compensation for Private Industry Workers in Financial Activities.
(3) Telephone Services	0.6	0.8	CPI for Telephone Services.
(4) All Other: Nonlabor-Related Services [3]	1.9	1.7	CPI for All Items less Food and Energy.
Total	100.0	100.0	

Note: The cost weights are calculated using three decimal places. For presentational purposes, we are displaying one decimal and therefore, the detail may not add to the total due to rounding.

[1] Contract labor is distributed to wages and salaries and employee benefits based on the share of total compensation that each category represents.

[2] The FY 2010-based IPPS market basket Miscellaneous Products cost category also includes Apparel and Machinery and Equipment cost categories. These costs were not broken out separately in the 2014-based IPPS market basket.

[3] The FY 2010-based IPPS market basket All Other: Nonlabor-Related Services cost category also includes the Postage cost category. These costs were not broken out separately in the 2014-based IPPS market basket.

Table IV–05 in the proposed rule (82 FR 19922) compares both the historical and forecasted percent changes in the FY 2010-based IPPS market basket and the proposed 2014-based IPPS market basket. The percent changes in the proposed rule were based on IHS Global Inc.'s (IGI's) fourth quarter 2016 forecast with historical data through third quarter 2016. The forecasted growth rates provided in Table IV–05 below are based on IGI's more recent second quarter 2017 forecast with historical data through first quarter 2017.

TABLE IV–05—FY 2010-BASED AND PROPOSED AND FINAL 2014-BASED IPPS HOSPITAL OPERATING INDEX PERCENT CHANGE, FY 2013 THROUGH FY 2020

Fiscal year (FY)	FY 2010-based IPPS market basket percent change	Proposed and final 2014-based IPPS market basket percent change
Historical data:		
FY 2013	2.0	2.0
FY 2014	1.8	1.8
FY 2015	1.8	1.6
FY 2016	1.8	1.8
Average FYs 2013–2016	1.9	1.8
Forecast:		
FY 2017	2.6	2.7
FY 2018	2.7	2.7
FY 2019	2.9	2.9
FY 2020	3.0	3.1
Average FYs 2017–2020	2.8	2.9

Source: IHS Global Inc., 2nd Quarter 2017 forecast.

The percent change in the proposed and final 2014-based IPPS market basket is, on average, 0.1 percentage point lower than the FY 2010-based IPPS market basket over the FY 2013 to FY 2016 historical time period and on average 0.1 percentage point higher over the FY 2017 to FY 2020 forecasted time period. The difference in the average growth rates is mostly a result of the lower compensation cost weight and the revised price proxy for the Fuel, Oil and Gasoline cost category. As stated in section IV.B.2. of the preamble of the FY 2018 IPPS/LTCH PPS proposed rule (and in section IV.B.2.a. of the preamble of this final rule), for the 2014-based IPPS market basket, we proposed to revise the price proxy for the Fuel: Oil and Gas cost category to be a blend of the PPI Industry for Petroleum Refineries (BLS series code PCU32411–32411–) and the PPI Commodity for Natural Gas (BLS series code WPU0531). The FY 2010-based IPPS market basket used only the PPI Industry for Petroleum Refineries.

3. Labor-Related Share

Under section 1886(d)(3)(E) of the Act, the Secretary estimates from time to time the proportion of payments that are labor-related. Section 1886(d)(3)(E) of the Act states that the Secretary shall adjust the proportion, (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs, of the DRG prospective payment rates. We refer to the proportion of hospitals' costs that are attributable to wages and wage-related costs as the ''labor-related share.''

The labor-related share is used to determine the proportion of the national PPS base payment rate to which the area wage index is applied. We include a cost category in the labor-related share if the costs are *labor intensive* and *vary with the local labor market.* For the FY 2018 IPPS/LTCH PPS proposed rule, we proposed (82 FR 19923) to include in the labor-related share the national average proportion of operating costs that are attributable to the following cost categories in the proposed 2014-based IPPS market basket: Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Facilities Support Services, Installation, Maintenance, and Repair Services, and All Other: Labor-Related Services. As noted in section IV.B.1.c. of the preamble of the proposed rule, for the proposed 2014-based IPPS market basket, we proposed the creation of a separate cost category for Installation, Maintenance, and Repair Services. These expenses were previously included in the All Other: Labor-Related Services cost category in the FY 2010-based IPPS market basket, along with other services, including, but not limited to, janitorial, waste management, security, and dry cleaning/laundry services. Because these services tend to be labor-intensive and are mostly performed at the facility (and, therefore, unlikely to be purchased in the national market), we continue to believe that they meet our definition of labor-related services.

Similar to the FY 2010-based IPPS market basket, we proposed that the Professional Fees: Labor-Related cost category includes expenses associated with advertising and a proportion of legal services, accounting and auditing, engineering, management consulting, and management of companies and enterprises expenses. As was done in the FY 2010-based IPPS market basket rebasing, we proposed to determine the proportion of legal, accounting and auditing, engineering, and management consulting services that meet our definition of labor-related services based on a survey of hospitals conducted by CMS in 2008. We notified the public of our intent to conduct this survey on December 9, 2005 (70 FR 73250) and did not receive any public comments in response to the notice (71 FR 8588).

A discussion of the composition of the survey and poststratification can be found in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43850 through 43856). Based on the weighted results of the survey, we determined that hospitals purchase, on average, the following portions of contracted professional services outside of their local labor market:

- 34 percent of accounting and auditing services;
- 30 percent of engineering services;
- 33 percent of legal services; and
- 42 percent of management consulting services.

We proposed to apply each of these percentages to its respective Benchmark I–O cost category underlying the professional fees cost category. This is the methodology that we used to separate the FY 2010-based IPPS market basket professional fees cost category into Professional Fees: Labor-Related and Professional Fees: Nonlabor-Related cost categories. We proposed to use the same methodology and survey results to separate the professional fees costs for the proposed 2014-based IPPS market basket into Professional Fees: Labor-Related and Professional Fees: Nonlabor-Related cost categories. We stated that we believe these survey results are appropriate to use for the 2014-based IPPS market basket as they empirically determine the proportion of contracted professional services purchased by the industry that is attributable to local firms and the proportion that is purchased from national firms.

In the proposed 2014-based IPPS market basket, nonmedical professional fees that were subject to allocation based on these survey results represent 4.9 percent of total operating costs (and are limited to those fees related to Accounting & Auditing, Legal, Engineering, and Management Consulting services). Based on our survey results, we proposed to apportion 3.1 percentage points of the 4.9 percentage point figure into the Professional Fees: Labor-Related share cost category and designate the remaining 1.8 percentage point into the Professional Fees: Nonlabor-Related cost category.

Comment: Several commenters expressed concern about the methodology CMS proposed to use to remove a portion of professional fees from the labor-related share. Several commenters believed the Professional Fees Survey that was gathered in 2008 is outdated. Some of those commenters stated that it is inappropriate to use data gathered in 2008 to adjust payments made in 2018. In addition, one commenter stated that the survey was outdated because hospitals have reduced staff since 2008 and rely more on consulting services for obtaining needed personnel expertise. A few commenters stated that if CMS' intention is to update the labor-related share to account for recent changes, it should also update these survey data.

A few commenters reiterated how, in previous comments, they stated that they did not believe the survey could be statistically representative because it was based on 108 hospitals. The commenters also stated that CMS failed to share data on the characteristics of the hospitals that responded to the survey, selection bias, or survey methodology. The commenters urged CMS not to use the results of this survey to estimate the proportion of professional fees that are labor-related. Several commenters urged CMS to continue to investigate alternative methodologies for determining the proportion that is labor-related before implementing any changes.

Response: We first utilized the Professional Fees Survey in the FY 2006-based IPPS market basket finalized in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43843). In response to our proposal to use this Professional Fees Survey in the FY 2010 IPPS/LTCH PPS proposed rule, commenters had similar requests for additional information on the survey, specifically requesting the characteristics of the hospitals that responded, possible selection bias, and survey methodology. For the FY 2010 IPPS/LTCH PPS final rule (74 FR 43853), we provided additional information on the Professional Fees Survey methodology, sample selection, and methodology for deriving the final weights. The FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19923) made note of this information and provided the **Federal Register** reference for the FY 2010 IPPS/LTCH PPS final rule (74 FR 43850 through 43856). Therefore, we disagree with the commenters' claim that we failed to share characteristics of the hospitals that responded to the survey, selection bias, and survey methodology.

With respect to the comment that the survey is outdated because hospitals have reduced staff since 2008 and rely more on consulting services for obtaining needed personnel expertise, the Professional Fees Survey is not used

to determine the level of hospital staffing relative to contract staffing. As stated above, the Medicare cost report data show that over the FY 2010 to FY 2014 time period, the Wages and Salaries and Employee Benefit cost weights decreased while the Labor-related services cost weight increased. This supports the commenter's claim that hospitals have reduced staff and are relying more on consulting services, and is reflected in the hospital market basket. The Professional Fees Survey is only used to determine the proportion of Professional Fees costs that are purchased within a hospital's local labor market, a proportion that we believe is unlikely to change significantly over time.

With respect to the commenters' concern regarding alternative methodologies, we are not aware of any other currently available data source regarding the proportion of Professional Fees that are labor-related. Therefore, the only possible alternatives to the current methods would be to assume that 100 percent of the accounting and auditing services, engineering services, legal services, and management consulting services are purchased in the national market or assume that 100 percent are purchased in the local labor market. Neither of these approaches seems reasonable, given that the 2008 Professional Fees Survey results in the assumption that 63 percent of those services are purchased locally (in aggregate) and the remaining 37 percent are purchased nationally. As stated in the FY 2018 IPPS/LTCH PPS proposed rule, we continue to believe the survey results are appropriate to use for the 2014-based IPPS market basket as they empirically determine the proportion of contracted professional services purchased by the industry that is attributable to local firms and the proportion that is purchased from national firms. We will continue to explore options for updating the Professional Fees Survey to reflect more recent data for incorporation into future market basket rebasing and labor-related share determinations. If conducted, we encourage providers to respond to the survey, which would be announced in the **Federal Register** as done previously. After consideration of the public comments we received, we are finalizing the use of the Professional Fees Survey as proposed.

In addition to the professional services listed earlier, we also proposed to classify a proportion of the home office/related organization contract labor expenses (as this cost category has been relabeled, as discussed earlier in section IV.B.1.a. of the preamble of this final rule, and is referred to throughout this discussion) into the Professional Fees: Labor-Related cost category as was done in the previous rebasing. For the FY 2010-based IPPS market basket, we obtained home office/related organization contract labor expenses from the Benchmark I–O data for the NAICS 55 industry (Management of Companies and Enterprises). As stated in section IV.B.1.a. of the preamble to the FY 2018 IPPS/LTCH PPS proposed rule, for the 2014-based IPPS market basket, we proposed to obtain these data from the Medicare cost reports. We believe that many of the home office/related organization contract labor expenses are labor-intensive and vary with the local labor market. However, data indicate that not all IPPS hospitals with home offices have home offices located in their local labor market. Therefore, we proposed to include in the labor-related share only a proportion of the home office/related organization contract labor expenses based on the methodology described below.

For the FY 2010-based IPPS market basket, we used data primarily from the Medicare cost reports and a CMS database of Home Office Medicare Records (HOMER) (a database that provides city and state information (addresses) for home offices). We determined the proportion of costs that should be allocated to the labor-related share based on the percent of hospital home office/related organization contract labor compensation as reported in Worksheet S–3, Part II. Using this methodology, we determined that 62 percent of hospitals' home office/related organization contract labor compensation costs were for home offices located in their respective local labor markets (defined as the same Metropolitan Statistical Area (MSA)). Therefore, we classified 62 percent of these costs into the Professional Fees: Labor-Related Services cost category and the remaining 38 percent into the Professional Fees: Nonlabor-Related Services cost category for the FY 2010-based IPPS market basket. For a detailed discussion of this analysis, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50601).

For the proposed 2014-based IPPS market basket, we conducted a similar analysis of home office data. For consistency, we believe that it is important for our analysis on home office data to be conducted on the same IPPS hospitals used to derive the proposed 2014-based IPPS market basket cost weights. The Medicare cost report requires a hospital to report information regarding their home office provider. Approximately 64 percent of IPPS hospitals reported some type of home office information on their Medicare cost report for 2014 (for example, city, State, and zip code). Using the data reported on the Medicare cost report, we compared the location of the hospital with the location of the hospital's home office. We then proposed to determine the proportion of costs that should be allocated to the labor-related share based on the percent of total hospital home office/related organization contract labor compensation costs (as reported in Worksheet S–3, Part II) for those hospitals that had home offices located in their respective local labor markets—defined as being in the same MSA. We determined a hospital's and home office's MSAs using their zip code information from the Medicare cost report. Using this methodology, we determined that 60 percent of hospitals' home office/related organization contract labor compensation costs were for home offices located in their respective local labor markets. Therefore, we proposed to allocate 60 percent of home office expenses to the labor-related share.

In the proposed 2014-based IPPS market basket, home office/related organization contract labor expenses that were subject to allocation based on the home office allocation methodology represent 4.2 percent of total operating costs. Based on the results of the home office analysis discussed earlier, we proposed to apportion 2.5 percentage points of the 4.2 percentage points figure into the Professional Fees: Labor-Related cost category and designate the remaining 1.7 percentage points into the Professional Fees: Nonlabor-Related cost category. In summary, based on the two allocations mentioned earlier, we apportioned 5.6 percentage points of the professional fees and home office/related organization contract labor cost weights into the Professional Fees: Labor-Related cost category. This amount was added to the portion of professional fees that we already identified as labor-related using the I–O data such as contracted advertising and marketing costs (approximately 1.2 percentage point of total operating costs) resulting in a Professional Fees: Labor-Related cost weight of 6.8 percent.

The FY 2018 IPPS/LTCH PPS proposed rule included Table IV–06 (82 FR 19924), which compared the proposed 2014-based labor-related share and the FY 2010-based labor-related share. As discussed in section IV.B.1.b. of the preamble of the FY 2018 IPPS/LTCH PPS proposed rule, the Wages and Salaries and Employee Benefits cost weights reflect contract labor costs. This

table is also included below and reflects the final 2014-based labor-related share.

TABLE IV–06—COMPARISON OF THE FY 2010-BASED LABOR-RELATED SHARE AND THE PROPOSED AND FINAL 2014-BASED LABOR-RELATED SHARE

	FY 2010-based IPPS market basket cost weights	Proposed and final 2014-based IPPS market basket cost weights
Wages and Salaries	47.2	43.4
Employee Benefits	13.1	12.4
Professional Fees: Labor-Related	5.5	6.8
Administrative and Facilities Support Services	0.6	1.0
Installation, Maintenance, and Repair Services [1]	.....	2.4
All Other: Labor-Related Services	3.1	2.3
Total Labor-Related Share	69.6	68.3

Note: Detail may not add to total due to rounding.

[1] Installation, Maintenance, and Repair Services costs were previously included in the All Other: Labor-Related Services cost category of the FY 2010-based IPPS market basket.

Using the cost category weights from the proposed 2014-based IPPS market basket, we calculated a labor-related share of 68.3 percent, approximately 1.3 percentage points lower than the current labor-related share of 69.6 percent. Therefore, we proposed to use a labor-related share of 68.3 percent for discharges occurring on or after October 1, 2017. We continue to believe, as we have stated in the past, that these operating cost categories are related to, influenced by, or vary with the local markets. Therefore, our definition of the labor-related share continues to be consistent with section 1886(d)(3) of the Act. We note that section 403 of Public Law 108–173 amended sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act to provide that the Secretary must employ 62 percent as the labor-related share unless 62 percent would result in lower payments to a hospital than would otherwise be made.

Comment: Several commenters stated that they were unable to replicate or verify the proposed labor-related share. One commenter stated that it is unclear how we determined that a reduction to the labor-related share from 69.6 percent to 68.3 percent was warranted since we did not release the base calculations. Several commenters further stated that not having access to this information severely limited their ability to comment sufficiently on this issue. The commenters requested that CMS provide all information necessary to replicate the agency's calculation of the labor-related share, including, but not limited to, greater clarity of data sources used; case counts at different points, such as number of providers after trimming; provider level data illustrating what information was used in the calculation; and the kinds of checks CMS made during calculations to assess and ensure accuracy. The commenters requested that this information be provided in advance of publication of the final rule.

Response: We disagree with the commenters' claim that we did not provide sufficiently detailed information regarding our calculations of the labor-related share. As stated in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19923), the labor-related share is derived using the cost weights of the proposed 2014-based IPPS market basket. The FY 2018 IPPS/LTCH PPS proposed rule included a detailed description of the data sources and methodology used to derive all of the market basket cost weights.

Specifically, section IV.B.1.a. of the preamble of the proposed rule (82 FR 19916) provided the detailed Medicare cost report methodology used to calculate the major cost weights of the proposed 2014-based IPPS market basket (including the specific Medicare cost report worksheets and trimming methodologies). Section IV.B.1.c. of the preamble of the proposed rule (82 FR 19918) provided the specific methodology and data source used to derive the remaining detailed cost weights. Section IV.B.3. of the preamble of proposed rule (82 FR 19923) provided information regarding how the Professional Fees cost category was divided between Labor-related and Nonlabor-related services. The data sources used to produce the market basket cost weights are publicly available. In addition, contact information for CMS staff was provided in the proposed rule to provide the opportunity to ask any specific questions regarding the methodology.

We note that we provided a similar detailed description of the methodologies used to derive the 2012-based IPF and 2012-based IRF market baskets in the FY 2016 IPF PPS proposed rule and the FY 2016 IRF PPS proposed rule, respectively. In those instances, stakeholders were able to use the detailed description in the proposed rules to closely replicate the proposed cost weights and suggest methodological changes that were considered during final rulemaking.

Therefore, for the reasons stated earlier, we believe that there was sufficient detail provided in the FY 2018 IPPS/LTCH PPS proposed rule to describe the proposed methodology for deriving the market basket cost weights and labor-related share.

Comment: Several commenters opposed the decrease in the labor-related share from 69.6 percent to 68.3 percent, stating that reducing the labor-related share further undervalues the very real differences in hospital-specific costs. These commenters stated that such a change to the labor-related share would specifically harm hospitals in higher-cost urban areas that already experience some of the highest labor costs in the country. Furthermore, they stated that they opposed reducing the sensitivity of the prospective payment system to the different circumstances of individual hospitals through the introduction of an approach that would foster the development of a reimbursement system that trends toward the mean despite unquestionable differences in hospital costs. The commenters urged CMS to withdraw the proposal to reduce the labor-related share for FY 2018.

Response: We disagree with the commenters' rationale for the request to

withdraw the proposal to reduce the labor-related share. The methodology used to derive the proposed labor-related share of 68.3 percent based on the proposed 2014-based market basket is the same methodology used to determine the current labor-related share of 69.6 percent using the FY 2010-based IPPS market basket. The decrease in the labor-related share of 1.3 percentage points stems from a decrease in the Wages and Salaries and Employee Benefit cost weights (which were derived from the Medicare cost reports), as discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19918), accounting for a decrease of 4.5 percentage points. This is partially offset by an increase in the Labor-related services cost weight, accounting for an increase of 3.2 percentage points. As stated in the FY 2018 IPPS/LTCH PPS proposed rule, the decrease in the Wages and Salaries cost weight from FY 2010 to FY 2014 occurred across most cost centers and in aggregate for the General Service (overhead), Inpatient Routine Service, Ancillary Service, and Outpatient Service cost centers.

Furthermore, the other components of the IPPS (including, but not limited to, MS–DRG, wage index, disproportionate share hospital adjustment, and indirect medical education adjustment) account for variations in costs among individual hospitals. After consideration of the public comments we received, we are finalizing our methodology for calculating the labor-related share of 68.3 percent using the 2014-based IPPS market basket cost weights.

C. Market Basket for Certain Hospitals Presently Excluded From the IPPS

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43857), we adopted the use of the FY 2006-based IPPS operating market basket percentage increase to update the target amounts for children's hospitals, PPS-excluded cancer hospitals and religious nonmedical health care institutions (RNHCIs). Children's hospitals and PPS-excluded cancer hospitals and RNHCIs are still reimbursed solely under the reasonable cost-based system, subject to the rate-of-increase limits. Under these limits, an annual target amount (expressed in terms of the inpatient operating cost per discharge) is set for each hospital based on the hospital's own historical cost experience trended forward by the applicable rate-of-increase percentages.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50603), under the broad authority in sections 1886(b)(3)(A) and (B), 1886(b)(3)(E), and 1871 of the Act and section 4454 of the BBA, consistent with our use of the IPPS operating market basket percentage increase to update target amounts, we adopted the use of the FY 2010-based IPPS operating market basket percentage increase to update the target amounts for children's hospitals, PPS-excluded cancer hospitals, and RNHCIs that are paid on the basis of reasonable cost subject to the rate-of-increase limits under § 413.40. In addition, as discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50156 through 50157), consistent with §§ 412.23(g), 413.40(a)(2)(ii)(A), and 413.40(c)(3)(viii), we also have used the percentage increase in the FY 2010-based IPPS operating market basket to update the target amounts for short–term acute care hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). These hospitals also are paid on the basis of reasonable cost, subject to the rate-of-increase limits under § 413.40.

Due to the small number of children's and cancer hospitals and RNHCIs and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico and because these facilities provide limited Medicare cost report data, we are unable to create a separate market basket specifically for these facilities. Due to the limited cost report data available, we stated that we believe that the proposed 2014-based IPPS operating market basket most closely represents the cost structure of children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico. We believe this is appropriate as the IPPS operating market basket would reflect the input price growth for providing inpatient hospital services (similar to the services provided by the above excluded facilities) based on the specific mix of goods and services required. Therefore, we proposed to use the 2014-based IPPS market basket percentage increase to update the target amounts for children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico that are paid on the basis of reasonable cost subject to the rate-of-increase limits under § 413.40. We stated that we believe it is the best available measure of the average increase in the prices of the goods and services purchased by children's hospitals, the cancer hospitals, RNHCIs, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico in order to provide care.

We did not receive any public comments on our proposal. Therefore, we are adopting the use of the 2014-based IPPS market basket percentage increase to update the target amounts for children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico that are paid on the basis of reasonable cost.

D. Rebasing and Revising the Capital Input Price Index (CIPI)

The CIPI was originally described in the FY 1993 IPPS final rule (57 FR 40016). There have been subsequent discussions of the CIPI presented in the IPPS proposed and final rules. The FY 2014 IPPS/LTCH PPS final rule (78 FR 50603 through 50607) described the most recent rebasing and revision of the CIPI to a FY 2010 base year, which reflected the capital cost structure of IPPS hospitals available at that time.

For the FY 2018 IPPS update, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19925 through 19929), we proposed to rebase and revise the CIPI to a 2014 base year to reflect a more current structure of capital costs for IPPS hospitals. This proposed 2014-based CIPI was derived using 2014 cost reports for IPPS hospitals, which includes providers whose cost reporting period began on or after October 1, 2013, and prior to September 30, 2014. While we proposed and finalized the title of the current CIPI in the FY 2014 IPPS/LTCH proposed and final rules as ''FY 2010-based CIPI'', for the proposed CIPI, we proposed to simply refer to the proposed CIPI as ''2014-based CIPI'' (dropping the reference to FY). As discussed in section IV.B. of the preamble of the proposed rule, for the 2014-based IPPS operating market basket, we proposed this change in naming convention for the market basket because the base year cost weight data for the proposed market basket do not reflect only fiscal year data. Similarly, the proposed 2014-based CIPI uses Medicare cost report data and other government data that reflect 2014 fiscal year, 2014 calendar year, and 2014 State fiscal year expenses to determine the base year cost weights and vintage weights. Given that it is based on a mix of classifications of 2014 data, we proposed to refer to the CIPI as ''2014-based'' instead of ''FY 2014-based'' or ''CY 2014-based''. However, the methods and data used to derive each of these CIPI are similar. As with the FY 2010-based index, we proposed to develop two sets of weights to derive

the proposed 2014-based CIPI. The first set of weights identifies the proportion of hospital capital expenditures attributable to each expenditure category, while the second set of weights is a set of relative vintage weights for depreciation and interest. The set of vintage weights is used to identify the proportion of capital expenditures within a cost category that is attributable to each year over the useful life of the capital assets in that category. A more thorough discussion of vintage weights is provided later in this section.

Using 2014 Medicare cost reports, we were able to group capital costs into the following categories: Depreciation, Interest, Lease, and Other. For each of these categories, we proposed to determine what proportion of total capital costs the category represents using the data reported by IPPS hospitals on Worksheet A–7, which is the same methodology used for the FY 2010-based CIPI. As shown in the left column of Table IV–07 in the proposed rule (82 FR 19926), in 2014, depreciation expenses accounted for 66.4 percent of total capital costs, interest expenses accounted for 16.3 percent, leasing expenses accounted for 11.8 percent, and other capital expenses accounted for 5.5 percent. This table is also listed below.

We also proposed to allocate lease costs across each of the remaining capital cost categories as was done in the FY 2010-based CIPI. This resulted in three primary capital cost categories in the proposed 2014-based CIPI: Depreciation, Interest, and Other. Lease costs are unique in that they are not broken out as a separate cost category in the proposed 2014-based CIPI. Rather, we proposed to proportionally distribute leasing costs among the cost categories of Depreciation, Interest, and Other, reflecting the assumption that the underlying cost structure of leases is similar to that of capital costs in general. As was done for the FY 2010-based CIPI, we proposed to assume that 10 percent of the lease costs as a proportion of total capital costs represents overhead and to assign those costs to the Other capital cost category accordingly. Therefore, we assumed that approximately 1.2 percent (11.8 percent x 0.1) of total capital costs represent lease costs attributable to overhead, and we proposed to add this 1.2 percent to the 5.5 percent Other cost category weight. We then proposed to distribute the remaining lease costs (10.6 percent, or 11.8 percent − 1.2 percent) proportionally across the three cost categories (Depreciation, Interest, and Other) based on the proportion that these categories comprise of the sum of the Depreciation, Interest, and Other cost categories (excluding lease expenses). For example, the Other cost category represented 6.3 percent of all three cost categories (Depreciation, Interest, and Other) prior to any lease expenses being allocated. This 6.3 percent is applied to the 10.6 percent of remaining lease expenses so that another 0.7 percent of lease expenses as a percent of total capital costs is allocated to the Other cost category. Therefore, the resulting proposed Other cost weight is 7.4 percent (5.5 percent + 1.2 percent + 0.7 percent). This is the same methodology used for the FY 2010-based CIPI. The resulting cost weights of the proposed allocation of lease expenses were shown in the right column of Table IV–07 in the proposed rule (82 FR 19926). This table is also included below and reflects the final allocation of lease expenses.

TABLE IV–07—PROPOSED AND FINAL ALLOCATION OF LEASE EXPENSES FOR THE PROPOSED AND FINAL 2014-BASED CIPI

Cost categories	Proposed and final cost shares obtained from medicare cost reports (percent of total capital costs)	Proposed and final cost shares after allocation of lease expenses (percent of total capital costs)
Depreciation	66.4	74.4
Interest	16.3	18.2
Lease	11.8	.....
Other	5.5	7.4

Finally, we proposed to further divide the Depreciation and Interest cost categories. We proposed to separate the Depreciation cost category into the following two categories: (1) Building and Fixed Equipment and (2) Movable Equipment. We also proposed to separate the Interest cost category into the following two categories: (1) Government/Nonprofit; and (2) For-profit.

To disaggregate the depreciation cost weight, we needed to determine the percent of total depreciation costs for IPPS hospitals (after the allocation of lease costs) that are attributable to building and fixed equipment, which we hereafter refer to as the ''fixed percentage.'' Based on Worksheet A–7 data from the 2014 IPPS Medicare cost reports, we have determined that depreciation costs for building and fixed equipment account for approximately 49 percent of total depreciation costs, while depreciation costs for movable equipment account for approximately 51 percent of total depreciation costs. As was done for the FY 2010-based CIPI, we proposed to apply this fixed percentage to the depreciation cost weight (after leasing costs are included) to derive a Depreciation cost weight attributable to Building and Fixed Equipment and a Depreciation cost weight attributable to Movable Equipment.

To disaggregate the interest cost weight, we needed to determine the percent of total interest costs for IPPS hospitals that are attributable to government and nonprofit facilities, which we hereafter refer to as the ''nonprofit percentage,'' because interest price pressures tend to differ between nonprofit and for-profit facilities. We proposed to use interest costs data from Worksheet A–7 of the 2014 Medicare cost reports for IPPS hospitals, which is the same methodology used for the FY 2010-based CIPI. The nonprofit percentage determined using this method is 86 percent. Table IV–08 in the proposed rule (82 FR 19927) provides a comparison of the FY 2010-based CIPI cost weights and the proposed 2014-based CIPI cost weights. This table is also included below and

reflects the final 2014-based CIPI cost weights.

After the capital cost category weights were computed, it was necessary to select appropriate price proxies to reflect the rate-of-increase for each expenditure category. We proposed to apply the same price proxies as were used in the FY 2010-based CIPI, which are listed below and provided in Table IV–08 in the proposed rule. We also proposed to continue to vintage weight the capital price proxies for Depreciation and Interest to capture the long-term consumption of capital. This vintage weighting method is the same method that was used for the FY 2010-based CIPI and is described below.

We proposed to continue to proxy the Depreciation—Building and Fixed Equipment cost category by the BEA Chained Price Index for Private Fixed Investment in Structures, Nonresidential, Hospitals and Special Care (BEA Table 5.4.4. Price Indexes for Private Fixed Investment in Structures by Type). As stated in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43860), for the FY 2006-based CIPI we finalized the use of this index to measure the price growth of this cost category. This BEA index is intended to capture prices for construction of facilities such as hospitals, nursing homes, hospices, and rehabilitation centers. For the Depreciation—Movable Equipment cost category, we proposed to continue to measure the price growth using the PPI Commodity for Machinery and Equipment (BLS series code WPU11). This price index reflects price inflation associated with a variety of machinery and equipment that would be utilized by hospitals including but not limited to communication equipment, computers, and medical equipment. For the Nonprofit Interest and For-profit Interest cost categories, we proposed to continue to measure the price growth using the average yield on domestic municipal bonds (Bond Buyer 20-bond index) and the average yield on Moody's Aaa bonds (Federal Reserve), respectively. As stated above, we proposed two proxies because interest price pressures tend to differ between nonprofit and for-profit facilities.

For the Other capital cost category (including insurances, taxes, and other capital-related costs), we proposed to continue to measure the price growth using the CPI for Rent of Primary Residence (All Urban Consumers) (BLS series code CUUS0000SEHA), which would reflect the price growth of these costs. We believe that these price proxies continue to be the most appropriate proxies for IPPS capital costs that meet our selection criteria of relevance, timeliness, availability, and reliability.

TABLE IV–08—PROPOSED AND FINAL 2014-BASED CIPI COST WEIGHTS AND PRICE PROXIES WITH FY 2010-BASED CIPI COST WEIGHTS INCLUDED FOR COMPARISON

Cost categories	FY 2010 cost weights	Proposed and final 2014 cost weights	Proposed and final price proxy
Total	100.0	100.0	
Depreciation	74.0	74.4	
Building and Fixed Equipment	36.2	36.7	BEA's Chained Price Index for Private Fixed Investment in Structures, Nonresidential, Hospitals and Special Care.
Movable Equipment	37.9	37.7	PPI Commodity for Machinery and Equipment.
Interest	19.2	18.2	
Government/Nonprofit	17.1	15.7	Average Yield on Domestic Municipal Bonds (Bond Buyer 20-Bond Index).
For-Profit	2.1	2.5	Average Yield on Moody's Aaa Bonds.
Other	6.8	7.4	CPI for Rent of Primary Residence.

Note: The cost weights are calculated using three decimal places. For presentational purposes, we are displaying one decimal and therefore, the detail may not add to the total due to rounding.

Because capital is acquired and paid for over time, capital expenses in any given year are determined by both past and present purchases of physical and financial capital. We stated in the proposed rule that the proposed vintage-weighted 2014-based CIPI is intended to capture the long-term consumption of capital, using vintage weights for depreciation (physical capital) and interest (financial capital). These vintage weights reflect the proportion of capital purchases attributable to each year of the expected life of building and fixed equipment, movable equipment, and interest. We proposed to use vintage weights to compute vintage-weighted price changes associated with depreciation and interest expenses.

Vintage weights are an integral part of the CIPI. Capital costs are inherently complicated and are determined by complex capital purchasing decisions, over time, based on such factors as interest rates and debt financing. In addition, capital is depreciated over time instead of being consumed in the same period it is purchased. By accounting for the vintage nature of capital, we are able to provide an accurate and stable annual measure of price changes. Annual nonvintage price changes for capital are unstable due to the volatility of interest rate changes and, therefore, do not reflect the actual annual price changes for IPPS capital costs. The CIPI reflects the underlying stability of the capital acquisition process.

To calculate the vintage weights for depreciation and interest expenses, we first needed a time series of capital purchases for building and fixed equipment and movable equipment. We found no single source that provides an appropriate time series of capital purchases by hospitals for all of the above components of capital purchases. The early Medicare cost reports did not have sufficient capital data to meet this need. Data we obtained from the American Hospital Association (AHA) did not include annual capital purchases. However, we were able to obtain data on total expenses back to 1963 from the AHA. Consequently, we proposed to use data from the AHA Panel Survey and the AHA Annual Survey to obtain a time series of total expenses for hospitals. We then proposed to use data from the AHA Panel Survey supplemented with the ratio of depreciation to total hospital expenses obtained from the Medicare cost reports to derive a trend of annual depreciation expenses for 1963 through 2014. We proposed to separate these depreciation expenses into annual amounts of building and fixed

equipment depreciation and movable equipment depreciation as determined earlier. From these annual depreciation amounts, we derived annual end-of-year book values for building and fixed equipment and movable equipment using the expected life for each type of asset category. We used the AHA data and similar methodology to derive the FY 2010-based IPPS capital market basket (78 FR 50604).

To continue to calculate the vintage weights for depreciation and interest expenses, we also needed to account for the expected lives for building and fixed equipment, movable equipment, and interest for the proposed 2014-based CIPI. We proposed to calculate the expected lives using Medicare cost report data. The expected life of any asset can be determined by dividing the value of the asset (excluding fully depreciated assets) by its current year depreciation amount. This calculation yields the estimated expected life of an asset if the rates of depreciation were to continue at current year levels, assuming straight-line depreciation. Using this proposed method, we determined the average expected life of building and fixed equipment to be equal to 27 years, and the average expected life of movable equipment to be equal to 12 years. For the expected life of interest, we believe that vintage weights for interest should represent the average expected life of building and fixed equipment because, based on previous research described in the FY 1997 IPPS final rule (61 FR 46198), the expected life of hospital debt instruments and the expected life of buildings and fixed equipment are similar. We note that the FY 2010-based CIPI was based on an expected average life of building and fixed equipment of 26 years and an expected average life of movable equipment of 12 years. Multiplying these expected lives by the annual depreciation amounts results in annual year-end asset costs for building and fixed equipment and movable equipment. We then calculated a time series, beginning in 1964, of annual capital purchases by subtracting the previous year's asset costs from the current year's asset costs.

For the building and fixed equipment and movable equipment vintage weights, we proposed to use the real annual capital-related purchase amounts for each asset type to capture the actual amount of the physical acquisition, net of the effect of price inflation.

These real annual capital-related purchase amounts are produced by deflating the nominal annual purchase amount by the associated price proxy as described in the proposed rule, and this final rule. For the interest vintage weights, we proposed to use the total nominal annual capital-related purchase amounts to capture the value of the debt instrument (including, but not limited to, mortgages and bonds). Using these capital purchases time series specific to each asset type, we proposed to calculate the vintage weights for building and fixed equipment, for movable equipment, and for interest.

The vintage weights for each asset type are deemed to represent the average purchase pattern of the asset over its expected life (in the case of building and fixed equipment and interest, 27 years, and in the case of movable equipment, 12 years). For each asset type, we proposed to use the time series of annual capital purchases amounts available from 2014 back to 1964. These data allow us to derive twenty-five 27-year periods of capital purchases for building and fixed equipment and interest, and forty 12-year periods of capital purchases for movable equipment. For each 27-year period for building and fixed equipment and interest, or 12-year period for movable equipment, we proposed to calculate annual vintage weights by dividing the capital-related purchase amount in any given year by the total amount of purchases over the entire 27-year or 12-year period. This calculation was done for each year in the 27-year or 12-year period and for each of the periods for which we have data. We then calculated the average vintage weight for a given year of the expected life by taking the average of these vintage weights across the multiple periods of data.

The vintage weights for the proposed 2014-based CIPI and the FY 2010-based CIPI were presented in Table IV–09 in the proposed rule (82 FR 19928). This table is also included below and reflects the final 2014-based CIPI.

TABLE IV–09—PROPOSED AND FINAL 2014–BASED CIPI AND FY 2010–BASED CIPI VINTAGE WEIGHTS

Year [1]	Building and fixed equipment		Movable equipment		Interest	
	Proposed and final 2014-based 27 years	FY 2010-based 26 years	Proposed and final 2014-based 12 years	FY 2010-based 12 years	Proposed and final 2014-based 27 years	FY 2010-based 26 years
1	0.024	0.023	0.062	0.064	0.012	0.012
2	0.025	0.024	0.064	0.068	0.014	0.013
3	0.027	0.026	0.070	0.071	0.015	0.015
4	0.028	0.028	0.074	0.073	0.017	0.017
5	0.030	0.029	0.078	0.076	0.019	0.018
6	0.031	0.031	0.082	0.078	0.021	0.021
7	0.033	0.032	0.086	0.084	0.023	0.023
8	0.034	0.034	0.088	0.088	0.025	0.025
9	0.035	0.036	0.092	0.092	0.027	0.028
10	0.036	0.038	0.097	0.098	0.029	0.030
11	0.037	0.040	0.102	0.103	0.030	0.033
12	0.039	0.041	0.105	0.106	0.033	0.036
13	0.040	0.042	.....	.....	0.035	0.038
14	0.040	0.042	.....	.....	0.037	0.040
15	0.039	0.043	.....	.....	0.037	0.043
16	0.039	0.044	.....	.....	0.040	0.045
17	0.040	0.044	.....	.....	0.041	0.047
18	0.042	0.044	.....	.....	0.045	0.048
19	0.042	0.044	.....	.....	0.048	0.051
20	0.042	0.044	.....	.....	0.050	0.052
21	0.043	0.045	.....	.....	0.052	0.056
22	0.043	0.045	.....	.....	0.054	0.057

TABLE IV–09—PROPOSED AND FINAL 2014–BASED CIPI AND FY 2010–BASED CIPI VINTAGE WEIGHTS—Continued

Year [1]	Building and fixed equipment		Movable equipment		Interest	
	Proposed and final 2014-based 27 years	FY 2010-based 26 years	Proposed and final 2014-based 12 years	FY 2010-based 12 years	Proposed and final 2014-based 27 years	FY 2010-based 26 years
23	0.042	0.045	.....	.....	0.055	0.060
24	0.042	0.046	.....	.....	0.057	0.062
25	0.043	0.045	.....	.....	0.059	0.064
26	0.043	0.045	.....	.....	0.061	0.066
27	0.043	.....	.....	.....	0.062	.....
Total	1.000	1.000	1.000	1.000	1.000	1.000

Note: Numbers may not add to total due to rounding.

[1] Vintage weight in the last year (for example, year 27 for the 2014-based CIPI) is applied to the most recent data point and prior vintage weights are applied going back in time. For example, year 27 vintage weight would be applied to the 2018q3 fixed price proxy level, year 26 vintage weight would be applied to the 2017q3 fixed price proxy level, and so forth.

The process of creating vintage-weighted price proxies requires applying the vintage weights to the price proxy index where the last applied vintage weight in Table IV–09 is applied to the most recent data point. We have provided on the CMS Web site an example of how the vintage weighting price proxies are calculated, using example vintage weights and example price indices. The example can be found under the following CMS Web site link: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html* in the zip file titled ''Weight Calculations as described in the IPPS FY 2010 Proposed Rule.''

Comment: A few commenters supported the proposal to rebase the CIPI.

Response: We appreciate the commenters' support.

We did not receive any detailed public comments on our methodology for deriving the proposed 2014-based CIPI. After consideration of the public comments we received, in this final rule, we are finalizing the 2014-based CIPI as proposed.

Table IV–10 in the proposed rule (82 FR 19929) compares both the historical and forecasted percent changes in the FY 2010-based CIPI and the proposed 2014-based CIPI. The percent changes in the proposed rule were based on IGI's fourth quarter 2016 forecast with historical data through third quarter 2016. The forecasted growth rates provided in Table IV–10 below are based on IGI's more recent second quarter 2017 forecast with historical data through first quarter 2017.

TABLE IV–10—COMPARISON OF FY 2010-BASED AND PROPOSED AND FINAL 2014-BASED CAPITAL INPUT PRICE INDEX, PERCENT CHANGE, FY 2013 THROUGH FY 2020

Fiscal year	CIPI, FY 2010-based	Proposed and final CIPI, 2014-based
Historical Data:		
FY 2013	1.1	1.0
FY 2014	1.2	1.2
FY 2015	1.2	1.1
FY 2016	1.1	1.0
Average FYs 2013–2016	1.2	1.1
Forecast:		
FY 2017	1.2	1.1
FY 2018	1.4	1.3
FY 2019	1.4	1.4
FY 2020	1.5	1.5
Average FYs 2017–2020	1.4	1.3

Source: IHS Global Inc., 2nd quarter 2017 forecast.

IGI forecasts a 1.3 percent increase in the proposed and final 2014-based CIPI for FY 2018, as shown in Table IV–10. The underlying vintage-weighted price increases for depreciation (including building and fixed equipment and movable equipment) and interest (including government/nonprofit and for-profit) based on the proposed 2014-based CIPI were included in Table IV–11 of the proposed rule (82 FR 19929). Again, the percent changes in the proposed rule were based on IGI's fourth quarter 2016 forecast with historical data through third quarter 2016. The forecasted growth rates provided in Table IV–11 below are based on IGI's more recent second quarter 2017 forecast with historical data through first quarter 2017.

TABLE IV–11—PROPOSED AND FINAL 2014-BASED CAPITAL INPUT PRICE INDEX PERCENT CHANGES, TOTAL AND DEPRECIATION AND INTEREST COMPONENTS—FYS 2013 THROUGH 2020

Fiscal year	Total	Depreciation	Interest
Historical Data:			
FY 2013	1.0	1.7	−2.5
FY 2014	1.2	1.8	−1.8
FY 2015	1.1	1.8	−2.7
FY 2016	1.0	1.7	−3.0
Forecast:			
FY 2017	1.1	1.6	−2.2
FY 2018	1.3	1.6	−1.3
FY 2019	1.4	1.6	−0.5
FY 2020	1.5	1.6	−0.1

Source: IHS Global Inc. 2nd quarter 2017 forecast.

Rebasing the CIPI from FY 2010 to 2014 decreased the percent change in the forecasted update for FY 2018 by 0.1 percentage point, from 1.4 percent to 1.3 percent, as shown in Table IV–10. The lower FY 2018 update is primarily due to a change in the vintage weights for the proposed and final 2014-based CIPI, which includes updating the asset purchase data through 2014 and changing the building and fixed equipment and interest asset lives from 26 years to 27 years. This lower update is only partially offset by the change in the base year weights, which produce a faster increase due to more weight being given to the Depreciation cost category and less weight being given to the Interest cost category. As shown in Table IV–11 in the proposed rule (82 FR 19929) and this final rule, for FY 2018, vintage-weighted price growth is projected to be positive for the Depreciation cost category and negative for the Interest cost category.

V. Other Decisions and Changes to the IPPS for Operating System

A. Changes to MS–DRGs Subject To Postacute Care Transfer Policy and MS–DRG Special Payments Policies (§ 412.4)

1. Background

Existing regulations at 42 CFR 412.4(a) define discharges under the IPPS as situations in which a patient is formally released from an acute care hospital or dies in the hospital. Section 412.4(b) defines acute care transfers, and § 412.4(c) defines postacute care transfers. Our policy set forth in § 412.4(f) provides that when a patient is transferred and his or her length of stay is less than the geometric mean length of stay for the MS–DRG to which the case is assigned, the transferring hospital is generally paid based on a graduated per diem rate for each day of stay, not to exceed the full MS–DRG payment that would have been made if the patient had been discharged without being transferred.

The per diem rate paid to a transferring hospital is calculated by dividing the full MS–DRG payment by the geometric mean length of stay for the MS–DRG. Based on an analysis that showed that the first day of hospitalization is the most expensive (60 FR 45804), our policy generally provides for payment that is twice the per diem amount for the first day, with each subsequent day paid at the per diem amount up to the full MS–DRG payment (§ 412.4(f)(1)). Transfer cases also are eligible for outlier payments. In general, the outlier threshold for transfer cases, as described in § 412.80(b), is equal to the fixed-loss outlier threshold for nontransfer cases (adjusted for geographic variations in costs), divided by the geometric mean length of stay for the MS–DRG, and multiplied by the length of stay for the case, plus 1 day.

We established the criteria set forth in § 412.4(d) for determining which DRGs qualify for postacute care transfer payments in the FY 2006 IPPS final rule (70 FR 47419 through 47420). The determination of whether a DRG is subject to the postacute care transfer policy was initially based on the Medicare Version 23.0 GROUPER (FY 2006) and data from the FY 2004 MedPAR file. However, if a DRG did not exist in Version 23.0 or a DRG included in Version 23.0 is revised, we use the current version of the Medicare GROUPER and the most recent complete year of MedPAR data to determine if the DRG is subject to the postacute care transfer policy. Specifically, if the MS–DRG's total number of discharges to postacute care equals or exceeds the 55th percentile for all MS–DRGs and the proportion of short-stay discharges to postacute care to total discharges in the MS–DRG exceeds the 55th percentile for all MS–DRGs, CMS will apply the postacute care transfer policy to that MS–DRG and to any other MS–DRG that shares the same base MS–DRG. The statute directs us to identify MS–DRGs based on a high volume of discharges to postacute care facilities and a disproportionate use of postacute care services. As discussed in the FY 2006 IPPS final rule (70 FR 47416), we determined that the 55th percentile is an appropriate level at which to establish these thresholds. In that same final rule (70 FR 47419), we stated that we will not revise the list of DRGs subject to the postacute care transfer policy annually unless we are making a change to a specific MS–DRG.

To account for MS–DRGs subject to the postacute care policy that exhibit exceptionally higher shares of costs very early in the hospital stay, § 412.4(f) also includes a special payment methodology. For these MS–DRGs, hospitals receive 50 percent of the full MS–DRG payment, plus the single per diem payment, for the first day of the stay, as well as a per diem payment for subsequent days (up to the full MS–DRG payment (§ 412.4(f)(6)). For an MS- DRG to qualify for the special payment methodology, the geometric mean length of stay must be greater than 4 days, and the average charges of 1-day discharge cases in the MS–DRG must be at least 50 percent of the average charges for all cases within the MS–DRG. MS–DRGs that are part of an MS–DRG severity level group will qualify under the MS–DRG special payment methodology policy if any one of the MS–DRGs that share that same base MS–DRG qualifies (§ 412.4(f)(6)).

2. Changes for FY 2018

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19929 through 19931), based on our annual review of MS–DRGs, we identified three MS–DRGs that we proposed to be included on the list of MS–DRGs subject to the special payment transfer policy. As we discussed in section II.F. of the preamble of that proposed rule, in

response to public comments and based on our analysis of FY 2016 MedPAR claims data, we proposed to make changes to MS–DRGs, effective for FY 2018.

As discussed in the preamble of the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19850), we proposed to delete MS–DRGs 984, 985, and 986 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC and without CC/MCC, respectively) and reassign the procedure codes currently assigned to these three MS–DRGs to MS–DRGs 987, 988, and 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC and without CC/MCC, respectively).

In light of the proposed changes to the MS–DRGs for FY 2018, according to the regulations under § 412.4(d), we evaluated proposed revised MS–DRGs 987, 988, and 989 (which would contain the proposed reassigned procedures from MS–DRGs 984, 985, and 986) against the general postacute care transfer policy criteria using the FY 2016 MedPAR data. If an MS–DRG qualified for the postacute care transfer policy, we also evaluated that MS–DRG under the special payment methodology criteria according to regulations at § 412.4(f)(6). We continue to believe it is appropriate to reassess MS–DRGs when proposing reassignment of procedure or diagnosis codes that would result in material changes to an MS–DRG. MS–DRGs 987, 988, and 989 are currently subject to the postacute care transfer policy. We stated in the proposed rule that as a result of our review, the proposed revised MS–DRGs 987, 988, and 989 continue to qualify to be included on the list of MS–DRGs that are subject to the postacute care transfer policy. We did not propose to change the postacute care transfer policy status for MS–DRGs 987, 988, and 989.

As discussed in section II.F.14.b. of the preamble of this FY 2018 IPPS/LTCH PPS final rule, we are finalizing the proposed revisions to these MS–DRGs. Using the March 2017 update of the FY 2016 MedPAR file, we developed the following chart which sets forth the most recent analysis of the postacute care transfer policy criteria completed for this final rule.

LIST OF REVISED MS–DRGS SUBJECT TO REVIEW OF POSTACUTE CARE TRANSFER POLICY STATUS FOR FY 2018

Revised MS–DRG	MS–DRG title	Total cases	Postacute care transfers (55th percentile: 1,418)	Short-stay postacute care transfers	Percent of short-stay postacute care transfers to all cases (55th percentile: 7.80629%)	Postacute care transfer policy status
987	Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC.	8,485	4,395	1,117	13.16441	Yes.
988	Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with CC.	8,876	3,774	817	9.20460	Yes.
989	Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis without MCC/CC.	2,364	* 568	53	* 2.24196	Yes. **

* Indicates a current postacute care transfer policy criterion that the MS–DRG did not meet.

** As described in the policy at 42 CFR 412.4(d)(3)(ii)(D), MS–DRGs that share the same base MS–DRG will all qualify under the postacute care transfer policy if any one of the MS–DRGs that share that same base MS–DRG qualifies.

As we discussed in the proposed rule, we also determined that proposed revised MS–DRGs 987, 988, and 989 would meet the criteria for the MS–DRG special payment methodology. MS–DRGs 987, 988, and 989 are not currently listed as being subject to the special payment policy. Therefore, we proposed that these three proposed revised MS–DRGs would be subject to the MS–DRG special payment methodology, effective FY 2018.

We did not receive any public comments on this proposal. Therefore, we are finalizing the proposed changes to the special payment policy status of MS–DRGs 987, 988, and 989. We note that, in a chart in the proposed rule (82 FR 19931), we erroneously listed the geometric mean length of stay for MS–DRG 988 as 8.6 days. The figure should have been 4.4 days (which, for this final rule, is revised to 4.3 days as a result of the most recent data analysis). Regardless, because the revised geometric mean length of stay is also greater than 4 days, MS–DRG 988 qualifies for special payment policy status, and as described in the policy at 42 CFR 412.4(d)(6)(iv), MS–DRGs 987 and 989 also qualify, consistent with our proposal. Using the March 2017 update of the FY 2016 MedPAR file, we developed the following chart which set forth the most recent data analysis of the special payment methodology criteria completed for this final rule.

LIST OF REVISED MS–DRGS SUBJECT TO REVIEW OF SPECIAL PAYMENT POLICY STATUS FOR FY 2018

Revised MS–DRG	MS–DRG title	Geometric mean length of stay	Average charges of 1-day discharges	50 percent of average charges for all cases within MS–DRG	Special payment policy status
987	Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC.	7.9	$33,424	$52,050	Yes *.
988	Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with CC.	4.3	34,443	28,404	Yes.

LIST OF REVISED MS–DRGS SUBJECT TO REVIEW OF SPECIAL PAYMENT POLICY STATUS FOR FY 2018—Continued

Revised MS–DRG	MS–DRG title	Geometric mean length of stay	Average charges of 1-day discharges	50 percent of average charges for all cases within MS–DRG	Special payment policy status
989	Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis without MCC/CC.	2.2	0	0	Yes.*

* As described in the policy at 42 CFR 412.4(d)(6)(iv), MS–DRGs that share the same base MS–DRG will all qualify under the MS–DRG special payment policy if any one of the MS–DRGs that share that same base MS–DRG qualifies.

The finalized special payment policy status of these three MS–DRGs is reflected in Table 5 associated with this final rule, which is listed in section VI. of the Addendum to this final rule and available via the Internet on the CMS Web site.

B. Changes in the Inpatient Hospital Update for FY 2018 (§ 412.64(d))

1. FY 2018 Inpatient Hospital Update

In accordance with section 1886(b)(3)(B)(i) of the Act, each year we update the national standardized amount for inpatient hospital operating costs by a factor called the ''applicable percentage increase.'' As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19931 through 19933), for FY 2018, we are setting the applicable percentage increase by applying the adjustments listed in this section in the same sequence as we did for FY 2017. Specifically, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. The applicable percentage increase under the IPPS is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to—

(a) A reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act;

(b) A reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful EHR users in accordance with section 1886(b)(3)(B)(ix) of the Act;

(c) An adjustment based on changes in economy-wide productivity (the multifactor productivity (MFP) adjustment); and

(d) An additional reduction of 0.75 percentage point as required by section 1886(b)(3)(B)(xii) of the Act.

Sections 1886(b)(3)(B)(xi) and (b)(3)(B)(xii) of the Act, as added by section 3401(a) of the Affordable Care Act, state that application of the MFP adjustment and the additional FY 2018 adjustment of 0.75 percentage point may result in the applicable percentage increase being less than zero.

We note that, in compliance with section 404 of the MMA, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19916 through 19923), we proposed to replace the FY 2010-based IPPS operating market basket with the rebased and revised 2014-based IPPS operating market basket for FY 2018. We proposed to base the proposed FY 2018 market basket update used to determine the applicable percentage increase for the IPPS on IHS Global Inc.'s (IGI's) fourth quarter 2016 forecast of the proposed 2014-based IPPS market basket rate-of-increase with historical data through third quarter 2016, which was estimated to be 2.9 percent. We proposed that if more recent data subsequently became available (for example, a more recent estimate of the market basket and the MFP adjustment), we would use such data, if appropriate, to determine the FY 2018 market basket update and the MFP adjustment in this final rule. We received public comments regarding the rebasing and revising of the IPPS operating market basket and refer readers to section IV.B. of this final rule for a complete discussion on the rebasing and revising of the market basket. In section IV.B., we are finalizing our proposals without modification and, therefore, are using the finalized rebased and revised 2014-based IPPS market basket rate-of-increase for FY 2018.

Based on the most recent data available for this FY 2018 IPPS/LTCH PPS final rule (that is, IGI's second quarter 2017 forecast of the 2014-based IPPS market basket rate-of-increase with historical data through first quarter 2017), we estimate that the FY 2018 market basket update used to determine the applicable percentage increase for the IPPS is 2.7 percent.

For FY 2018, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the standardized amount as specified in the table that appears later in this section.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the MFP adjustment. As we explained in that rule, section 1886(b)(3)(B)(xi)(II) of the Act, as added by section 3401(a) of the Affordable Care Act, defines this productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business MFP (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period). The Bureau of Labor Statistics (BLS) publishes the official measure of private nonfarm business MFP. We refer readers to the BLS Web site at *http://www.bls.gov/mfp* for the BLS historical published MFP data. MFP is derived by subtracting the contribution of labor and capital input growth from output growth. The projections of the components of MFP are currently produced by IGI, a nationally recognized economic forecasting firm with which CMS contracts to forecast the components of the market baskets and MFP. As we discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49509), beginning with the FY 2016 rulemaking cycle, the MFP adjustment is calculated using the revised series developed by IGI to proxy the aggregate capital inputs. Specifically, in order to generate a forecast of MFP, IGI forecasts BLS aggregate capital inputs using a

regression model. A complete description of the MFP projection methodology is available on the CMS Web site at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html.* As discussed in the FY 2016 IPPS/LTCH PPS final rule, if IGI makes changes to the MFP methodology, we will announce them on our Web site rather than in the annual rulemaking.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19932), for FY 2018, we proposed an MFP adjustment of 0.4 percentage point. Similar to the market basket update, for the proposed rule, we used IGI's fourth quarter 2016 forecast of the MFP adjustment to compute the proposed MFP adjustment. As noted previously, we proposed that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2018 market basket update and the MFP adjustment for the final rule. Based on the most recent data available for this final rule, we have determined an MFP adjustment of 0.6 percentage point for FY 2018.

We did not receive any public comments on our proposal to use the most recent available data to determine the final market basket update and the MFP adjustment. Therefore, for this final rule, we are finalizing a market basket update of 2.7 percent and an MFP adjustment of 0.6 percentage point based on the most recent available data.

Based on the most recent data available for this final rule, as described previously, we have determined four applicable percentage increases to the standardized amount for FY 2018, as specified in the following table:

FY 2018 APPLICABLE PERCENTAGE INCREASES FOR THE IPPS

FY 2018	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is not a meaningful EHR user	Hospital did not submit quality data and is a meaningful EHR user	Hospital did not submit quality data and is not a meaningful EHR user
Market Basket Rate-of-Increase	2.7	2.7	2.7	2.7
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.675	−0.675
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−2.025	0.0	−2.025
MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.6	−0.6	−0.6	−0.6
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.75	−0.75	−0.75	−0.75
Applicable Percentage Increase Applied to Standardized Amount	1.35	−0.675	0.675	−1.35

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19932), we proposed to revise the existing regulations at 42 CFR 412.64(d) to reflect the current law for the FY 2018 update. Specifically, in accordance with section 1886(b)(3)(B) of the Act, we proposed to revise paragraph (vii) of § 412.64(d)(1) to include the applicable percentage increase to the FY 2018 operating standardized amount as the percentage increase in the market basket index, subject to the reductions specified under § 412.64(d)(2) for a hospital that does not submit quality data and § 412.64(d)(3) for a hospital that is not a meaningful EHR user, less an MFP adjustment and less an additional reduction of 0.75 percentage point.

We did not receive any public comments on our proposed changes to the regulations at § 412.64(d)(1)(vii) and, therefore, are finalizing these proposed changes without modification in this final rule.

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase to the hospital-specific rates for SCHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital-specific rates for SCHs also is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act.

As discussed in section V.H. of the preamble of the FY 2018 IPPS/LTCH PPS proposed rule and in this final rule, section 205 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted on April 16, 2015) extended the MDH program (which, under previous law, was to be in effect for discharges on or before March 31, 2015 only) for discharges occurring on or after April 1, 2015, through FY 2017 (that is, for discharges occurring on or before September 30, 2017). Therefore, under current law, the MDH program will expire at the end of FY 2017.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19932), for FY 2018, we proposed updates to the hospital-specific rates applicable to SCHs based on IGI's fourth quarter 2016 forecast of the proposed 2014-based IPPS market basket update with historical data through third quarter 2016. Similarly, we used IGI's fourth quarter 2016 forecast of the MFP adjustment. We proposed that if more recent data subsequently became available (for example, a more recent estimate of the market basket increase and the MFP adjustment), we would use such data, if appropriate, to determine the update in the final rule.

We did not receive any public comments with regard to our proposal. Therefore, we are finalizing the proposal to determine the update to the hospital-specific rates for SCHs in this final rule using the most recent data available.

For this final rule, based on the most recent available data, we are finalizing the following updates to the hospital-specific rates applicable to SCHs (using IGI's second quarter 2017 forecast of the 2014-based IPPS market basket update and the MFP adjustment): An update of 1.35 percent for a hospital that submits quality data and is a meaningful EHR user; an update of 0.675 percent for a hospital that fails to submit quality data and is a meaningful EHR user; an update of –0.675 percent for a hospital that submits quality data and is not a meaningful EHR user; and an update of –1.35 percent for a hospital that fails to submit quality data and is not a meaningful EHR user.

2. FY 2018 Puerto Rico Hospital Update

As discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56937 through 56938), prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national

standardized amount and 25 percent of the Puerto Rico-specific standardized amount. Section 601 of Public Law 114–113 amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount.

Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount under the amendments to section 1886(d)(9)(E) of the Act, there is no longer a need for us to determine an update to the Puerto Rico standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the same update to the national standardized amount discussed under section V.B.1. of the preamble of this final rule. Accordingly, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19932 through 19933), for FY 2018, we proposed an applicable percentage increase of 1.75 percent to the standardized amount for hospitals located in Puerto Rico. We did not receive any public comments on our proposal. Based on the most recent available data, we are finalizing an applicable percentage increase of 1.35 percent to the standardized amount for hospitals located in Puerto Rico.

We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for ''subsection (d)'' hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico.

In addition, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016, and also to apply the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act to Puerto Rico hospitals that are not meaningful EHR users, effective FY 2022. Accordingly, because the provisions of section 1886(b)(3)(B)(ix) of the Act are not applicable to hospitals located in Puerto Rico until FY 2022, the adjustments under this provision are not applicable for FY 2018.

C. Change to Volume Decrease Adjustment for Sole Community Hospitals (SCHs) and Medicare-Dependent, Small Rural Hospitals (MDHs) (§§ 412.92 and 412.108)

1. Background

Sections 1886(d)(5)(D) and (d)(5)(G) of the Act provide special payment protections under the IPPS to sole community hospitals (SCHs) and Medicare-dependent, small rural hospitals (MDHs), respectively. Section 1886(d)(5)(D)(iii) of the Act defines an SCH in part as a hospital that the Secretary determines is located more than 35 road miles from another hospital or that, by reason of factors such as isolated location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of inpatient hospital services reasonably available to Medicare beneficiaries. The regulations at 42 CFR 412.92 set forth the criteria that a hospital must meet to be classified as a SCH. For more information on SCHs, we refer readers to the FY 2009 IPPS/LTCH PPS final rule (74 FR 43894 through 43897).

Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area, has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (that is, not less than 60 percent of its inpatient days or discharges during the cost reporting period beginning in FY 1987 or two of the three most recently audited cost reporting periods for which the Secretary has a settled cost report were attributable to inpatients entitled to benefits under Part A). The regulations at 42 CFR 412.108 set forth the criteria that a hospital must meet to be classified as an MDH. The MDH program is not authorized by statute beyond September 30, 2017. Therefore, beginning October 1, 2017, all hospitals that previously qualified for MDH status under section 1886(d)(5)(G) of the Act will no longer have MDH status and will be paid based on the IPPS Federal rate. For additional information on the MDH program and the payment methodology, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51683 through 51684).

2. Changes to the Volume Decrease Adjustment Calculation Methodology for SCHs

Section 1886(d)(5)(D)(ii) and section 1886(d)(5)(G)(iii) of the Act require that the Secretary adjust the payments made to an SCH and MDH, respectively, as may be necessary to fully compensate the hospital for the fixed costs it incurs in providing inpatient hospital services, including the reasonable cost of maintaining necessary core staff and services, when it experiences a decrease of more than 5 percent in its total number of inpatient discharges due to circumstances beyond its control. These adjustments are known as ''volume decrease adjustments.''

The regulations governing volume decrease adjustments are found at 42 CFR 412.92(e) for SCHs and § 412.108(d) for MDHs. As noted earlier, the MDH program is set to expire as of October 1, 2017. As such, we proposed that if the MDH program ends up being extended by law, similar to how it was extended by section 205 of the MACRA (Pub. L. 114–10) and prior legislation, the proposed changes to the volume decrease adjustment methodology and the proposed amendment to § 412.92(e)(3) for SCHs would also be made to the parallel requirements for MDHs under § 412.108(d)(3).

To qualify for a volume decrease adjustment, the SCH must: (a) Submit documentation demonstrating the size of the decrease in discharges and the resulting effect on per discharge costs; and (b) show that the decrease is due to circumstances beyond the hospital's control. If an SCH demonstrates to the MAC's satisfaction that it has suffered a qualifying decrease in total inpatient discharges, the MAC determines the appropriate amount, if any, due to the SCH as an adjustment.

As we have noted in Section 2810.1 of the Provider Reimbursement Manual, Part 1 (PRM–1) and in adjudications rendered by the PRRB and the CMS Administrator, under the current methodology, the MAC determines a volume decrease adjustment amount not to exceed a cap calculated as the difference between the lesser of (1) the hospital's current year's Medicare inpatient operating costs or (2) its prior year's Medicare inpatient operating costs multiplied by the appropriate IPPS update factor, and the hospital's total MS–DRG revenue for inpatient operating costs (including outlier payments, DSH payments, and IME payments). In determining the volume decrease adjustment amount, the MAC considers the individual hospital's needs and circumstances, including the reasonable cost of maintaining necessary core staff and services in view of minimum staffing requirements imposed by State agencies; the hospital's fixed costs (including whether any semi-fixed costs are to be considered fixed) other than those costs paid on a reasonable cost basis; and the length of time the hospital has experienced a decrease in utilization.

We have set forth interpretive guidance regarding volume decrease adjustments in the preambles to various rules and in Section 2810.1 of the PRM–1. The adjustment also has been the subject of a series of adjudications, rendered by the PRRB and the CMS Administrator. For example, we refer readers to *Greenwood County Hospital Eureka, Kansas,* v. *Blue Cross Blue Shield Association/Blue Cross Blue Shield of Kansas,* 2006 WL 3050893 (PRRB August 29, 2006); *Unity Healthcare Muscatine, Iowa* v. *Blue Cross Blue Shield Association/ Wisconsin Physicians Service,* 2014 WL 5450066 (CMS Administrator September 4, 2014); *Lakes Regional Healthcare Spirit Lake, Iowa* v. *Blue Cross Blue Shield Association/Wisconsin Physicians Service,* 2014 WL 5450078 (CMS Administrator September 4, 2014); *Fairbanks Memorial Hospital* v. *Wisconsin Physician Services/BlueCross BlueShield Association,* 2015 WL 5852432 (CMS Administrator, August 5, 2015); *St. Anthony Regional Hospital* v. *Wisconsin Physicians Service,* 2016 WL 7744992 (CMS Administrator October 3, 2016); and *Trinity Regional Medical Center* v. *Wisconsin Physician Services,* 2017 WL 2403399 (CMS Administrator February 9, 2017). In those adjudications, the PRRB and the CMS Administrator have recognized that: (1) The volume decrease adjustment is intended to compensate qualifying SCHs for their fixed costs only, and that variable costs are to be excluded from the adjustment; and (2) an SCH's volume decrease adjustment should be reduced to reflect the compensation of fixed costs that has already been made through MS–DRG payments.

However, some hospitals have recently expressed concerns regarding the exact calculations that the MACs use when determining the volume decrease adjustment. The issue also has been addressed in some recent decisions of the PRRB. As the above referenced Administrator decisions illustrate and explain, under the current calculation methodology, the MACs calculate the volume decrease adjustment by subtracting the entirety of the hospital's total MS–DRG revenue for inpatient operating costs, including outlier payments and IME and DSH payments in the cost reporting period in which the volume decrease occurred, from fixed costs in the cost reporting period in which the volume decrease occurred, minus any adjustment for excess staff. If the result of that calculation is greater than zero and less than the cap, the hospital receives that amount in a lump-sum payment. If the result of that calculation is zero or less than zero, the hospital does not receive a volume decrease payment adjustment.

Under the IPPS, MS–DRG payments are not based on an individual hospital's actual costs in a given cost reporting period. However, the main issue raised by the PRRB and individual hospitals is that, under the current calculation methodology, if the hospital's total MS–DRG revenue for treating Medicare beneficiaries for which it incurs inpatient operating costs (consisting of fixed, semi-fixed, *and* variable costs) exceeds the hospital's fixed costs, the calculation by the MACs results in no volume decrease adjustment for the hospital. In some recent decisions, the PRRB has indicated that it believes it would be more appropriate for the MACs to adjust the hospital's total MS–DRG revenue from Medicare by looking at the ratio of a hospital's fixed costs to its total costs (as determined by the MAC) and applying that ratio as a proxy for the share of the hospital's MS–DRG payments that it assumes are attributable (or allocable) to fixed costs, and then comparing that estimate of the fixed portion of MS–DRG payments to the hospital's fixed costs. In this way, the calculation would compare estimated Medicare revenue for fixed costs to the hospital's fixed costs when determining the volume decrease adjustment.

We continue to believe that our current approach in calculating volume decrease adjustments is reasonable and consistent with the statute. The relevant statutory provisions, at sections 1886(d)(5)(D)(ii) and 1886(d)(5)(G)(iii) of the Act, are silent about and thus delegate to the Secretary the responsibility of determining which costs are to be deemed ''fixed'' and what level of adjustment to IPPS payments may be necessary to ensure that total Medicare payments have fully compensated an SCH or MDH for its ''fixed costs.'' These provisions suggest that the volume decrease adjustment amount should be reduced (or eliminated as the case may be) to the extent that some or all of an SCH's or MDH's fixed costs have already been compensated through other Medicare subsection (d) payments. The Secretary's current approach is also consistent with the regulations and the PRM–1. Like the statute, the relevant regulations do not address variable costs, and the regulations and the PRM–1 (along with the Secretary's preambles to issued rules (48 FR 39781 through 39782 and 55 FR 15156) and adjudications) all make it clear that the volume decrease adjustment is intended to compensate qualifying SCHs and MDHs for their fixed costs, not for their variable costs, and that variable costs are to be excluded from the volume decrease adjustment calculation. Nevertheless, we understand why hospitals might take the view that CMS should make an effort, in some way, to ascertain whether a portion of MS–DRG payments can be allocated or attributed to fixed costs in order to fulfill the statutory mandate to ''fully compensate'' a qualifying SCH for its fixed costs.

Accordingly, after considering these views, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19933), we proposed to prospectively change how the MACs calculate the volume decrease adjustments and require that the MACs compare estimated Medicare revenue for fixed costs to the hospital's fixed costs to remove any conceivable possibility that a hospital that qualifies for the volume decrease adjustment could ever be less than fully compensated for fixed costs as a result of the application of the adjustment. We proposed that, in order to estimate the fixed portion of the Medicare revenue, the MACs would apply the ratio of the hospital's fixed costs to total costs in the cost reporting period when it experienced the volume decrease to the hospital's total Medicare revenue in that same cost reporting period. We proposed to revise the regulations at 42 CFR 412.92(e)(3) to reflect our proposed change in the MAC's calculation of the volume decrease adjustment that would apply prospectively to cost reporting periods beginning on or after October 1, 2017, and to reflect that the language requiring that the volume decrease adjustment amount not exceed the difference between the hospital's Medicare inpatient operating costs and the hospital's total DRG revenue for inpatient operating costs would only apply to cost reporting periods beginning before October 1, 2017, but not to subsequent cost reporting periods. Under the proposed methodology, if a hospital's total MS–DRG payment is less than its total Medicare inpatient operating costs, the sum of any resulting volume decrease adjustment payment and its MS–DRG payment would never exceed its total Medicare inpatient operating costs due to the fact that the fixed cost percentage is applied to the MS–DRG payment in calculating the volume decrease adjustment amount. By taking the ratio derived from the subset of fixed costs to total costs and applying that same ratio to the MS–DRG payment, we ensure that the sum of a hospital's IPPS payment

and its volume decrease adjustment payment would never exceed its total Medicare inpatient operating costs, thus negating the need for a cap calculation. Thus, the proposed methodology would render the current volume decrease adjustment cap calculation obsolete. Conversely, if a hospital's total MS–DRG payment is greater than its total Medicare inpatient operating costs, calculating a volume decrease adjustment using the proposed methodology would result in a negative payment amount, which would yield a volume decrease adjustment payment of zero. Finally, if a hospital's total MS–DRG payment is equal to its total Medicare inpatient operating costs, calculating a volume decrease adjustment using the proposed methodology would also yield a volume decrease adjustment payment of zero. Furthermore, we believe that because a hospital could not foresee a decrease in its volume from one year to the next and would therefore not plan for a volume decrease adjustment, the volume decrease adjustment payment should therefore not be limited to a cap that is based on the previous year's costs. For these reasons, we proposed to remove the cap calculation from the volume decrease adjustment calculation methodology in future periods. We believe that this new approach to calculating the volume decrease adjustment, like the current methodology, is reasonable and consistent with the statute.

We proposed that these proposed changes in the MAC's calculation of the volume decrease adjustment would be prospective, effective for cost reporting periods beginning on or after October 1, 2017. We indicated in the proposed rule that if these proposed changes are adopted, we also intended to update Section 2810.1 of the PRM–1 to reflect the changes in the calculation of the volume decrease adjustment by the MAC. For volume decrease adjustments for earlier cost reporting periods, we stated that the current calculation methodology would continue. In addition, we stated that we were not proposing to change any part of the methodology, criteria, rules, or presumptions we consider and apply in determining whether to classify a given cost as fixed, semi-fixed, or variable for purposes of the volume decrease adjustment.

In the proposed rule, we presented the following example to illustrate the calculation of the volume decrease adjustment by the MAC under our proposed change. We note that, as presented in our proposed rule, the example may have implied that under the proposed methodology, the MACs would apply the ratio of the hospital's Medicare fixed costs to total Medicare costs, rather than ''the ratio of the hospital's fixed costs to total costs in the cost reporting period when it experienced the volume decrease to the hospital's total Medicare revenue in that same cost reporting period,'' as stated elsewhere in the preamble (82 FR 19934). We have modified the example below to address this inconsistency and to clarify our intent by including additional details to more clearly illustrate how Medicare fixed costs and the fixed MS–DRG revenue are calculated and used in the calculation, including to reflect that this same ratio, that is, the hospital's fixed inpatient costs to total inpatient costs, is applied to total Medicare costs to arrive at fixed Medicare costs, as under the current methodology.

Example: In its cost reporting period beginning October 1, 2017, Hospital A has total Medicare inpatient operating costs equaling $1,600,000 and total MS–DRG revenue (including outlier payments, IME and DSH) of $1,400,000. The MAC determines that the hospital qualifies for a volume decrease adjustment for this cost reporting period. The MAC classifies $2,720,000 of Hospital A's total (Medicare and non-Medicare) costs as fixed and $480,000 as variable. Hospital A's fixed cost ratio is therefore .85 = $2,720,000/($2,720,000 + $480,000) = $2,720,000/$3,200,000. The MAC applies this ratio to the (1) total MS–DRG revenue of $1,400,000 to estimate the hospital's fixed MS–DRG revenue to be $1,190,000 and (2) total Medicare inpatient operating costs to estimate the hospital's fixed Medicare costs to be $1,360,000. The volume decrease adjustment payment is then calculated by comparing the fixed MS–DRG revenue of $1,190,000 to the Medicare fixed costs of $1,360,000, resulting in a volume decrease adjustment payment of $170,000 ($1,360,000 minus $1,190,000).

Under the current methodology used by the MACs, Hospital A would receive no volume decrease adjustment payment because its total MS–DRG revenue from Medicare of $1,400,000 exceeded the hospital's Medicare fixed costs of $1,360,000. Furthermore, under the current methodology, but not under our proposed methodology, it is possible that a hospital would still receive no volume decrease adjustment payment even if its Medicare fixed costs exceeded its total MS–DRG revenue if those fixed costs exceeded the previous year's costs updated for inflation.

We also proposed changes to an adjustment that might be made to a hospital's staffing costs in calculating the volume decrease adjustment. The statute and regulations and the PRM–1 imply, and we have expressly indicated in prior rulemaking, most recently in the FY 2006 rulemaking, our belief that not all staff costs can necessarily be considered fixed costs (71 FR 48056 through 48060). Therefore, we currently require a hospital, when applying for a volume decrease adjustment, to demonstrate that it appropriately adjusted the number of staff in inpatient areas of the hospital based on the decrease in the number of inpatient days but not beyond minimum levels as required by State or local laws. If a hospital does not appropriately adjust its number of staff, the cost of maintaining those staff members is deducted from the total volume decrease adjustment payment. In reviewing the volume decrease adjustment calculation, we have also weighed the administrative burden on the hospital of making this demonstration to CMS, as compared to an assumption that it is likely that a hospital would, in its normal course of business, adjust its staffing levels as revenue declines. In the absence of evidence to contrary, we believe that a hospital would adjust its staffing levels as revenue declines rather than maintain those staffing levels for the sole purpose of potentially having those staffing costs eventually reflected in a Medicare volume decrease adjustment payment that the hospital may or may not qualify for when it files its cost report. Therefore, we proposed to modify the volume decrease adjustment process to no longer require that a hospital explicitly demonstrate that it appropriately adjusted the number of staff in inpatient areas of the hospital based on the decrease in the number of inpatient days and to no longer require the MAC to adjust the volume decrease adjustment payment amount for excess staffing. We proposed that these changes would be effective for cost reporting periods beginning on or after October 1, 2017.

Comment: Commenters supported CMS' proposed changes to the volume decrease adjustment methodology to (1) apply the ratio of the hospital's fixed costs to total costs in the cost reporting period when it experienced the volume decrease to the hospital's total Medicare revenue in that same cost reporting period; (2) remove the cap calculation from the volume decrease adjustment calculation methodology in future periods; (3) no longer require that a hospital explicitly demonstrate that it appropriately adjusted the number of

staff in inpatient areas of the hospital based on the decrease in the number of inpatient days; and (4) no longer require the MAC to adjust the volume decrease adjustment payment amount for excess staffing. However, commenters suggested that CMS apply these proposals retrospectively with a gamut of suggestions as to the specific types of volume decrease adjustment determinations for which to apply the proposed methodology: Pending volume decrease adjustment determinations; volume decrease adjustment determinations currently under appeal; unsettled cost reports; volume decrease adjustment determinations that are still within the PRRB appeal timeline; volume decrease adjustment determinations for which the MAC has issued a recoupment demand; volume decrease adjustment determinations for all open cost reports, regardless of whether an appeal was made; and all open cost reports, including those for which a volume decrease adjustment was not requested.

Some commenters asserted that what CMS outlined in the proposed rule as its ''current methodology'' was not, in fact, the current methodology being applied consistently across the board and that applying that methodology to pending volume decrease adjustment cases would amount to retroactive rulemaking. The commenters added that the proposed methodology, or the ''proxy methodology,'' is not, in fact, new because it has been referenced in PRRB decisions and has been used by some MACs at times. Other commenters stated that critical funding to hospitals for pending volume decrease adjustment determinations should not be at risk due to a lack of standardization across CMS and MAC decisions.

Response: We appreciate the commenters' support of our proposed changes to the volume decrease adjustment methodology. We disagree with the commenters' assertion that the methodology that we outlined as our ''current methodology'' is not current but a new methodology that we are introducing as ''current.'' While there may have been inconsistencies in volume decrease adjustment determinations made by some MACs, inconsistent MAC determinations and PRRB decisions that are subsequently reversed by the Administrator do not establish agency policy nor bind the agency. Furthermore, our current methodology has been upheld by the PRRB in *Greenwood County Hospital Eureka, Kansas,* v. *Blue Cross Blue Shield Association/Blue Cross Blue Shield of Kansas,* 2006 WL 3050893 (PRRB, August 29, 2006) and clearly outlined in the Administrator's decisions in *Unity Healthcare Muscatine, Iowa* v. *Blue Cross Blue Shield Association/Wisconsin Physicians Service,* 2014 WL 5450066 (CMS Administrator September 4, 2014); *Lakes Regional Healthcare Spirit Lake, Iowa* v. *Blue Cross Blue Shield Association/Wisconsin Physicians Service,* 2014 WL 5450078 (CMS Administrator September 4, 2014); *Fairbanks Memorial Hospital* v. *Wisconsin Physician Services/BlueCross BlueShield Association,* 2015 WL 5852432 (CMS Administrator, August 5, 2015); *St. Anthony Regional Hospital* v. *Wisconsin Physicians Service,* 2016 WL 7744992 (CMS Administrator October 3, 2016); and *Trinity Regional Medical Center* v. *Wisconsin Physician Services,* 2017 WL 2403399 (CMS Administrator February 9, 2017), to name a few. For these reasons, we disagree with the commenters that our current policy was not the established policy, and we believe that applying this policy does not constitute retroactive rulemaking. Indeed, some of these same commenters are currently awaiting a court decision in a pending appeal in which they challenged the exact methodology which they claim in their comments is not ''current policy'' but a redefined ''new policy.''

We also do not agree that we should apply our proposed methodology retroactively. The IPPS is a prospective system and, absent legislation, a judicial decision, or other compelling considerations to the contrary, we generally make changes to IPPS regulations effective prospectively based on the date of discharge or the start of a cost reporting period within a certain Federal fiscal year. We believe following our usual approach and applying the new methodology for cost reporting periods beginning on or after October 1, 2017 would allow for the most equitable application of this methodology among all IPPS providers seeking to qualify for volume decrease adjustments. For these reasons, we are finalizing that our proposed changes to the volume decrease adjustment methodology will apply prospectively for cost reporting periods beginning on or after October 1, 2017.

Comment: One commenter suggested that, because CMS did not issue updated core staffing factors for FY 2012 or later, the proposed change to no longer require a hospital to explicitly demonstrate that it appropriately adjusted the number of staff in inpatient areas of the hospital based on the decrease in the number of inpatient days and to no longer require the MAC to adjust the volume decrease adjustment payment amount for excess staffing be effective for cost reporting periods beginning on or after October 1, 2011.

Response: We appreciate the commenter's support of our effort to streamline the volume decrease adjustment determination process by eliminating the core staffing adjustment. However, we disagree with the suggestion to apply this change retroactively. As noted earlier, the IPPS is a prospective system and we generally make changes effectively prospectively. The absence of updated core staffing data does not undermine the policy that we expressly indicated in prior rulemaking. Therefore, we do not see any compelling reason to apply this change retrospectively.

Comment: Some commenters addressed areas of volume decrease adjustment policy for which we did not propose any changes. These included waiving the requirement for hospitals to demonstrate that the decrease in discharges was beyond the hospital's control; to no longer require the removal of variable costs and calculate the volume decrease adjustment by subtracting the MS–DRG payment from total inpatient costs; shortening the timeline in which MACs need to make volume decrease adjustment determinations; and stopping MACs from rejecting requests for volume decrease adjustments before an NPR is issued.

Response: We appreciate the commenters' concerns. However, because we did not make any proposals related to these specific policy areas and we consider these comments to be out of the scope of the proposed rule, we are not addressing them in this final rule.

After consideration of the public comments we received, we are finalizing our policies as proposed, with one modification to our proposed amendment to § 412.92(e)(3) to reflect these policies. We are finalizing our proposal to prospectively require that the MACs compare Medicare revenue allocable to fixed costs from the cost reporting period in which the hospital experienced the volume decrease to the hospital's fixed costs from that same cost reporting period when calculating a volume decrease adjustment and that the cap will no longer be applied to the volume decrease adjustment calculation methodology. We proposed to revise the regulations at § 412.92(e)(3) to reflect these changes. However, our proposed regulatory text did not precisely capture the new calculation methodology that we described in the preamble to the proposed rule, and which we are now finalizing, in one respect. Specifically,

the preamble to the proposed rule stated that, under the proposed change in the MAC's calculation of the volume decrease adjustment, ''in order to estimate the fixed portion of the Medicare revenue, the MACs would apply *the ratio of the hospital's fixed costs to total costs* in the cost reporting period when it experienced the volume decrease to the hospital's total Medicare revenue in that same cost reporting period'' (82 FR 19934). By contrast, the proposed regulatory text in the proposed rule stated that the ratio to be applied by the MAC would be ''the ratio of the hospital's fixed Medicare inpatient operating costs to its total Medicare inpatient operating costs'' (82 FR 20161). Therefore, consistent with the proposed policy which we are now finalizing, we are deleting the two instances of the words ''Medicare'' that appear in the clause quoted in the preceding sentence. Accordingly, as finalized, the second sentence of § 412.92(e)(3) specifies that, effective for cost reporting periods beginning on or after October 1, 2017, the MAC determines a lump sum adjustment amount equal to the difference between the hospital's fixed Medicare inpatient operating costs and the hospital's total MS–DRG revenue based on MS–DRG-adjusted prospective payment rates for inpatient operating costs (including outlier payments for inpatient operating costs determined under subpart F of Part 412 and additional payments made for inpatient operating costs for hospitals that serve a disproportionate share of low-income patients as determined under § 412.106 and for indirect medical education costs as determined under § 412.105) multiplied by the ratio of the hospital's fixed inpatient operating costs to its total inpatient operating costs. We also are finalizing our proposal to prospectively modify the volume decrease adjustment process to no longer require that a hospital explicitly demonstrate that it appropriately adjusted the number of staff in inpatient areas of the hospital based on the decrease in the number of inpatient days and to no longer require the MAC to adjust the volume decrease adjustment payment amount for excess staffing. These changes will be effective for cost reporting periods beginning on or after October 1, 2017. As we noted earlier, we proposed that if the MDH program ends up being extended by law, similar to how it was extended by section 205 of the MACRA (Pub. L. 114–10) and prior legislation, these changes to the volume decrease adjustment methodology and the amendment to § 412.92(e)(3) for SCHs would also be made to the parallel requirements for MDHs under § 412.108(d)(3). To that end, we are modifying the regulations at § 412.108(d)(3) by modifying the introductory paragraph to cross-reference the requirements found at § 412.92(e)(3). This will allow for consistency in the regulations governing volume decrease adjustments should the MDH program be extended.

D. Rural Referral Centers (RRCs) Annual Updates to Case-Mix Index and Discharge Criteria (§ 412.96)

Under the authority of section 1886(d)(5)(C)(i) of the Act, the regulations at § 412.96 set forth the criteria that a hospital must meet in order to qualify under the IPPS as a rural referral center (RRC). RRCs receive some special treatment under both the DSH payment adjustment and the criteria for geographic reclassification.

Section 402 of Public Law 108–173 raised the DSH payment adjustment for RRCs such that they are not subject to the 12-percent cap on DSH payments that is applicable to other rural hospitals. RRCs also are not subject to the proximity criteria when applying for geographic reclassification. In addition, they do not have to meet the requirement that a hospital's average hourly wage must exceed, by a certain percentage, the average hourly wage of the labor market area in which the hospital is located.

Section 4202(b) of Public Law 105–33 states, in part, that any hospital classified as an RRC by the Secretary for FY 1991 shall be classified as such an RRC for FY 1998 and each subsequent fiscal year. In the August 29, 1997 IPPS final rule with comment period (62 FR 45999), we reinstated RRC status for all hospitals that lost that status due to triennial review or MGCRB reclassification. However, we did not reinstate the status of hospitals that lost RRC status because they were now urban for all purposes because of the OMB designation of their geographic area as urban. Subsequently, in the August 1, 2000 IPPS final rule (65 FR 47089), we indicated that we were revisiting that decision. Specifically, we stated that we would permit hospitals that previously qualified as an RRC and lost their status due to OMB redesignation of the county in which they are located from rural to urban, to be reinstated as an RRC. Otherwise, a hospital seeking RRC status must satisfy all of the other applicable criteria. We use the definitions of ''urban'' and ''rural'' specified in Subpart D of 42 CFR part 412. One of the criteria under which a hospital may qualify as an RRC is to have 275 or more beds available for use (§ 412.96(b)(1)(ii)). A rural hospital that does not meet the bed size requirement can qualify as an RRC if the hospital meets two mandatory prerequisites (a minimum case-mix index (CMI) and a minimum number of discharges), and at least one of three optional criteria (relating to specialty composition of medical staff, source of inpatients, or referral volume). (We refer readers to § 412.96(c)(1) through (c)(5) and the September 30, 1988 **Federal Register** (53 FR 38513) for additional discussion.) With respect to the two mandatory prerequisites, a hospital may be classified as an RRC if—

- The hospital's CMI is at least equal to the lower of the median CMI for urban hospitals in its census region, excluding hospitals with approved teaching programs, or the median CMI for all urban hospitals nationally; and
- The hospital's number of discharges is at least 5,000 per year, or, if fewer, the median number of discharges for urban hospitals in the census region in which the hospital is located. The number of discharges criterion for an osteopathic hospital is at least 3,000 discharges per year, as specified in section 1886(d)(5)(C)(i) of the Act.

1. Case-Mix Index (CMI)

Section 412.96(c)(1) provides that CMS establish updated national and regional CMI values in each year's annual notice of prospective payment rates for purposes of determining RRC status. The methodology we used to determine the national and regional CMI values is set forth in the regulations at § 412.96(c)(1)(ii). The national median CMI value for FY 2018 is based on the CMI values of all urban hospitals nationwide, and the regional median CMI values for FY 2018 are based on the CMI values of all urban hospitals within each census region, excluding those hospitals with approved teaching programs (that is, those hospitals that train residents in an approved GME program as provided in § 413.75). These values are based on discharges occurring during FY 2016 (October 1, 2015 through September 30, 2016), and include bills posted to CMS' records through March 2016.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19936), we proposed that, in addition to meeting other criteria, if rural hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2017, they must have a CMI value for FY 2016 that is at least—

- 1.6635 (national—all urban); or
- The median CMI value (not transfer-adjusted) for urban hospitals

(excluding hospitals with approved teaching programs as identified in § 413.75) calculated by CMS for the census region in which the hospital is located.

The proposed median CMI values by region were set forth in the proposed rule (82 FR 19936). We stated in the proposed rule that we intended to update these proposed CMI values in the FY 2018 final rule to reflect the updated FY 2016 MedPAR file, which will contain data from additional bills received through March 2017. We did not receive any public comments on our proposal. Based on the latest available data (FY 2016 bills received through March 2017), in addition to meeting other criteria, if rural hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2017, they must have a CMI value for FY 2016 that is at least—

- 1.6638 (national—all urban); or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 413.75) calculated by CMS for the census region in which the hospital is located.

The final CMI values by region are set forth in the table below:

Region	Case-mix index value
1. New England (CT, ME, MA, NH, RI, VT)	1.4192
2. Middle Atlantic (PA, NJ, NY)	1.5133
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.5405
4. East North Central (IL, IN, MI, OH, WI)	1.5896
5. East South Central (AL, KY, MS, TN)	1.5086
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.6344
7. West South Central (AR, LA, OK, TX)	1.6950
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.7580
9. Pacific (AK, CA, HI, OR, WA)	1.6473

A hospital seeking to qualify as an RRC should obtain its hospital-specific CMI value (not transfer-adjusted) from its MAC. Data are available on the Provider Statistical and Reimbursement (PS&R) System. In keeping with our policy on discharges, the CMI values are computed based on all Medicare patient discharges subject to the IPPS MS–DRG-based payment.

2. Discharges

Section 412.96(c)(2)(i) provides that CMS set forth the national and regional numbers of discharges criteria in each year's annual notice of prospective payment rates for purposes of determining RRC status. As specified in section 1886(d)(5)(C)(ii) of the Act, the national standard is set at 5,000 discharges. In the FY 2018 IPPS/LTCH PPS proposed rule, for FY 2018, we proposed to update the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2015 (that is, October 1, 2014 through September 30, 2015), which were the latest cost report data available at the time this proposed rule was developed. Therefore, we proposed that, in addition to meeting other criteria, a hospital, if it is to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2017, must have, as the number of discharges for its cost reporting period that began during FY 2015, at least—

- 5,000 (3,000 for an osteopathic hospital); or
- The median number of discharges for urban hospitals in the census region in which the hospital is located. (We refer readers to the table set forth in the FY 2018 IPPS/LTCH PPS proposed rule at 82 FR 19936.) In the proposed rule, we stated that we intended to update these numbers in the FY 2018 final rule based on the latest available cost report data.

We did not receive any public comments on our proposal.

Based on the latest discharge data available at this time, that is, for cost reporting periods that began during FY 2015, the final median number of discharges for urban hospitals by census region are set forth in the following table.

Region	Number of discharges
1. New England (CT, ME, MA, NH, RI, VT)	8,080
2. Middle Atlantic (PA, NJ, NY)	9,988
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	10,552
4. East North Central (IL, IN, MI, OH, WI)	8,181
5. East South Central (AL, KY, MS, TN)	8,647
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	7,709
7. West South Central (AR, LA, OK, TX)	5,325
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	8,735
9. Pacific (AK, CA, HI, OR, WA)	9,101

We note that the median number of discharges for hospitals in each census region is greater than the national standard of 5,000 discharges. Therefore, under this final rule, 5,000 discharges is the minimum criterion for all hospitals, except for osteopathic hospitals for which the minimum criterion is 3,000 discharges.

E. Payment Adjustment for Low-Volume Hospitals (§ 412.101)

1. Expiration of Temporary Changes to Low-Volume Hospital Payment Policy

Under section 1886(d)(12) of the Act, as amended, most recently by section 204 of the Medicare Access and CHIP

Reauthorization Act of 2015 (MACRA), Public Law 114–10, the temporary changes in the low-volume hospital payment policy originally provided by the Affordable Care Act and extended through subsequent legislation are effective through FY 2017. Beginning with FY 2018, the preexisting low-volume hospital payment adjustment and qualifying criteria, as implemented in FY 2005 and discussed later in this section, will resume. We discuss the payment policies for FY 2018 in section V.E.3. of the preamble of this final rule.

2. Background

Section 1886(d)(12) of the Act, as added by section 406(a) of Public Law 108–173, provides for a payment adjustment to account for the higher costs per discharge for low-volume hospitals under the IPPS, effective beginning FY 2005. Sections 3125 and 10314 of the Affordable Care Act amended section 1886(d)(12) of the Act by modifying the definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals, effective only for discharges occurring during FYs 2011 and 2012. Specifically, the provisions of the Affordable Care Act amended the qualifying criteria for low-volume hospitals to specify, for FYs 2011 and 2012, that a hospital qualifies as a low-volume hospital if it is more than 15 road miles from another subsection (d) hospital and has less than 1,600 discharges of individuals entitled to, or enrolled for, benefits under Medicare Part A during the fiscal year. In addition, the statute, as amended by the Affordable Care Act, provides that the low-volume hospital payment adjustment (that is, the percentage increase) is determined using a continuous linear sliding scale ranging from 25 percent for low-volume hospitals with 200 or fewer discharges of individuals entitled to, or enrolled for, benefits under Medicare Part A in the fiscal year to 0 percent for low-volume hospitals with greater than 1,600 discharges of such individuals in the fiscal year. The temporary changes to the low-volume hospital qualifying criteria and the payment adjustment originally provided by the Affordable Care Act were extended by subsequent legislation, most recently through FY 2017 by section 204 of the MACRA. (We refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56941 through 59943) for a detailed summary of the applicable legislation.) Under current law, beginning with FY 2018, the preexisting low-volume hospital qualifying criteria and payment adjustment, as implemented in FY 2005 and described in this section, will resume. The regulations implementing the low-volume hospital adjustment provided by section 1886(d)(12) of the Act are located at 42 CFR 412.101.

The additional payment adjustment to a low-volume hospital provided for under section 1886(d)(12) of the Act is in addition to any payment calculated under this section. Therefore, the additional payment adjustment is based on the per discharge amount paid to the qualifying hospital under section 1886 of the Act. In other words, the low-volume add-on payment amount is based on total per discharge payments made under section 1886 of the Act, including capital, DSH, IME, and outliers. For hospitals paid based on the hospital-specific rate, the low-volume add-on payment amount is based on either the Federal rate or the hospital-specific rate, whichever results in a greater operating IPPS payment.

Section 1886(d)(12)(C)(i) of the Act defines a low-volume hospital, for fiscal years other than FYs 2011 through 2017, as a subsection (d) hospital (as defined in paragraph (1)(B)) that the Secretary determines is located more than 25 road miles from another subsection (d) hospital and that has less than 800 discharges during the fiscal year. Section 1886(d)(12)(C)(ii) of the Act further stipulates that the term ''discharge'' means an inpatient acute care discharge of an individual, regardless of whether the individual is entitled to benefits under Medicare Part A. Therefore, for fiscal years other than FYs 2011 through 2017, the term ''discharge'' refers to total discharges, regardless of payer (that is, not only Medicare discharges). Furthermore, section 1886(d)(12)(B) of the Act requires, for discharges occurring in FYs 2005 through 2010 and FY 2018 and subsequent years, that the Secretary determine an applicable percentage increase for these low-volume hospitals based on the ''empirical relationship'' between the standardized cost-per-case for such hospitals and the total number of discharges of such hospitals and the amount of the additional incremental costs (if any) that are associated with such number of discharges. The statute thus mandates that the Secretary develop an empirically justifiable adjustment based on the relationship between costs and discharges for these low-volume hospitals. Section 1886(d)(12)(B)(iii) of the Act limits the applicable percentage increase adjustment to no more than 25 percent.

Based on an analysis we conducted for the FY 2005 IPPS final rule (69 FR 49099 through 49102), a 25-percent low-volume adjustment to all qualifying hospitals with less than 200 discharges was found to be most consistent with the statutory requirement to provide relief to low-volume hospitals where there is empirical evidence that higher incremental costs are associated with low numbers of total discharges. In the FY 2006 IPPS final rule (70 FR 47432 through 47434), we stated that multivariate analyses supported the existing low-volume adjustment implemented in FY 2005.

3. Payment Adjustment for FY 2018 and Subsequent Fiscal Years

In accordance with section 1886(d)(12) of the Act, beginning with FY 2018, the low-volume hospital definition and payment adjustment methodology will revert back to the statutory requirements that were in effect prior to the amendments made by the Affordable Care Act and extended by subsequent legislation. Therefore, effective for FY 2018 and subsequent years, in order to qualify as a low-volume hospital, a subsection (d) hospital must be more than 25 road miles from another subsection (d) hospital and have less than 200 discharges (that is, less than 200 discharges total, including both Medicare and non-Medicare discharges) during the fiscal year. As discussed earlier, the statute specifies that a low-volume hospital must have less than 800 discharges during the fiscal year. However, as required by section 1886(d)(12)(B)(i) of the Act and as discussed earlier, the Secretary has developed an empirically justifiable payment adjustment based on the relationship, for IPPS hospitals with less than 800 discharges, between the additional incremental costs (if any) that are associated with a particular number of discharges. Based on an analysis we conducted for the FY 2005 IPPS final rule (69 FR 49099 through 49102), a 25-percent low-volume adjustment to all qualifying hospitals with less than 200 discharges was found to be most consistent with the statutory requirement to provide relief for low-volume hospitals where there is empirical evidence that higher incremental costs are associated with low numbers of total discharges. (Under the policy we established in that same final rule, hospitals with between 200 and 799 discharges do not receive a low-volume hospital adjustment.)

As described earlier, for FYs 2005 through 2010 and FY 2018 and subsequent years, the discharge determination is made based on the hospital's number of total discharges, that is, Medicare and non-Medicare discharges. The hospital's most recently

submitted cost report is used to determine if the hospital meets the discharge criterion to receive the low-volume payment adjustment in the current year (§ 412.101(b)(2)(i)). We use cost report data to determine if a hospital meets the discharge criterion because this is the best available data source that includes information on both Medicare and non-Medicare discharges. We note that, for FYs 2011 through 2017, we used the most recently available MedPAR data to determine the hospital's Medicare discharges because only Medicare discharges were used to determine if a hospital met the discharge criterion for those years.

For FY 2018 and for subsequent fiscal years, in addition to a discharge criterion, the eligibility for the low-volume payment adjustment is also dependent upon the hospital meeting the mileage criterion specified at § 412.101(b)(2)(i). Specifically, to meet the mileage criterion to qualify for the low-volume payment adjustment for FY 2018 and subsequent fiscal years, a hospital must be located more than 25 road miles from the nearest subsection (d) hospital. We define, at § 412.101(a), the term ''road miles'' to mean ''miles'' as defined at § 412.92(c)(1) (75 FR 50238 through 50275 and 50414).

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50275 and 50414) and subsequent rulemaking, most recently in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56942 through 56943), we discussed the process for requesting and obtaining the low-volume hospital payment adjustment. In order to qualify for the low-volume hospital payment adjustment, a hospital must provide to its MAC sufficient evidence to document that it meets the discharge and distance requirements. The MAC will determine, based on the most recent data available, if the hospital qualifies as a low-volume hospital, so that the hospital will know in advance whether or not it will receive a payment adjustment. The MAC and CMS may review available data, in addition to the data the hospital submits with its request for low-volume hospital status, in order to determine whether or not the hospital meets the qualifying criteria.

In order to receive a low-volume hospital payment adjustment under § 412.101, a hospital must notify and provide documentation to its MAC that it meets the mileage criterion. The use of a Web-based mapping tool as part of documenting that the hospital meets the mileage criterion for low-volume hospitals is acceptable. The MAC will determine if the information submitted by the hospital, such as the name and street address of the nearest hospitals, location on a map, and distance (in road miles, as defined in the regulations at § 412.101(a)) from the hospital requesting low-volume hospital status, is sufficient to document that it meets the mileage criterion. If not, the MAC will follow up with the hospital to obtain additional necessary information to determine whether or not the hospital meets the low-volume mileage criterion. In addition, the MAC will refer to the hospital's most recently submitted cost report to determine whether or not the hospital meets the discharge criterion. A hospital should refer to its most recently submitted cost report for total discharges (Medicare and non-Medicare) in order to decide whether or not to apply for low-volume hospital status for a particular fiscal year. A hospital must continue to meet the qualifying criteria at § 412.101(b)(2)(i) as a low-volume hospital (that is, the discharge criterion and the mileage criterion) in order to receive the payment adjustment in that year; that is, low-volume hospital status is not based on a ''one-time'' qualification (75 FR 50238 through 50275).

As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19938), in order to be a low-volume hospital in FY 2018 and subsequent fiscal years, in accordance with our previously established procedure, a hospital must make a written request for low-volume hospital status that is received by its MAC by September 1 immediately preceding the start of the Federal fiscal year for which the hospital is applying for low-volume hospital status in order for the 25-percent, low-volume, add-on payment adjustment to be applied to payments for its discharges for the fiscal year beginning on or after October 1 immediately following the request (that is, the start of the Federal fiscal year). For a hospital whose request for low-volume hospital status is received after September 1, if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC will apply the 25-percent, low-volume, add-on payment adjustment to determine payment for the hospital's discharges for the fiscal year, effective prospectively within 30 days of the date of the MAC's low-volume status determination.

Specifically, for FY 2018, a hospital must make a written request for low-volume hospital status that is received by its MAC no later than September 1, 2017, in order for the 25-percent, low-volume, add-on payment adjustment to be applied to payments for its discharges beginning on or after October 1, 2017 (through September 30, 2018). Under this procedure, a hospital that qualified for the low-volume hospital payment adjustment for FY 2017 may continue to receive a low-volume hospital payment adjustment for FY 2018 without reapplying if it meets both the discharge criterion and the mileage criterion applicable for FY 2018. As in previous years, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19938), we proposed that such a hospital must send written verification that is received by its MAC no later than September 1, 2017, stating that it meets the mileage criterion applicable for FY 2018. For FY 2018, we further proposed that this written verification must also state, based upon the most recently submitted cost report, that the hospital meets the discharge criterion applicable for FY 2018 (that is, less than 200 discharges total, including both Medicare and non-Medicare discharges). If a hospital's request for low-volume hospital status for FY 2018 is received after September 1, 2017, and if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC will apply the 25-percent, low-volume, add-on payment adjustment to determine the payment for the hospital's FY 2018 discharges, effective prospectively within 30 days of the date of the MAC's low-volume hospital status determination. We noted that this process mirrors our established application process but is updated to ensure that providers currently receiving the low-volume hospital payment adjustment verify that they meet both the mileage criterion and the discharge criterion applicable for FY 2018 to continue receiving the adjustment for FY 2018. For additional information on our established application process for the low-volume hospital payment adjustment, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56942 through 56943).

Comment: A few commenters expressed concern about the financial impact of the expiration of the temporary changes to the low-volume hospital payment adjustment provided for by the Affordable Care Act and extended through subsequent legislation (most recently the MACRA). Some commenters supported legislative action that would make permanent these changes to the low-volume hospital payment adjustment. Other commenters requested that CMS use the existing statutory authority to make the low-volume adjustment to qualifying hospitals that have less than 800 total discharges rather than only to qualifying hospitals that have less than 200 total discharges. These commenters did not provide any data analysis in support of

their comments to expand the low-volume hospital adjustment to qualifying hospitals that have less than 800 total discharges.

One commenter questioned whether CMS would be making any claims processing or cost report changes in light of the expiration of the temporary changes to the low-volume hospital payment adjustment.

Response: As noted earlier in the preamble of this final rule and as discussed in response to public comments in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53408 through 53409) and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50612 through 50613), to implement the original low-volume hospital payment adjustment provision, and as mandated by statute, we developed an empirically justified adjustment based on the relationship between costs and total discharges of hospitals with less than 800 total (Medicare and non-Medicare) discharges. Specifically, we performed several regression analyses to evaluate the relationship between hospitals' costs per case and discharges, and found that an adjustment for hospitals with less than 200 total discharges is most consistent with the statutory requirement to provide for additional payments to low-volume hospitals where there is empirical evidence that higher incremental costs are associated with lower numbers of discharges (69 FR 49101 through 49102). Based on these analyses, we established a low-volume hospital policy under which qualifying hospitals with less than 200 total discharges receive a payment adjustment of an additional 25 percent. (Section 1886(d)(12)(B)(iii) of the Act limits the applicable percentage increase adjustment to no more than 25 percent.) In the future, we may reevaluate the low-volume hospital adjustment policy; that is, the definition of a low-volume hospital and the payment adjustment. However, because we are not aware of any analysis or empirical evidence that would support expanding the originally established a low-volume hospital adjustment policy, we did not make any proposals regarding the low-volume hospital payment adjustment for FY 2018 and are not making any changes to the low-volume hospital payment adjustment policy in this final rule.

Therefore, the low-volume hospital definition and payment adjustment methodology will revert back to the policy established under statutory requirements that were in effect prior to the amendments made by the Affordable Care Act and extended through subsequent legislation (most recently the MACRA).

With regard to the comment regarding revisions to claims processing or the cost report, any such changes will be addressed through subregulatory guidance or other avenues, as appropriate.

After consideration of the public comments we received, we are finalizing our proposals as described above, without modification.

As described earlier, for FYs 2005 through 2010 and FY 2018 and subsequent fiscal years, the discharge determination will be made based on the hospital's number of total discharges; that is, Medicare and non-Medicare discharges. The hospital's most recently submitted cost report is used to determine if the hospital meets the discharge criterion to receive the low-volume hospital payment adjustment in the current year (§ 412.101(b)(2)(i)). We use cost report data to determine if a hospital meets the discharge criterion because this is the best available data source that includes information on both Medicare and non-Medicare discharges. As we noted in the proposed rule, for FYs 2011 through 2017, we used the most recently available MedPAR data to determine the hospital's Medicare discharges because only Medicare discharges were used to determine if a hospital met the discharge criterion for those years. In addition to a discharge criterion, the eligibility for the low-volume hospital payment adjustment also will be dependent upon the hospital meeting the mileage criterion specified at § 412.101(b)(2)(i). Specifically, to meet the mileage criterion to qualify for the low-volume hospital payment adjustment for FY 2018 and subsequent fiscal years, a hospital must be located more than 25 road miles from the nearest subsection (d) hospital.

For FY 2018, as discussed in the proposed rule, we will continue to use the established process for requesting and obtaining the low-volume hospital payment adjustment. That is, in order to receive a low-volume hospital payment adjustment under § 412.101, a hospital must notify and provide documentation to its MAC that it meets the discharge and distance requirements. The MAC will determine, based on the most recent data available, if the hospital qualifies as a low-volume hospital, so that the hospital will know in advance whether or not it will receive a payment adjustment. The MAC and CMS may review available data, in addition to the data the hospital submits with its request for low-volume hospital status, in order to determine whether or not the hospital meets the qualifying criteria. (For additional details on our established process for the low-volume hospital payment adjustment, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56942 through 56943).)

Consistent with our previously established procedure, for FY 2018, a hospital must make a written request for low-volume hospital status that is received by its MAC no later than September 1, 2017, in order for the 25-percent low-volume hospital payment adjustment to be applied to payments for its discharges beginning on or after October 1, 2017 (through September 30, 2018). Under this procedure, a hospital that qualified for the low-volume hospital payment adjustment for FY 2017 may continue to receive a low-volume hospital payment adjustment for FY 2018 without reapplying if it meets both the discharge criterion and the mileage criterion applicable for FY 2018. As in previous years, such a hospital must send written verification that is received by its MAC no later than September 1, 2017, stating that it meets the mileage criterion applicable for FY 2018. In addition, for such a hospital, this written verification must also state, based upon the most recently submitted cost report, that the hospital meets the discharge criterion applicable for FY 2018 (that is, less than 200 discharges total, including both Medicare and non-Medicare discharges). If a hospital's request for low-volume hospital status for FY 2018 is received after September 1, 2017, and if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC will apply the 25-percent low-volume hospital payment adjustment to determine the payment for the hospital's FY 2018 discharges, effective prospectively within 30 days of the date of the MAC's low-volume hospital status determination.

In the FY 2016 IPPS interim final rule with comment period (80 FR 49594 through 49597 and 49767), we made conforming changes to the regulations at 42 CFR 412.101 to reflect the extension of the changes to the qualifying criteria and the payment adjustment methodology for low-volume hospitals through FY 2017 in accordance with section 204 of the MACRA. Under these revisions, beginning with FY 2018, consistent with current law, the low-volume hospital qualifying criteria and payment adjustment methodology will return to the criteria and methodology that were in effect prior to the amendments made by the Affordable Care Act (that is, the low-volume hospital payment policy in effect for FYs 2005 through 2010). Therefore, no

further revisions to the policy or to the regulations at § 412.101 are required to conform them to the statutory requirement that the low-volume hospital policy in effect prior to the Affordable Care Act will again be in effect for FY 2018 and subsequent years.

As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19938), for this reason, we did not propose specific amendments to the regulations at § 412.101 to reflect the expiration of the temporary changes to the low-volume hospital payment adjustment policy originally provided for by the Affordable Care Act, but we proposed that if these temporary changes to the low-volume hospital payment policy were to be extended by law, similar to extensions provided most recently through FY 2017 by MACRA, we would make conforming changes to the regulations at § 412.101(b) through (d), as appropriate, to reflect any such extension. Because, as of the time of the development of this final rule, these temporary changes to the low-volume hospital payment policy have not been extended by law, we are not making any such conforming changes. As noted previously, any changes to the cost report will be addressed through subregulatory guidance or other avenues, as appropriate.

4. Parallel Low-Volume Hospital Payment Adjustment Regarding Hospitals Operated by the Indian Health Services (IHS) or a Tribe

As previously stated, section 1886(d)(12)(C) of the Act and our regulations at 42 CFR 412.101(b)(2) require that, in order to qualify for the low-volume hospital payment adjustment, a hospital must be located more than a specified number of miles from the nearest subsection (d) hospital (referred to as the mileage criterion). Section 1886(d)(1)(B) of the Act defines a ''subsection (d) hospital'' as a hospital located in one of the 50 States or District of Columbia, other than the specified excluded types of hospitals. As stated in prior rulemaking (for example, 79 FR 50153 (August 22, 2014), 78 FR 61194 and 61196 (October 3, 2013), 78 FR 50710 (August 19, 2013), 78 FR 27623 (May 10, 2013), 77 FR 53397 (August 31, 2012), 77 FR 27965 (May 11, 2012), 75 FR 50307 (August 16, 2010)), CMS considers IHS and Tribal hospitals to be subsection (d) hospitals. However, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19939), we stated that, given the unique nature of IHS and Tribal hospitals and the populations they serve, as discussed below, we believe it would be appropriate to provide additional flexibility in determining eligibility for the low-volume hospital payment adjustment for IHS and Tribal hospitals and non-IHS hospitals that are located less than the specified mileage from one another. Specifically, we proposed that, for an IHS or Tribal hospital, only its proximity to other IHS or Tribal hospitals would be used to determine if the mileage criterion is met. Similarly, for a non-IHS hospital, only its proximity to other non-IHS hospitals would be used to determine if the mileage criterion is met.

Except for emergencies and a few other limited special cases, those individuals who are not members of a federally recognized Tribe are not eligible for treatment at IHS or Tribal hospitals. Therefore, such a hospital is not a valid option for the general Medicare population, including local residents who are not members of a federally recognized Tribe or not otherwise eligible for IHS services. Therefore, we stated that we believe it would be appropriate to not consider IHS and Tribal hospitals when evaluating whether a non-IHS hospital meets the mileage criterion.

Likewise, we stated that we believe it would be appropriate to not consider non-IHS hospitals when evaluating whether an IHS or Tribal hospital meets the mileage criterion. The principal mission of the IHS is the provision of health care to American Indians and Alaska Natives throughout the United States. In carrying out that mission, IHS operates under two primary authorizing statutes. The first statute, the Snyder Act, authorizes IHS to expend such moneys as Congress may determine from time to time appropriate for the conservation of the health of American Indians or Alaska Natives. We refer readers to 25 U.S.C. 13 (providing that the Bureau of Indian Affairs (BIA) will expend funds as appropriated for, among other things, the conservation of health of American Indians and Alaska Natives); and 42 U.S.C. 2001(a) (transferring the responsibility for American Indian and Alaska Native health care from BIA to HHS). The second statute, the Indian Health Care Improvement Act (IHCIA), established IHS as an agency within the Public Health Service of HHS and provides authority for numerous programs to address particular health initiatives for American Indians and Alaska Natives, such as alcohol and substance abuse and diabetes (25 U.S.C. 1601 *et seq.*).

IHS and Tribal hospitals are charged with addressing the health of American Indians and Alaska Natives and are uniquely situated to provide services to this population. For this reason, we stated that we believe it would be appropriate to not consider the non-IHS hospitals when evaluating whether an IHS or Tribal hospital meets the mileage criterion.

Because IHS and Tribal hospitals are subsection (d) hospitals, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19339), we proposed to use our authority under section 1886(d)(5)(I)(i) of the Act to provide an adjustment equal to the applicable low-volume adjustment provided for under section 1886(d)(12) of the Act for an IHS or Tribal hospital whose sole disqualifier for the low-volume hospital adjustment is its proximity to a non-IHS hospital, and for a non-IHS hospital whose sole disqualifier is its proximity to an IHS or Tribal hospital. Such an adjustment would provide that, practically speaking, an IHS or Tribal hospital would be able to receive a low-volume hospital adjustment based on its distance to the nearest IHS or Tribal hospital, and a non-IHS hospital would be able to qualify to receive a low-volume hospital adjustment based on its distance to the nearest non-IHS hospital. We believe it is appropriate to apply this authority here, given the unique characteristics of IHS and Tribal hospitals, as discussed above. To implement this proposed adjustment, we proposed to revise 42 CFR 412.101 by adding paragraph (e) to provide that, for discharges occurring in FY 2018 and subsequent years, only the distance between IHS or Tribal hospitals would be considered when assessing whether an IHS or Tribal hospital meets the mileage criterion under § 412.101(b)(2). Similarly, only the distance between non-IHS hospitals would be considered when assessing whether a non-IHS hospital meets the mileage criterion under § 412.101(b)(2).

Comment: Commenters supported the proposed parallel adjustment so that, for discharges occurring in FY 2018 and subsequent years, only the distance between IHS or Tribal hospitals would be considered when assessing whether an IHS or Tribal hospital meets the mileage criterion under § 412.101(b)(2), and similarly, only the distance between non-IHS hospitals would be considered when assessing whether a non-IHS hospital meets the mileage criterion under § 412.101(b)(2). Several commenters urged CMS to apply this proposal retroactively as, according to some commenters, they did not believe CMS has always considered IHS and Tribal hospitals to be subsection (d) hospitals for purposes of the low-volume payment adjustment, while other commenters believed that IHS and Tribal hospitals are not ''like'' hospitals. Some commenters asked CMS to state in

its final rule that the proposed addition of paragraph (e) to § 412.101 is a codification and clarification of existing policy regarding dissimilar hospitals, and that under that policy it is proper to approve a low-volume hospital adjustment to a hospital despite its proximity to an IHS or Tribal hospital. In general, commenters pointed to one or more of the following reasons in support of their assertion that the proposed rule is a codification and clarification of existing policy rather than a new policy: (1) Published CMS and MAC guidance that commenters claim has provided for a ''like hospital'' standard since the implementation of the adjustment (for example, Transmittal 1347, Change Request 8627 (February 14, 2014)); (2) a hospital that is within 15 miles of an IHS hospital and also has sole community hospital status indicates that such hospitals and IHS facilities are not ''like hospitals''; (3) assertions that some MACs had, at times for some cost reporting periods (or portions thereof), allowed non-IHS hospitals whose sole disqualifier was proximity to an IHS or Tribal hospital to receive a low-volume hospital adjustment; and (4) two Departmental Appeals Board decisions for cases which involved CAH designation not eligibility for a low-volume hospital adjustment (*Cibola General Hospital,* DAB No. 2387 (2011) and *La Paz Regional Hospital,* DAB CR 2883 (2013)), that commenters asserted found that ''IHS facilities should be disregarded in determining a hospital's eligibility for Medicare program classifications that are based on proximity to other Medicare hospitals.''

Response: We appreciate the commenters' support of our proposal. Because we have consistently considered IHS and Tribal hospitals to be subsection (d) hospitals, as noted in the preambles of the above cited rules, we believe it is inappropriate to apply this parallel adjustment retroactively. While CMS may have in certain instances used terms such as ''like'' in place of ''subsection (d)'' when issuing subregulatory guidance for the low-volume hospital adjustment and there may have been inconsistencies in low-volume hospital adjustment determinations made by some contractors, these factors do not establish agency policy or bind the agency. Indeed, CMS' regulations at § 412.101(b)(2) clearly refer to the proximity to the nearest subsection (d) hospital, consistent with section 1886(d)(12)(C)(i) of the Act, but neither the statutory nor the regulatory provisions that govern the low-volume hospital adjustment refer to a ''like'' hospital standard. The SCH regulations at § 412.92(a), by comparison, expressly refer to proximity to a ''like'' hospital (as defined at § 412.92(c)(2)), consistent with section 1886(d)(5)(D)(iii) of the Act.

Moreover, the DAB decisions cited by the commenters concerned the certification of a hospital for CAH status, not the requirements for determining proximity to a subsection (d) hospital for purposes of the low-volume hospital payment adjustment. To the extent that these decisions could be interpreted to mean that the DAB has held that IHS hospitals may not, by implication, be subsection (d) hospitals, we reiterate that CMS has a longstanding policy of considering IHS and Tribal hospitals to be subsection (d) hospitals (as noted in the preambles to the rules cited above). As a result, we believe that it is necessary to amend the regulation governing the low-volume hospital payment adjustment in order to provide flexibility in determining eligibility for the adjustment. Therefore, after consideration of the public comments we received, we are finalizing this proposal, including our proposed revisions to 42 CFR 412.101, without modification.

F. Indirect Medical Education (IME) Payment Adjustment Factor for FY 2018 (§ 412.105)

Under the IPPS, an additional payment amount is made to hospitals with residents in an approved graduate medical education (GME) program in order to reflect the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The payment amount is determined by use of a statutorily specified adjustment factor. The regulations regarding the calculation of this additional payment, known as the IME adjustment, are located at § 412.105. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51680) for a full discussion of the IME adjustment and IME adjustment factor. Section 1886(d)(5)(B)(ii)(XII) of the Act provides that, for discharges occurring during FY 2008 and fiscal years thereafter, the IME formula multiplier is 1.35. Accordingly, in the FY 2018 IPPS/LTH PPS proposed rule (82 FR 19940), we stated that, for discharges occurring during FY 2018, the formula multiplier is 1.35. We estimate that application of this formula multiplier for the FY 2018 IME adjustment will result in an increase in IPPS payment of 5.5 percent for every approximately 10 percent increase in the hospital's resident-to-bed ratio.

Comment: One commenter stated that it appreciated that the resident-to-bed ratio is statutorily required for purposes of calculating the IME adjustment. The commenter requested that, in order to respond to physician shortages, policymakers provide additional funding to train future physicians and urged CMS to consider additional funding that would supplement the current IME adjustment factor.

Response: We appreciate the commenter's comment. As noted above, the IME adjustment factor is statutory and the calculation of the IME payment is also specified in statute. Accordingly, for discharges occurring during FY 2018, the formula multiplier is 1.35.

G. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2018 (§ 412.106)

1. General Discussion

Section 1886(d)(5)(F) of the Act provides for additional Medicare payments to subsection (d) hospitals that serve a significantly disproportionate number of low-income patients. The Act specifies two methods by which a hospital may qualify for the Medicare disproportionate share hospital (DSH) adjustment. Under the first method, hospitals that are located in an urban area and have 100 or more beds may receive a Medicare DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to needy patients with low incomes. This method is commonly referred to as the ''Pickle method.'' The second method for qualifying for the DSH payment adjustment, which is the most common, is based on a complex statutory formula under which the DSH payment adjustment is based on the hospital's geographic designation, the number of beds in the hospital, and the level of the hospital's disproportionate patient percentage (DPP). A hospital's DPP is the sum of two fractions: the ''Medicare fraction'' and the ''Medicaid fraction.'' The Medicare fraction (also known as the ''SSI fraction'' or ''SSI ratio'') is computed by dividing the number of the hospital's inpatient days that are furnished to patients who were entitled to both Medicare Part A and Supplemental Security Income (SSI) benefits by the hospital's total number of patient days furnished to patients entitled to benefits under Medicare Part A. The Medicaid fraction is computed by dividing the hospital's number of inpatient days furnished to patients

who, for such days, were eligible for Medicaid, but were not entitled to benefits under Medicare Part A, by the hospital's total number of inpatient days in the same period.

Because the DSH payment adjustment is part of the IPPS, the statutory references to ''days'' in section 1886(d)(5)(F) of the Act have been interpreted to apply only to hospital acute care inpatient days. Regulations located at § 412.106 govern the Medicare DSH payment adjustment and specify how the DPP is calculated as well as how beds and patient days are counted in determining the Medicare DSH payment adjustment. Under § 412.106(a)(1)(i), the number of beds for the Medicare DSH payment adjustment is determined in accordance with bed counting rules for the IME adjustment under § 412.105(b).

Section 3133 of the Patient Protection and Affordable Care Act, as amended by section 10316 of the same Act and section 1104 of the Health Care and Education Reconciliation Act (Pub. L. 111–152), added a section 1886(r) to the Act that modifies the methodology for computing the Medicare DSH payment adjustment. (For purposes of this final rule, we refer to these provisions collectively as section 3133 of the Affordable Care Act.) Beginning with discharges in FY 2014, hospitals that qualify for Medicare DSH payments under section 1886(d)(5)(F) of the Act receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments. This provision applies equally to hospitals that qualify for DSH payments under section 1886(d)(5)(F)(i)(I) of the Act and those hospitals that qualify under the Pickle method under section 1886(d)(5)(F)(i)(II) of the Act.

The remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured, is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The payments to each hospital for a fiscal year are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all hospitals that receive Medicare DSH payments for that fiscal year.

As provided by section 3133 of the Affordable Care Act, section 1886(r) of the Act requires that, for FY 2014 and each subsequent fiscal year, a subsection (d) hospital that would otherwise receive DSH payments made under section 1886(d)(5)(F) of the Act receives two separately calculated payments. Specifically, section 1886(r)(1) of the Act provides that the Secretary shall pay to such subsection (d) hospital (including a Pickle hospital) 25 percent of the amount the hospital would have received under section 1886(d)(5)(F) of the Act for DSH payments, which represents the empirically justified amount for such payment, as determined by the MedPAC in its March 2007 Report to Congress. We refer to this payment as the ''empirically justified Medicare DSH payment.''

In addition to this empirically justified Medicare DSH payment, section 1886(r)(2) of the Act provides that, for FY 2014 and each subsequent fiscal year, the Secretary shall pay to such subsection (d) hospital an additional amount equal to the product of three factors. The first factor is the difference between the aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if subsection (r) did not apply and the aggregate amount of payments that are made to subsection (d) hospitals under section 1886(r)(1) of the Act for such fiscal year. Therefore, this factor amounts to 75 percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act.

The second factor is, for FYs 2014 through 2017, 1 minus the percent change in the percent of individuals under the age of 65 who are uninsured, determined by comparing the percent of such individuals who were uninsured in 2013, the last year before coverage expansion under the Affordable Care Act (as calculated by the Secretary based on the most recent estimates available from the Director of the Congressional Budget Office before a vote in either House on the Health Care and Education Reconciliation Act of 2010 that, if determined in the affirmative, would clear such Act for enrollment), and the percent of individuals who were uninsured in the most recent period for which data are available (as so calculated) minus 0.1 percentage point for FY 2014, and minus 0.2 percentage point for FYs 2015 through 2017. For FYs 2014 through 2017, the baseline for the estimate of the change in uninsurance is fixed by the most recent estimate of the Congressional Budget Office before the final vote on the Health Care and Education Reconciliation Act of 2010, which is contained in a March 20, 2010 letter from the Director of the Congressional Budget Office to the Speaker of the House. (The March 20, 2010 letter is available for viewing on the following Web site: *https://www.cbo.gov/sites/default/files/111th-congress-2009-2010/costestimate/amendreconprop.pdf.*)

For FY 2018 and subsequent fiscal years, the second factor is 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who were uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS), and the percent of individuals who were uninsured in the most recent period for which data are available (as so estimated and certified), minus 0.2 percentage point for FYs 2018 and 2019.

The third factor is a percent that, for each subsection (d) hospital, represents the quotient of the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data), including the use of alternative data where the Secretary determines that alternative data are available which are a better proxy for the costs of subsection (d) hospitals for treating the uninsured, and the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act. Therefore, this third factor represents a hospital's uncompensated care amount for a given time period relative to the uncompensated care amount for that same time period for all hospitals that receive Medicare DSH payments in the applicable fiscal year, expressed as a percent.

For each hospital, the product of these three factors represents its additional payment for uncompensated care for the applicable fiscal year. We refer to the additional payment determined by these factors as the ''uncompensated care payment.''

Section 1886(r) of the Act applies to FY 2014 and each subsequent fiscal year. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50620 through 50647) and the FY 2014 IPPS interim final rule with comment period (78 FR 61191 through 61197), we set forth our policies for implementing the required changes to the Medicare DSH payment methodology made by section 3133 of the Affordable Care Act for FY 2014. In those rules, we noted that, because section 1886(r) of the Act modifies the payment required under section 1886(d)(5)(F) of the Act, it affects only the DSH payment under the operating IPPS. It does not revise or replace the

capital IPPS DSH payment provided under the regulations at 42 CFR part 412, subpart M, which were established through the exercise of the Secretary's discretion in implementing the capital IPPS under section 1886(g)(1)(A) of the Act.

Finally, section 1886(r)(3) of the Act provides that there shall be no administrative or judicial review under section 1869, section 1878, or otherwise of any estimate of the Secretary for purposes of determining the factors described in section 1886(r)(2) of the Act or of any period selected by the Secretary for the purpose of determining those factors. Therefore, there is no administrative or judicial review of the estimates developed for purposes of applying the three factors used to determine uncompensated care payments, or the periods selected in order to develop such estimates.

2. Eligibility for Empirically Justified Medicare DSH Payments and Uncompensated Care Payments

As indicated earlier, the payment methodology under section 3133 of the Affordable Care Act applies to ''subsection (d) hospitals'' that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act. Therefore, hospitals must receive empirically justified Medicare DSH payments in a fiscal year in order to receive an additional Medicare uncompensated care payment for that year. Specifically, section 1886(r)(2) of the Act states that, in addition to the payment made to a subsection (d) hospital under section 1886(r)(1) of the Act, the Secretary shall pay to such subsection (d) hospitals an additional amount. Because section 1886(r)(1) of the Act refers to empirically justified Medicare DSH payments, the additional payment under section 1886(r)(2) of the Act is limited to hospitals that receive empirically justified Medicare DSH payments in accordance with section 1886(r)(1) of the Act for the applicable fiscal year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and the FY 2014 IPPS interim final rule with comment period (78 FR 61193), we provided that hospitals that are not eligible to receive empirically justified Medicare DSH payments in a fiscal year will not receive uncompensated care payments for that year. We also specified that we would make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status for the applicable fiscal year (using the most recent data that are available). We indicated that our final determination on the hospital's eligibility for uncompensated care payments will be based on the hospital's actual DSH status at cost report settlement for that payment year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50006), we specified our policies for several specific classes of hospitals within the scope of section 1886(r) of the Act. We refer readers to those two final rules for a detailed discussion of our policies. In summary, we specified the following:

- *Subsection (d) Puerto Rico hospitals* that are eligible for DSH payments also are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the new payment methodology (78 FR 50623 and 79 FR 50006).
- *Maryland hospitals* are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the payment methodology of section 1886(r) of the Act because they are not paid under the IPPS. As discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50007), effective January 1, 2014, the State of Maryland elected to no longer have Medicare pay Maryland hospitals in accordance with section 1814(b)(3) of the Act and entered into an agreement with CMS that Maryland hospitals will be paid under the Maryland All-Payer Model. However, under the Maryland All-Payer Model, Maryland hospitals still are not paid under the IPPS. Therefore, they remain ineligible to receive empirically justified Medicare DSH payments or uncompensated care payments under section 1886(r) of the Act.
- *SCHs that are paid under their hospital-specific rate* are not eligible for Medicare DSH payments. SCHs that are paid under the IPPS Federal rate receive interim payments based on what we estimate and project their DSH status to be prior to the beginning of the Federal fiscal year (based on the best available data at that time) subject to settlement through the cost report, and if they receive interim empirically justified Medicare DSH payments in a fiscal year, they also will receive interim uncompensated care payments for that fiscal year on a per discharge basis, subject as well to settlement through the cost report. Final eligibility determinations will be made at the end of the cost reporting period at settlement, and both interim empirically justified Medicare DSH payments and uncompensated care payments will be adjusted accordingly (78 FR 50624 and 79 FR 50007).
- *MDHs* are paid based on the IPPS Federal rate or, if higher, the IPPS Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate from certain specified base years (76 FR 51684). The IPPS Federal rate used in the MDH payment methodology is the same IPPS Federal rate that is used in the SCH payment methodology. Section 205 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Public Law 114–10, enacted April 16, 2015, extended the MDH program for discharges on or after April 1, 2015, through September 30, 2017. Because MDHs are paid based on the IPPS Federal rate, for FY 2017, MDHs continue to be eligible to receive empirically justified Medicare DSH payments and uncompensated care payments if their DPP is at least 15 percent. We apply the same process to determine MDHs' eligibility for empirically justified Medicare DSH and uncompensated care payments, as we do for all other IPPS hospitals, through September 30, 2017. We note that there has not been legislation at the time of development of this final rule that would extend the MDH program beyond September 30, 2017. However, if the MDH program were to be extended beyond its current expiration date, similar to how it was extended under MACRA, MDHs would continue to be paid based on the IPPS Federal rate or, if higher, the IPPS Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate from certain specified base years. Accordingly, if the MDH program were to be extended beyond its current expiration date of September 30, 2017, we would continue to make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status for the applicable fiscal year (using the most recent data that are available). Our final determination on the hospital's eligibility for uncompensated care payments would be based on the hospital's actual DSH status at cost report settlement for that payment year. In addition, as we do for all IPPS hospitals, we would calculate a numerator for Factor 3 for all MDHs, regardless of whether they are projected to be eligible for Medicare DSH payments during the fiscal year, but the denominator for Factor 3 would be based on the uncompensated care data from the hospitals that we have projected to be eligible for Medicare DSH payments during the fiscal year.

These policies for MDHs would only apply in FY 2018 if the MDH program is extended by statute, beyond its current expiration date of September 30, 2017.

• *IPPS hospitals that have elected to participate in the Bundled Payments for Care Improvement initiative and IPPS hospitals that are participating in the mandatory Comprehensive Care for Joint Replacement Model, the Episode Payment Models, or the Cardiac Rehabilitation Incentive Payment Model* continue to be paid under the IPPS (77 FR 53342) and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments (78 FR 50625 and 79 FR 50008).

• *Hospitals Participating in the Rural Community Hospital Demonstration Program* are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act because they are not paid under the IPPS (78 FR 50625 and 79 FR 50008). The Rural Community Hospital Demonstration Program was originally authorized for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), and extended for another 5-year period by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 114–255). The period of performance for this 5-year extension period ended December 31, 2016. Section 15003 of the 21st Century Cures Act (Pub. L. 114–255), enacted December 13, 2016, again amended section 410A of Public Law 108–173 to require a 10-year extension period (in place of the 5-year extension required by the Affordable Care Act), to begin on the date immediately following the last day of the initial 5-year period. Section 15003 also requires that, no later than 120 days after enactment of Public Law 114–255, the Secretary issue a solicitation to select additional hospitals to participate in the demonstration program for the second 5 years of the 10-year extension period so long as the maximum number of 30 hospitals stipulated by the Affordable Care Act is not exceeded. (We refer readers to section V.L. of the preamble of this final rule for a full discussion of the provisions of section 15003 of Public Law 114–255 and our implementation of this provision.) As of the time of development of this final rule, the entire set of hospitals that will participate in the second 5 years of the extension period is unknown. However, we intend to apply a similar payment methodology during the remainder of the extension period. As a result, we expect that hospitals participating in the demonstration will not receive empirically justified DSH payments, and that they will be excluded from receiving interim and final uncompensated care payments for FY 2018 and subsequent fiscal years for the duration of the second 5 years of the extension period.

3. Empirically Justified Medicare DSH Payments

As we have discussed earlier, section 1886(r)(1) of the Act requires the Secretary to pay 25 percent of the amount of the Medicare DSH payment that would otherwise be made under section 1886(d)(5)(F) of the Act to a subsection (d) hospital. Because section 1886(r)(1) of the Act merely requires the program to pay a designated percentage of these payments, without revising the criteria governing eligibility for DSH payments or the underlying payment methodology, we stated in the FY 2014 IPPS/LTCH PPS final rule that we did not believe that it was necessary to develop any new operational mechanisms for making such payments. Therefore, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50626), we implemented this provision by advising MACs to simply adjust the interim claim payments to the requisite 25 percent of what would have otherwise been paid. We also made corresponding changes to the hospital cost report so that these empirically justified Medicare DSH payments can be settled at the appropriate level at the time of cost report settlement. We provided more detailed operational instructions and cost report instructions following issuance of the FY 2014 IPPS/LTCH PPS final rule that are available on the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2014-Transmittals-Items/R5P240.html*.

4. Uncompensated Care Payments

As we discussed earlier, section 1886(r)(2) of the Act provides that, for each eligible hospital in FY 2014 and subsequent years, the uncompensated care payment is the product of three factors. These three factors represent our estimate of 75 percent of the amount of Medicare DSH payments that would otherwise have been paid, an adjustment to this amount for the percent change in the national rate of uninsurance compared to the rate of uninsurance in 2013, and each eligible hospital's estimated uncompensated care amount relative to the estimated uncompensated care amount for all eligible hospitals. Below we discuss the data sources and methodologies for computing each of these factors, our final policies for FYs 2014 through 2017, and our proposed and final policies for FY 2018.

a. Calculation of Factor 1 for FY 2018

Section 1886(r)(2)(A) of the Act establishes Factor 1 in the calculation of the uncompensated care payment. Section 1886(r)(2)(A) of the Act states that this factor is equal to the difference between (1) the aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if section 1886(r) of the Act did not apply for such fiscal year (as estimated by the Secretary); and (2) the aggregate amount of payments that are made to subsection (d) hospitals under section 1886(r)(1) of the Act for such fiscal year (as so estimated). Therefore, section 1886(r)(2)(A)(i) of the Act represents the estimated Medicare DSH payments that would have been made under section 1886(d)(5)(F) of the Act if section 1886(r) of the Act did not apply for such fiscal year. Under a prospective payment system, we would not know the precise aggregate Medicare DSH payment amount that would be paid for a Federal fiscal year until cost report settlement for all IPPS hospitals is completed, which occurs several years after the end of the Federal fiscal year. Therefore, section 1886(r)(2)(A)(i) of the Act provides authority to estimate this amount, by specifying that, for each fiscal year to which the provision applies, such amount is to be estimated by the Secretary. Similarly, section 1886(r)(2)(A)(ii) of the Act represents the estimated empirically justified Medicare DSH payments to be made in a fiscal year, as prescribed under section 1886(r)(1) of the Act. Again, section 1886(r)(2)(A)(ii) of the Act provides authority to estimate this amount.

Therefore, Factor 1 is the difference between our estimates of: (1) The amount that would have been paid in Medicare DSH payments for the fiscal year, in the absence of the new payment provision; and (2) the amount of empirically justified Medicare DSH payments that are made for the fiscal year, which takes into account the requirement to pay 25 percent of what would have otherwise been paid under section 1886(d)(5)(F) of the Act. In other words, this factor represents our estimate of 75 percent (100 percent minus 25 percent) of our estimate of Medicare DSH payments that would otherwise be made, in the absence of section 1886(r) of the Act, for the fiscal year.

As we did for FY 2017, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR

19943), in order to determine Factor 1 in the uncompensated care payment formula for FY 2018, we proposed to continue the policy established in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50628 through 50630) and in the FY 2014 IPPS interim final rule with comment period (78 FR 61194) of determining Factor 1 by developing estimates of both the aggregate amount of Medicare DSH payments that would be made in the absence of section 1886(r)(1) of the Act and the aggregate amount of empirically justified Medicare DSH payments to hospitals under 1886(r)(1) of the Act. These estimates will not be revised or updated after we know the final Medicare DSH payments for FY 2018.

Therefore, in order to determine the two elements of proposed Factor 1 for FY 2018 (Medicare DSH payments *prior* to the application of section 1886(r)(1) of the Act, and empirically justified Medicare DSH payments *after* application of section 1886(r)(1) of the Act), for the proposed rule, we used the most recently available projections of Medicare DSH payments for the fiscal year, as calculated by CMS' Office of the Actuary using the most recently filed Medicare hospital cost report with Medicare DSH payment information and the most recent Medicare DSH patient percentages and Medicare DSH payment adjustments provided in the IPPS Impact File.

For purposes of calculating proposed Factor 1 and modeling the impact of the FY 2018 IPPS/LTCH PPS proposed rule, we used the Office of the Actuary's January 2017 Medicare DSH estimates, which were based on data from the December 2016 update of the Medicare Hospital Cost Report Information System (HCRIS) and the FY 2017 IPPS/LTCH PPS final rule IPPS Impact file, published in conjunction with the publication of the FY 2017 IPPS/LTCH PPS final rule. Because SCHs that are projected to be paid under their hospital-specific rate are excluded from the application of section 1886(r) of the Act, these hospitals also were excluded from the January 2017 Medicare DSH estimates. Furthermore, because section 1886(r) of the Act specifies that the uncompensated care payment is in addition to the empirically justified Medicare DSH payment (25 percent of DSH payments that would be made without regard to section 1886(r) of the Act), Maryland hospitals participating in the Maryland All-Payer Model that do not receive DSH payments were also excluded from the Office of the Actuary's January 2017 Medicare DSH estimates. Hospitals that had been participating in the Rural Community Hospital Demonstration Program through December 31, 2016 were included in these estimates. (As discussed earlier, the Affordable Care Act authorized a 5-year extension period for the demonstration, which ended December 31, 2016.) The demonstration was extended for an additional 5 years by section 15003 of Public Law 114–255. Although the hospitals that will participate in the second 5 years of the extension period had not been determined at the time of development of the proposed rule, we stated that we intend to apply a similar payment methodology during the second 5 years of the extension period as for the earlier periods of the demonstration. Therefore, hospitals participating in the demonstration would not be eligible to receive DSH payments. We stated in the proposed rule that if the hospitals participating in the second 5 years of the extension period are known prior to the development of the Medicare DSH estimates for the FY 2018 final rule, these hospitals would be excluded from the Office of the Actuary's final Medicare DSH estimates for FY 2018.

For the proposed rule, using the data sources discussed earlier, the Office of the Actuary used the most recently submitted Medicare cost report data to identify Medicare DSH payments and the most recent Medicare DSH payment adjustments provided in the IPPS Impact File, and applied inflation updates and assumptions for future changes in utilization and case-mix to estimate Medicare DSH payments for the upcoming fiscal year. The January 2017 Office of the Actuary estimate for Medicare DSH payments for FY 2017, without regard to the application of section 1886(r)(1) of the Act, was approximately $16.003 billion. This estimate excluded Maryland hospitals participating in the Maryland All-Payer Model and SCHs paid under their hospital-specific payment rate. Therefore, based on the January 2017 estimate, the estimate for empirically justified Medicare DSH payments for FY 2017, with the application of section 1886(r)(1) of the Act, was approximately $4.001 billion (or 25 percent of the total amount of estimated Medicare DSH payments for FY 2018). Under § 412.l06(g)(1)(i) of the regulations, Factor 1 is the difference between these two estimates of the Office of the Actuary. Therefore, in the proposed rule, we proposed that Factor 1 for FY 2018 was $12,001,915,095.04, which is equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2017 ($16,002,553,460.05 minus $4,000,638,365.01). We invited public comments on our proposed calculation of Factor 1 for FY 2018.

Comment: A number of commenters requested greater transparency in the methodology used by CMS and the OACT to estimate aggregate DSH payments that would have been paid absent implementation of the Affordable Cart Act, particularly with respect to the calculation of estimated DSH payments for purposes of determining Factor 1. The commenters believed that CMS has not adequately explained its methodology in calculating DSH payments and urged CMS to clarify the methodology and provide additional information on the factor assumptions used to make these projections. One commenter noted that providing a table explaining the factors applied for FYs 2015–2018 to estimate Medicare DSH expenditures using a 2014 baseline is not sufficient, given that CMS does not provide more detail on the completion factor used to adjust the FY 2015 and FY 2016 claims data used for the ''Discharges'' column. The commenter stated that this lack of information severely limited the public's ability to comment on the projections and estimates for Factor 1. Commenters also requested that this information be provided in advance of the publication of the FY 2018 IPPS/LTCH PPS final rule and in future proposed rules each year.

The majority of comments on Factor 1 related to the ''Other'' and ''Discharges'' factors that are used to estimate Medicare DSH expenditures. Some commenters stated that there is variability in the factors and requested full disclosure of the methodology and the various components used to estimate the catch-all ''Other'' column. A number of commenters noted that, other than the statements in the proposed rule, CMS provided no further explanation for the specific items that make up the ''Other'' column or the value of each component. Specifically, one commenter expressed concern that the annual growth rate due to ''other'' factors projected by CMS increased from 4.9 percent in FY 2015 to 6.9 percent in FY 2017, while it decreased by 1 percent in FY 2018. Commenters requested that CMS provide a breakdown of the factors influencing these changes and their impact on FY 2018 DSH estimates to allow providers to understand and verify these projections, as well as to make meaningful comments, if warranted.

Many commenters also asked CMS to explain how Medicaid expansion is accounted for in the ''Other'' column used to determine the Factor 1 estimate.

A few commenters stated that the effect of Medicaid expansion on the agency's projection of the amount of traditional DSH payments that would have been paid in FY 2014, absent of the Affordable Care Act, has varied erratically in the agency's successive rulemakings for FYs 2015 through 2018. Another commenter noted that the most recent Congressional Budget Office report showed a 32-percent increase in Medicaid/CHIP enrollment as a result of Medicaid expansion, and expected that this increase in enrollment would result in a substantial increase in DSH payments that is not reflected in OACT's DSH estimate for Factor 1.

Commenters objected to CMS' statement from prior rulemaking that ''the increase due to Medicaid expansion is not as large as commenters contended due to the actuarial assumption that the new enrollees are healthier than the average Medicaid recipient, and, therefore, use fewer hospital services.'' Some commenters asserted that there is no solid evidentiary basis for the assumption that new Medicaid enrollees are healthier, and requested that CMS reconsider and discontinue use of this assumption. In addition, the commenters argued that CMS should by now have accurate information regarding States that have expanded Medicaid, and that CMS should utilize the available enrollment and/or utilization information from Medicaid expansion programs either to support or refute the assumption that the Medicaid expansion population is healthier than the average Medicaid recipient. Many commenters also stated that the level of Medicaid expansion included in the calculation of Factor 1, including the adjustments made to Factor 1 to account for the estimated Medicaid expansion in FY 2018, is unclear. The commenters requested that CMS resolve the inconsistency with the decrease in the uninsured rate from 14 percent in 2013 to 8.15 percent in 2018 due to Medicaid expansion, and fully account for the increase in Medicaid participation in the Factor 1 calculation.

Response: We thank the commenters for their input. As in previous years, we would like to clarify that Factor 1 is not estimated in isolation. The Factor 1 estimates for proposed rules are generally consistent with the economic assumptions and actuarial analysis used to develop the President's Budget estimates under current law, and the Factor 1 estimates for the final rule are generally consistent with those used for the Midsession Review of the President's Budget. For additional information on the development of the President's Budget, we refer readers to the Office of Management and Budget Web site at: *https://www.whitehouse.gov/omb/budget*. For additional information on the specific economic assumptions used in the Midsession Review of the President's FY 2018 Budget, we refer readers to the ''Midsession Review of the President's FY 2018 Budget'' available on the Office of Management and Budget Web site at: *https://www.whitehouse.gov/omb/budget*. For a general overview of the principal steps involved in projecting future inpatient costs and utilization, we refer readers to the ''2017 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds'' available on the CMS Web site at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/index.html?redirect=/reportstrustfunds/* under ''Downloads.'' For the OACT's memorandum describing its methodology and estimates, we refer readers to ''OACT Memorandum on DSH Factor 1 for FY 2018'' available on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html* under ''Downloads''.

As we did in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56950), later in this section, we provide additional information regarding the data sources, methods, and assumptions employed by the actuaries in determining the OACT's updated estimate of Factor 1 for FY 2018. We believe that this discussion addresses the methodological concerns raised by commenters regarding the various assumptions used in the estimate, including the ''Other'' and ''Discharges'' assumptions and also provides additional information regarding how we address the Medicaid and CHIP expansion. However, we note that, with regard to the commenters' questions and concerns regarding the use of completion factors to adjust preliminary data, the OACT assumed a discharge completion factor of 99 percent for FY 2015 and 98 percent for FY 2016. Similarly, the OACT assumed that case-mix for these years was stabilized at the time of the estimate and no additional completion factor adjustment was needed. These assumptions are consistent with historical patterns of completion factors that have been determined for discharge and case-mix numbers.

Regarding the commenters' assertion that Medicaid expansion is not adequately accounted for in the ''Other'' column and that there is no evidentiary basis for the assumption that the newly covered Medicaid expansion population is healthier than the average Medicaid recipient, we note that, based on data from the Midsession Review of the President's Budget, the OACT assumed per capita spending for Medicaid beneficiaries who enrolled due to the expansion to be 50 percent of the average per capita spending of a pre-expansion Medicaid beneficiary due to the better health of these beneficiaries. This assumption is consistent with recent internal estimates of Medicaid per capita spending pre-expansion and post-expansion.

Comment: In addition to requesting that the methodology and assumptions used for Factor 1 be made public before the publication of the final rule and with the proposed rule each subsequent year, commenters requested that CMS furnish interested parties with advance opportunity to comment on new calculations based on the more recent data that CMS intends ultimately to use for the final rule. One commenter believed that CMS' rulemaking is flawed because different data and calculations are used in the final rule than were used for purposes of the proposed rule, without any opportunity for the hospitals to comment. This commenter requested that CMS make clear that it will use different or updated data to determine payments for uncompensated care in the final rule. The commenter believed that the proposal to determine the amount of hospitals' uncompensated care payments based on data first released with the final rule and on which hospitals will have no meaningful opportunity to comment violates notice-and-comment rulemaking requirements. As discussed earlier, several commenters noted the variability in the values of the ''Other'' column as well as in the factor applied to account for Medicaid expansion; one of the commenters called on CMS to explain why these values were allowed to change from one rulemaking to the next when the agency has otherwise taken the position that the estimates used to determine uncompensated care payments should be fixed when made and not be reconciled with data that become available later.

Response: We believe that stakeholders had notice and a full opportunity to comment on the methodology that would be used to determine uncompensated care payments, including the data sources that would be used. As a result, commenters had a full opportunity to raise any concerns regarding the appropriateness of the data generally, even if the actual data were not yet

available, consistent with the requirements for notice-and-comment rulemaking under the Administrative Procedure Act. With respect to concerns about the variability of the factors used to estimate Factor 1, we note that, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50630), using the discretion afforded in the statute to estimate the aggregate amount of DSH payments that would be made in the absence of section 1886(r) of the Act, we finalized a policy of defining the methodology for calculating Factor 1 using the OACT's biannual Medicare DSH payment projections, which are typically available around February of each year (based on data from December of the previous year) as part of the President's Budget, and around July (based on data from June) as part of the Midsession Review of the President's Budget.

Comment: One commenter requested that, in light of its concerns about the data sources and methods used to estimate Factor 1, CMS adopt a process to reconcile data for Factor 1. Commenters noted their concern that the DSH payment estimates for FY 2014 through FY 2017, as displayed in the table for factors applied to update the Medicare DSH baseline in the FY 2018 proposed rule, compared to original projections from the respective payment year from the FY 2014 through FY 2017 final rules, show that Factor 1 would have been higher, in retrospect, over that period of time. In other words, commenters noted how, based on the more recent data used in the FY 2018 proposed rule, the Factor 1 estimates are higher compared to the data available at the time of the past final rules.

Response: We continue to believe that applying our best estimates prospectively is most conducive to administrative efficiency, finality, and predictability in payments (78 FR 50628; 79 FR 50010; 80 FR 49518; and 81 FR 56949). We believe that, in affording the Secretary the discretion to estimate the amount of these payments and by including a prohibition against administrative and judicial review of those estimates in section 1886(r)(3) of the Act, Congress recognized the importance of finality and predictability in payments. As a result, we do not agree with the commenter that we should establish a process for reconciling our estimate of Factor 1. However, we note that, in reviewing the OACT's prior estimates for DSH payments compared to more updated estimates and/or actual experience, from FY 2005 to FY 2017, the original estimates have been higher than either the more updated estimates and/or actual experience for 8 of the 14 years and lower than actual experience in only 6 years.

After consideration of the public comments received, we are finalizing our proposed methodology for calculating Factor 1 for FY 2018. We discuss the resulting Factor 1 amount for FY 2018 below.

To determine Factor 1 and to model the impact of this provision for FY 2018, we used the Office of the Actuary's June 2017 Medicare DSH estimates based on data from the March 2017 update of the cost report data for FY 2014 included in the HCRIS and the Impact File published in conjunction with the publication of the FY 2017 IPPS/LTCH PPS final rule. Because SCHs that are projected to be paid under their hospital-specific rate are excluded from the application of section 1886(r) of the Act, these hospitals also were excluded from the June 2017 Medicare DSH estimates. Furthermore, because Maryland hospitals participating in the Maryland All-Payer Model do not receive DSH payments, these hospitals also are excluded from the Office of the Actuary's Medicare DSH estimates. At the time of development of this final rule, the set of hospitals participating in the Rural Community Hospital Demonstration program is still unknown. As a result, it was not possible for these hospitals to be excluded from the Office of the Actuary's Medicare DSH estimates. However, we expect that hospitals participating in the demonstration will not receive empirically justified DSH payments, and that they will be excluded from receiving interim and final uncompensated care payments for FY 2018 and subsequent fiscal years for the duration of the second 5 years of the extension period.

For this final rule, using the data sources discussed above, the Office of the Actuary used the most recently submitted Medicare cost report data for FY 2014 to identify Medicare DSH payments and the most recent Medicare DSH payment adjustments provided in the Impact File published in conjunction with the publication of the FY 2017 IPPS/LTCH PPS final rule and applied update factors and assumptions for future changes in utilization and case-mix to estimate Medicare DSH payments for the upcoming fiscal year. The June 2017 Office of the Actuary estimate for Medicare DSH payments for FY 2018, without regard to the application of section 1886(r)(1) of the Act, was approximately $15.533 billion. This estimate excluded Maryland hospitals participating in the Maryland All-Payer Model and SCHs paid under their hospital-specific payment rate. Therefore, based on the June 2017 estimate, the estimate for empirically justified Medicare DSH payments for FY 2018, with the application of section 1886(r)(1) of the Act, is approximately $3.888 billion (or 25 percent of the total amount of estimated Medicare DSH payments for FY 2018). Under § 412.106(g)(1)(i) of the regulations, Factor 1 is the difference between these two estimates of the Office of the Actuary. Therefore, in this final rule, Factor 1 for FY 2018 is $11,664,704,643.27, which is equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2018 ($15,552,939,524.36 minus $3,888,234,881.09).

The Office of the Actuary's final estimates for FY 2018 began with a baseline of $12.395 billion in Medicare DSH expenditures for FY 2014. The following table shows the factors applied to update this baseline through the current estimate for FY 2018:

FACTORS APPLIED FOR FY 2015 THROUGH FY 2018 TO ESTIMATE MEDICARE DSH EXPENDITURES USING 2014 BASELINE

FY	Update	Discharges	Case-mix	Other	Total	Estimated DSH payment (in billions) *
2015	1.014	1.0068	1.005	1.0496	1.0769	$13.348
2016	1.009	0.9742	1.027	1.0685	1.0787	14.398
2017	1.0015	0.9952	1.005	1.0535	1.0553	15.194
2018	1.018088	1.0070	1.005	0.9935	1.0236	15.533

* Rounded.

In this table, the ''Discharges'' column shows the increase in the number of Medicare fee-for-service (FFS) inpatient hospital discharges. The figures for FY 2015 and FY 2016 are based on Medicare claims data that have been adjusted by a completion factor. The discharge figure for FY 2017 is based on preliminary data for 2017. The discharge figure for FY 2018 is an assumption based on recent trends recovering back to the long-term trend and assumptions related to how many beneficiaries will be enrolled in Medicare Advantage (MA) plans. The case-mix column shows the increase in case-mix for IPPS hospitals. The case-mix figures for FY 2015 and FY 2016 are based on actual data adjusted by a completion factor. The FY 2017 increase is based on preliminary data.

The FY 2018 increase is based on the recommendation of the 2010–2011 Medicare Technical Review Panel. The ''Other'' column shows the increase in other factors that contribute to the Medicare DSH estimates. These factors include the difference between the total inpatient hospital discharges and the IPPS discharges, and various adjustments to the payment rates that have been included over the years but are not reflected in the other columns (such as the change in rates for the 2-midnight stay policy). In addition, the ''Other'' column includes a factor for the Medicaid expansion due to the Affordable Care Act. The factor for Medicaid expansion was developed using public information and statements for each State regarding its intent to implement the expansion. Based on this information, it is assumed that 50 percent of all individuals who were potentially newly eligible Medicaid enrollees in 2016 resided in States that had elected to expand Medicaid eligibility and, for 2017 and thereafter, that 55 percent of such individuals would reside in expansion States. In the future, these assumptions may change based on actual participation by States. For a discussion of general issues regarding Medicaid projections, we refer readers to the 2016 Actuarial Report on the Financial Outlook for Medicaid (*https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/MedicaidReport2016.pdf*). We note that, in developing their estimates of the effect of Medicaid expansion on Medicare DSH expenditures, our actuaries have assumed that the new Medicaid enrollees are healthier than the average Medicaid recipient and, therefore, use fewer hospital services.

The table below shows the factors that are included in the ''Update'' column of the above table:

FY	Market basket percentage	Affordable Care Act payment reductions	Multifactor productivity adjustment	Documentation and coding	Total update percentage
2015	2.9	−0.2	−0.5	−0.8	1.4
2016	2.4	−0.2	−0.5	−0.8	0.9
2017	2.7	−0.75	−0.3	−1.5	0.15
2018	2.7	−0.75	−0.6	0.4588	1.8088

Note: All numbers are based on Midsession Review of FY 2018 President's Budget projections.

b. Calculation of Factor 2 for FY 2018

(1) Background

Section 1886(r)(2)(B) of the Act establishes Factor 2 in the calculation of the uncompensated care payment. Specifically, section 1886(r)(2)(B)(i) of the Act provides that, for each of FYs 2014, 2015, 2016, and 2017, a factor equal to 1 minus the percent change in the percent of individuals under the age of 65 who are uninsured, as determined by comparing the percent of such individuals (1) who were uninsured in 2013, the last year before coverage expansion under the Affordable Care Act (as calculated by the Secretary based on the most recent estimates available from the Director of the Congressional Budget Office before a vote in either House on the Health Care and Education Reconciliation Act of 2010 that, if determined in the affirmative, would clear such Act for enrollment); and (2) who are uninsured in the most recent period for which data are available (as so calculated), minus 0.1 percentage point for FY 2014 and minus 0.2 percentage point for each of FYs 2015, 2016, and 2017.

Section 1886(r)(2)(B)(i)(I) of the Act further indicates that the percent of individuals under 65 without insurance in 2013 must be the percent of such individuals who were uninsured in 2013, the last year before coverage expansion under the Affordable Care Act (as calculated by the Secretary based on the most recent estimates available from the Director of the Congressional Budget Office before a vote in either House on the Health Care and Education Reconciliation Act of 2010 that, if determined in the affirmative, would clear such Act for enrollment). The Health Care and Education Reconciliation Act (Pub. L. 111–152) was enacted on March 30, 2010. It was passed in the House of Representatives on March 21, 2010, and by the Senate on March 25, 2010. Because the House of Representatives was the first House to vote on the Health Care and Education Reconciliation Act of 2010 on March 21, 2010, we have determined that the most recent estimate available from the Director of the Congressional Budget Office ''*before* a vote in either House on the Health Care and Education Reconciliation Act of 2010 . . .'' (emphasis added) appeared in a March 20, 2010 letter from the director of the CBO to the Speaker of the House. Therefore, we believe that only the estimates in this March 20, 2010 letter meet the statutory requirement under section 1886(r)(2)(B)(i)(I) of the Act. (To view the March 20, 2010 letter, we refer readers to the Web site at: *https://www.cbo.gov/sites/default/files/111th-congress-2009-2010/costestimate/amendreconprop.pdf*.)

In its March 20, 2010 letter to the Speaker of the House of Representatives, the CBO provided two estimates of the ''post-policy uninsured population.'' The first estimate is of the ''Insured Share of the Nonelderly Population Including All Residents'' (82 percent) and the second estimate is of the ''Insured Share of the Nonelderly Population Excluding Unauthorized Immigrants'' (83 percent). In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50631), we used the first estimate that includes all residents, including unauthorized immigrants. We stated that we believe this estimate is most consistent with the statute, which requires us to measure ''the percent of individuals under the age of 65 who are

uninsured'' and provides no exclusions except for individuals over the age of 65. In addition, we stated that we believe that this estimate more fully reflects the levels of uninsurance in the United States that influence uncompensated care for hospitals than the estimate that reflects only legal residents. The March 20, 2010 CBO letter reports these figures as the estimated percentage of individuals with insurance. However, because section 1886(r)(2)(B)(i) of the Act requires that we compare the percent of individuals who are uninsured in the most recent period for which data are available with the percent of individuals who were uninsured in 2013, in the FY 2014 IPPS/LTCH PPS final rule, we used the CBO insurance rate figure and subtracted that amount from 100 percent (that is, the total population without regard to insurance status) to estimate the 2013 baseline percent of individuals without insurance. Therefore, for FYs 2014 through 2017, our estimate of the uninsurance percentage for 2013 was 18 percent.

Section 1886(r)(2)(B)(i) of the Act requires that we compare the baseline uninsurance rate to the percent of such individuals who are uninsured in the most recent period for which data are available (as so calculated). In the FY 2014, FY 2015, FY 2016, and FY 2017 IPPS/LTCH PPS final rules (78 FR 50634, 79 FR 50014, 80 FR 49522, and 81 FR 56952, respectively), we used the same data source, CBO estimates, to calculate this percent of individuals without insurance. In response to public comments, we also agreed that we should normalize the CBO estimates, which are based on the calendar year, for the Federal fiscal years for which each calculation of Factor 2 is made (78 FR 50633). Therefore, for the FY 2017 IPPS/LTCH PPS final rule (81 FR 56952), we used the most recently available estimate of the uninsurance rate, which was based on the CBO's March 2016 estimates of the effects of the Affordable Care Act on health insurance coverage (which are available at *https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/reports/51385-HealthInsuranceBaseline.pdf*). The CBO's March 2016 estimate of individuals under the age of 65 with insurance in CY 2016 was 90 percent. Therefore, the CBO's most recent estimate of the rate of uninsurance in CY 2016 was 10 percent (that is, 100 percent minus 90 percent). The CBO's March 2016 estimate of individuals under the age of 65 with insurance in CY 2017 was also 90 percent. Therefore, the CBO's most recent estimate of the rate of uninsurance in CY 2017 available for the FY 2017 final rule was also 10 percent (that is, 100 percent minus 90 percent).

The calculation of the final Factor 2 for FY 2017, employing a weighted average of the CBO projections for CY 2016 and CY 2017, was as follows:

- CY 2016 rate of insurance coverage (March 2016 CBO estimate): 90 percent.
- CY 2017 rate of insurance coverage (March 2016 CBO estimate): 90 percent.
- FY 2016 rate of insurance coverage: (90 percent * .25) + (90 percent * .75) = 90 percent.
- Percent of individuals without insurance for 2013 (March 2010 CBO estimate): 18 percent.
- Percent of individuals without insurance for FY 2017 (weighted average): 10 percent.

$1 - |((0.10–0.18)/0.18)| = 1 - 0.4444 = 0.5555$ (55.56 percent)

0.5556 (55.56 percent) − .002 (0.2 percentage points for FY 2017 under section 1886(r)(2)(B)(i) of the Act) = 0.5536 or 55.36 percent

0.5536 = Factor 2

Therefore, the final Factor 2 for FY 2017 was 55.36 percent.

The FY 2017 final uncompensated care amount was: $10,797,476,782.62 × 0.5536 = $5,977,483,146.86.

FY 2017 Uncompensated Care Total Available ...	$5,977,483,146.86

(2) Methodology for Calculation of Factor 2 for FY 2018

Section 1886(r)(2)(B)(ii) of the Act permits the use of a data source other than the CBO estimates to determine the percent change in the rate of uninsurance beginning in FY 2018. In addition, for FY 2018 and subsequent years, the statute does not require that the estimate of the percent of individuals who are uninsured be limited to individuals who are under 65. Specifically, the statute states that, for FY 2018 and subsequent fiscal years, the second factor is 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who were uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS) and the percent of individuals who were uninsured in the most recent period for which data are available (as so estimated and certified), minus 0.2 percentage point for FYs 2018 and 2019. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56952), we indicated that we planned to address changes to the methodology for determining Factor 2 and the viability of potential alternative data sources in the FY 2018 IPPS/LTCH PPS proposed rule.

As we discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19945), in our analysis of a potential data source for the rate of uninsurance for purposes of computing Factor 2 in FY 2018, we considered the following: (a) The extent to which the source accounted for the full U.S. population; (b) the extent to which the source comprehensively accounted for both public and private health insurance coverage in deriving its estimates of the number of uninsured; (c) the extent to which the source utilized data from the Census Bureau; (d) the timeliness of the estimates; (e) the continuity of the estimates over time; (f) the accuracy of the estimates; and (g) the availability of projections (including the availability of projections using an established estimation methodology that would allow for calculation of the rate of uninsurance for the applicable Federal fiscal year). As we explained in the proposed rule, these considerations are consistent with the statutory requirement that this estimate be based on data from the Census Bureau or other sources the Secretary determines appropriate and help to ensure the data source will provide reasonable estimates for the rate of uninsurance that are available in conjunction with the IPPS rulemaking cycle.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19946 and 19947), we explained that we have determined that the source that, on balance, best meets all of these considerations is the uninsured estimates produced by CMS' Office of the Actuary (OACT) as part of the development of the National Health Expenditure Accounts (NHEA). The NHEA represents the government's official estimates of economic activity (spending) within the health sector. The information contained in the NHEA has been used to study numerous topics related to the health care sector, including, but not limited to, changes in the amount and cost of health services purchased and the payers or programs that provide or purchase these services; the economic causal factors at work in the health sector; the impact of policy changes, including major health reform; and comparisons to other countries' health spending. Of relevance to the determination of Factor 2 is that the comprehensive and integrated structure of the NHEA creates an ideal tool for evaluating changes to the health care system, such as the mix of the insured and uninsured because this mix is integral to the well-established NHEA

methodology. Below we describe some aspects of the methodology used to develop the NHEA that we believe are particularly relevant in estimating the percent change in the rate of uninsurance for FY 2018. A full description of the methodology used to develop the NHEA is available on the CMS Web site at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/DSM-15.pdf*.

The NHEA estimates of U.S. population reflect the Census Bureau's definition of the resident-based population, which includes all people who usually reside in the 50 States or the District of Columbia, but excludes residents living in Puerto Rico and areas under U.S. sovereignty, members of the U.S. Armed Forces overseas, and U.S. citizens whose usual place of residence is outside of the United States, plus a small (typically less than 0.2 percent of population) adjustment to reflect Census undercounts. In past years, the estimates for Factor 2 were made using the CBO's uninsured population estimates for the under 65 population. For FY 2018 and subsequent years, the statute does not restrict the estimate to the measurement of the percent of individuals under the age of 65 who are uninsured. Accordingly, as we explained in the proposed rule, we believe it is appropriate to use an estimate that reflects the rate of uninsurance in the United States across all age groups. In addition, we continue to believe that a resident-based population estimate more fully reflects the levels of uninsurance in the United States that influence uncompensated care for hospitals than an estimate that reflects only legal residents. The NHEA estimates of uninsurance are for the total U.S. population (all ages) and not by specific age cohort, such as the population under the age of 65.

The NHEA includes comprehensive enrollment estimates for total private health insurance (PHI) (including direct and employer-sponsored plans), Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and other public programs, and estimates of the number of individuals who are uninsured. Estimates of total PHI enrollment are available for 1960 through 2015, estimates of Medicaid, Medicare, and CHIP enrollment are available for the length of the respective programs, and all other estimates (including the more detailed estimates of direct-purchased and employer-sponsored insurance) are available for 1987 through 2015. The NHEA data are publicly available on the CMS Web site at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/index.html*. In order to compute Factor 2, the first metric that is needed is the proportion of the total U.S. population that was uninsured in 2013. In developing the estimates for the NHEA, OACT's methodology included using the number of uninsured individuals for 1987 through 2009 based on the enhanced Current Population Survey (CPS) from the State Health Access Data Assistance Center (SHADAC). The CPS, sponsored jointly by the U.S. Census Bureau and the U.S. Bureau of Labor Statistics (BLS), is the primary source of labor force statistics for the population of the United States. (We refer readers to the Web site at: *http://www.census.gov/programs-surveys/cps.html*.) The enhanced CPS, available from SHADAC (available at *http://datacenter.shadac.org*) accounts for changes in the CPS methodology over time. OACT further adjusts the enhanced CPS for an estimated undercount of Medicaid enrollees (a population that is often not fully captured in surveys that include Medicaid enrollees due to a perceived stigma associated with being enrolled in the Medicaid program or confusion about the source of their health insurance).

To estimate the number of uninsured individuals for 2010 through 2014, OACT extrapolates from the 2009 CPS data using data from the National Health Interview Survey (NHIS) The NHIS is one of the major data collection programs of the National Center for Health Statistics (NCHS), which is part of the Centers for Disease Control and Prevention (CDC). The U.S. Census Bureau is the data collection agent for the NHIS.

The NHIS results have been instrumental over the years in providing data to track health status, health care access, and progress toward achieving national health objectives. For further information regarding the NHIS, we refer readers to the CDC Web site at: *https://www.cdc.gov/nchs/nhis/index.htm*. For 2015, the estimate of the rate of uninsurance in the NHEA matches with the estimate from the NHIS.

The next metrics needed to compute Factor 2 are projections of the rate of uninsurance in both calendar years 2017 and 2018. On an annual basis, the OACT projects enrollment and spending trends for the coming 10-year period. Those projections (currently for years 2016 through 2025) use the latest NHEA historical data, which presently run through 2015. The NHEA projection methodology accounts for expected changes in enrollment across all of the categories of insurance coverage previously listed. The sources for projected growth rates in enrollment for Medicare, Medicaid, and CHIP include the latest Medicare Trustees Report, the Medicaid Actuarial Report, or other updated estimates as produced by the OACT. Projected rates of growth in enrollment for private health insurance and the uninsured are based largely on OACT's econometric models, which rely on the set of macroeconomic assumptions underlying the latest Medicare Trustees Report. Greater detail can be found in OACT's report titled ''Projections of National Health Expenditure: Methodology and Model Specification,'' which is available on the CMS Web site at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology.pdf* As discussed in the proposed rule, the use of data from the NHEA to estimate the rate of uninsurance is consistent with the statute and meets the criteria we have identified for determining the appropriate data source. Section 1886(r)(2)(B)(ii) of the Act instructs the Secretary to estimate the rate of uninsurance for purposes of Factor 2 based on data from the Census Bureau or other sources the Secretary determines appropriate. The NHEA utilizes data from the Census Bureau; the estimates are available in time for the IPPS rulemaking cycle; the estimates are produced by OACT on an annual basis and are expected to continue to be produced for the foreseeable future; and projections are available for calendar year time periods that span the upcoming fiscal year. Timeliness and continuity are important considerations because of our need to be able to update this estimate annually. Accuracy is also a very important consideration and, all things being equal, we would choose the most accurate data source that sufficiently meets our other criteria.

Using these data sources and the methodologies described above, OACT estimates that the uninsured rate for the historical, baseline year of 2013 was 14 percent and for CYs 2017 and 2018 is 8.3 percent and 8.1 percent, respectively. As required by section 1886(r)(2)(B)(ii) of the Act, the Chief Actuary of CMS has certified these estimates. As with the CBO estimates on which we based Factor 2 in prior fiscal years, the NHEA estimates are for a calendar year. In the rulemaking for FY 2014, many commenters noted that the

uncompensated care payments are made on fiscal year and not a calendar year basis and requested that CMS normalize the CBO estimate to reflect a fiscal year basis. Specifically, commenters requested that CMS calculate a weighted average of the CBO estimate for October through December 2013 and the CBO estimate for January through September 2014 when determining Factor 2 for FY 2014. We agreed with the commenters that normalizing the estimate to cover FY 2014 rather than CY 2014 would more accurately reflect the rate of uninsurance that hospitals would experience during the FY 2014 payment year. Accordingly, we estimated the rate of uninsurance for FY 2014 by calculating a weighted average of the CBO estimates for CY 2013 and CY 2014 (78 FR 50633). We have continued this weighted average approach in each fiscal year since FY 2014.

We continue to believe that, in order to estimate the rate of uninsurance during a fiscal year more accurately, Factor 2 should reflect the estimated rate of uninsurance that hospitals will experience during the fiscal year, rather than the rate of uninsurance during only one of the calendar years that the fiscal year spans. However, we have concerns about the future potential for the uninsured rate to vary nonuniformly in the 2 calendar years that the fiscal year spans (for example, due to changes in the economy or changes in legislation). Nevertheless, for FY 2018, because OACT's current estimates of the percent of individuals without insurance in CY 2017 and CY 2018 are relatively close, we stated in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19947) that we do not believe this is a significant policy issue, and we proposed to continue with the weighted average approach used in past fiscal years in order to estimate the rate of uninsurance for FY 2018.

The calculation of the proposed Factor 2 for FY 2018 using a weighted average of OACT's projections for CY 2017 and CY 2018 was as follows:

- Percent of individuals without insurance for CY 2013: 14 percent.
- Percent of individuals without insurance for CY 2017: 8.3 percent.
- Percent of individuals without insurance for CY 2018: 8.1 percent.
- Percent of individuals without insurance for FY 2018 (0.25 times 0.083) + (0.75 times 0.081): 8.15 percent

$1 - |((0.0815–0.14)/0.14)| = 1 - 0.4179 =$ 0.5821 (58.21 percent)

$1 - |((0.0815–0.14)/0.14)| = 1 - 0.4179 =$ 0.5821 (58.21 percent)

0.5821 (58.21 percent) − .002 (0.2 percentage points for FY 2018 under section 1886(r)(2)(B)(ii) of the Act) = 0.5801 or 58.01 percent

0.5801 = Factor 2

Therefore, the proposed Factor 2 for FY 2018 was 58.01 percent.

The proposed FY 2018 uncompensated care amount was: $12,001,915,095.04 × 0.5801 = $6,962,310,946.63.

Proposed FY 2018 Uncompensated Care Total Available	$6,962,310,946.63

We invited public comments on our proposed methodology for calculation of Factor 2 for FY 2018.

Comment: Several commenters supported the proposal to use the uninsured estimates produced by CMS' OACT as part of the development of the NHEA in estimating the percent change in the rate of uninsurance for FY 2018. Some of these commenters stated that, in their view, the estimates produced by OACT are timely, complete, and more accurately capture the change in the number of uninsured individuals than CBO's historical estimate of the rate of uninsurance in 2013. A few commenters noted that the data source adds greater transparency to the process as the NHEA estimates are publicly available, while other commenters urged CMS to ensure that all data are provided with complete transparency of the type of data and data collection methods that are used. One commenter requested further explanation for our assumption regarding underreporting of Medicaid coverage in the survey data and the corresponding adjustment to our estimate of the rate of uninsurance, and then contended that this assumption was applied inconsistently between Factors 1 and 2.

Commenters supported the proposed methodology for determining Factor 2 because they believed it provides a more accurate comparison when evaluating changes in the uninsured population since 2013, noting that the amount available to make uncompensated care payments in FY 2017 was lower using CBO estimates than if the NHEA data had been used. A number of commenters asked CMS to retrospectively apply the NHEA estimates when measuring the effect of changes in Medicare DSH policy across time periods prior to FY 2018. Some of these commenters recognized that CMS does not have the authority to retroactively change estimates from prior years, but suggested that CMS consider this point in its analysis of payment changes occurring from the proposal to move from the use of low-income patient days to Worksheet S–10 data to estimate uncompensated care.

Several commenters requested that CMS use the most recent estimates available and update them in a timely manner. The commenters also requested that CMS account for any legislative or policy changes that may have an effect on the uninsurance rate during FY 2018.

Several commenters expressed concern about the sustainability of continued reductions to aggregate uncompensated care payments due to the application of Factor 2. The commenters noted that, as insurance coverage increases, the aggregate amount available for uncompensated care payments will decline and thus reduce the amount of payments to be made.

Response: We appreciate the commenters' support for our proposal to begin using the uninsured estimates produced by OACT in the computation of Factor 2 for FY 2018. Section 1886(r)(2)(B)(ii) of the Act permits us to use a data source other than CBO estimates to determine the percent change in the rate of uninsurance beginning in FY 2018. We believe that the NHEA data, on balance, best meet all of our considerations to ensure that the data source meets the statutory requirement that the estimate be based on data from the Census Bureau or other sources the Secretary determines appropriate and will provide reasonable estimates of the rate of uninsurance that are available in conjunction with the IPPS rulemaking cycle. In the FY 2018 IPPS/LTCH PPS proposed rule, we provided additional information regarding the data sources, methods, and assumptions employed by the actuaries in determining the OACT's updated estimate of Factor 2 for FY 2018. We believe that this discussion addresses the concerns raised by commenters regarding the various assumptions used in the estimate. Regarding the assumption of undercount for Medicaid enrollees in surveys, we refer readers to research by Michael Davern, et al. as cited by the NHEA's Methodology Paper available on the CMS Web site at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/DSM-15.pdf*. With respect to the commenters' request to retrospectively apply the NHEA estimates when measuring the effect of changes in Medicare DSH policy, section 1886(r)(2)(B)(ii) of the Act states that, for FY 2018 and subsequent fiscal years, Factor 2 is determined by comparing the percent of individuals who were uninsured in 2013, as

estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS, and the percent of individuals who were uninsured in the most recent period for which data are available, as so estimated and certified. Because the statute specifies the use of these estimates only for FY 2018 and subsequent years, and section 1886(r)(2)(B)(i) of the Act expressly requires the use of CBO estimates for prior fiscal years, we do not believe that we have authority to use the NHEA data to retroactively recalculate uninsurance rates for previous years.

In response to the commenters who requested that we update the estimates and account for any legislative or policy changes that may affect the uninsurance rate in FY 2018, in the FY 2018 IPPS/LTCH PPS proposed rule, we indicated that we considered timeliness and accuracy when selecting the NHEA as the appropriate data on which to base our estimates of the rate of uninsurance. Furthermore, we continue to believe that applying our best estimate of the change in the rate of uninsurance for a fiscal year prospectively would be most conducive to administrative efficiency, finality, and predictability in payments.

Finally, in response to concerns about the decrease in the amount available to make uncompensated care payments, we believe that the intent of the statute is to reduce the amount available to make uncompensated care payments to reflect the decline in the number of uninsured individuals and the expected corresponding decrease in the amount of uncompensated care.

After consideration of the public comments we received, we are finalizing the proposed calculation of Factor 2 for this FY 2018 IPPS/LTCH PPS final rule. The estimates of the percent of uninsured individuals have been certified by the Chief Actuary of CMS as discussed in the proposed rule. The final calculation using a weighted average of OACT's projections for CY 2017 and CY 2018 is as follows:

- Percent of individuals without insurance for CY 2013: 14 percent.
- Percent of individuals without insurance for CY 2017: 8.3 percent.
- Percent of individuals without insurance for CY 2018: 8.1 percent.
- Percent of individuals without insurance for FY 2018 (0.25 times 0.083) + (0.75 times 0.081): 8.15 percent

$1 - |((0.0815 - 0.14)/0.14)| = 1 - 0.4179 =$ 0.5821 (58.21 percent)

0.5821 (58.21 percent) − .002 (0.2 percentage points for FY 2018 under section 1886(r)(2)(B)(ii) of the Act) = 0.5801

0.5801 = Factor 2

Therefore, the final Factor 2 for FY 2018 is 58.01 percent.

The FY 2018 final uncompensated care amount is: $11,664,704,643.27 × 0.5801 = $6,766,695,163.56.

FY 2018 Uncompensated Care Total Available ...	$6,766,695,163.56

c. Calculation of Factor 3 for FY 2018

(1) Background

Section 1886(r)(2)(C) of the Act defines Factor 3 in the calculation of the uncompensated care payment. As we have discussed earlier, section 1886(r)(2)(C) of the Act states that Factor 3 is equal to the percent, for each subsection (d) hospital, that represents the quotient of (1) the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data (including, in the case where the Secretary determines alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating the uninsured, the use of such alternative data)); and (2) the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act for such period (as so estimated, based on such data).

Therefore, Factor 3 is a hospital-specific value that expresses the proportion of the estimated uncompensated care amount for each subsection (d) hospital and each subsection (d) Puerto Rico hospital with the potential to receive Medicare DSH payments relative to the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the fiscal year for which the uncompensated care payment is to be made. Factor 3 is applied to the product of Factor 1 and Factor 2 to determine the amount of the uncompensated care payment that each eligible hospital will receive for FY 2014 and subsequent fiscal years. In order to implement the statutory requirements for this factor of the uncompensated care payment formula, it was necessary to determine: (1) The definition of uncompensated care or, in other words, the specific items that are to be included in the numerator (that is, the estimated uncompensated care amount for an individual hospital) and the denominator (that is, the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the applicable fiscal year); (2) the data source(s) for the estimated uncompensated care amount; and (3) the timing and manner of computing the quotient for each hospital estimated to receive Medicare DSH payments. The statute instructs the Secretary to estimate the amounts of uncompensated care for a period based on appropriate data. In addition, we note that the statute permits the Secretary to use alternative data in the case where the Secretary determines that such alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured.

In the course of considering how to determine Factor 3 during the rulemaking process for FY 2014, we considered defining the amount of uncompensated care for a hospital as the uncompensated care costs of each hospital and determined that Worksheet S–10 of the Medicare cost report potentially provides the most complete data regarding uncompensated care costs for Medicare hospitals. However, because of concerns regarding variations in the data reported on Worksheet S–10 and the completeness of these data, we did not propose to use data from Worksheet S–10 to determine Factor 3 for FY 2014, the first year this provision was in effect, or for FY 2015, 2016, or 2017. When we first discussed using Worksheet S–10 to allocate hospitals' shares of uncompensated care costs in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50638), we explained why we believed that it was premature to use uncompensated care costs reported on Worksheet S–10 for FY 2014. Specifically, at that time, the most recent available cost reports would have been from FYs 2010 and 2011, which were submitted on or after May 1, 2010, when the new Worksheet S–10 went into effect. We believed that concerns about the standardization and completeness of the Worksheet S–10 data could be more acute for data collected in the first year of the Worksheet's use (78 FR 50635). In addition, we believed that it would be most appropriate to use data elements that have been historically publicly available, subject to audit, and used for payment purposes (or that the public understands will be used for payment purposes) to determine the amount of uncompensated care for purposes of Factor 3 (78 FR 50635). At the time we issued the FY 2014 IPPS/LTCH PPS final rule, we did not believe that the available data regarding uncompensated care from Worksheet S–10 met these criteria and, therefore, we believed they were not reliable enough to use for determining FY 2014 uncompensated care payments. Accordingly, for FY

2014, we concluded that utilization of insured low-income patients would be a better proxy for the costs of hospitals in treating the uninsured. For FYs 2015, 2016, and 2017, the cost reports used for calculating uncompensated care payments (that is, FYs 2011, 2012, and 2013) were also submitted prior to the time that hospitals were on notice that Worksheet S–10 could be the data source for calculating uncompensated care payments. Therefore, we believed it was also appropriate to use proxy data to calculate Factor 3 for these years.

We stated in the preamble of the FY 2017 IPPS/LTCH PPS proposed rule that we believed that, for FY 2018, many of the above concerns would no longer be relevant. That is, hospitals were on notice as of FY 2014 that Worksheet S–10 could eventually become the data source for CMS to calculate uncompensated care payments. Furthermore, hospitals' cost reports from FY 2014 had been publicly available for some time, and CMS had analyses of Worksheet S–10 conducted both internally and by stakeholders demonstrating that Worksheet S–10 accuracy had improved over time. Specifically, as discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25090), MedPAC has provided analyses that found that current Worksheet S–10 data are a better proxy for predicting audited uncompensated care costs than Medicaid/Medicare SSI days, and that the data on Worksheet S–10 would improve over time as the data are actually used to make payments. CMS has also undertaken an extensive analysis of the Worksheet S–10 data, benchmarking it against the data on uncompensated care costs reported to the Internal Revenue Service (IRS) on Form 990 by not-for-profit hospitals. (This analysis, performed by Dobson DaVanzo & Associates, LLC, under contract to CMS, was included in a report entitled ''Improvements to Medicare Disproportionate Share Hospital (DSH) Payments Report: Benchmarking S–10 Data Using IRS Form 990 Data and Worksheet S–10 Trend Analyses,'' which is available on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html* under the Downloads section.) The analysis determined a strong and converging correlation between the amounts for Factor 3 derived using the IRS Form 990 and Worksheet S–10 data, suggesting that Worksheet S–10 uncompensated care data are becoming more stable over time. As we discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19947 through 19948), given these results and in light of the fact that hospitals have been on notice since the FY 2014 rulemaking that CMS intended eventually to use Worksheet S–10 as the data source for calculating uncompensated care payments, we believed it would be appropriate to propose to begin incorporating Worksheet S–10 data for purposes of calculating Factor 3 starting in FY 2018. In section IV.F.4.d. of the preamble of the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25090 through 25094), we proposed a methodology and timeline for incorporating Worksheet S–10 data in the calculation of Factor 3 beginning in FY 2018 and invited public comments on that proposal.

While some commenters, including MedPAC, were supportive of the proposal, many other commenters expressed concerns about a perceived lack of clarity in the Worksheet S–10 instructions and their belief in the necessity of a strict audit mechanism to capture aberrant uncompensated care costs reported on Worksheet S–10. Many commenters also cited the report from Dobson DaVanzo, which concluded that hospitals are doing a better job of reporting their uncompensated care data on Worksheet S–10 than they did a few years ago. However, these commenters disagreed with CMS about the significance of this observation. One commenter stated that even if it is true in the aggregate that hospitals are reporting data more accurately on Worksheet S–10, the zero-sum nature of the calculation of uncompensated care payments is such that the remaining inaccuracy and lack of uniformity in the data reported can have a very large impact on hospitals. The commenter asserted that if hospitals, for whatever reason, over-report their uncompensated care, they benefit financially from doing so, while those that do not aggressively report suffer financial harm. The commenter concluded that, for this reason, the possibility that some hospitals are generally ''doing better'' with reporting data is not good enough. All hospitals must do better, and until they do, the commenter believed that data from Worksheet S–10 are not accurate enough for public policymaking purposes. Other commenters asserted that the Dobson/DaVanzo study did not illustrate or even evaluate whether data from Worksheet S–10 are a reasonable proxy for the costs hospitals incur in providing care to the uninsured. These commenters pointed to their own analyses, which indicated that the most notable aberrations in Worksheet S–10 data reporting occur among public hospitals, which do not file a Form 990 and are therefore missing from the Dobson/DaVanzo analysis.

On balance, after considering all of the comments, we elected not to finalize our proposal to begin to incorporate Worksheet S–10 into the calculation of Factor 3 for FY 2018 in the FY 2017 IPPS/LTCH PPS final rule. We stated that we were postponing the decision regarding when to begin incorporating data from Worksheet S–10 and proceeding with certain additional quality control and data improvement measures to the Worksheet S–10 instructions as commenters had requested. We indicated that we would consider further whether the current Worksheet S–10 data or a proxy should be used to calculate Factor 3 for FY 2018 and subsequent fiscal years. We also expressed our intention to explore whether there is an appropriate proxy for uncompensated care that could be used to calculate Factor 3 until we determine that data from the revised Worksheet S–10 can be used for this purpose. We stated that we would undertake notice-and-comment rulemaking to address the issue of the appropriate data to use to determine Factor 3 for FY 2018 and subsequent years.

(2) Data Sources for FY 2018

Since the publication of the FY 2017 final rule and as part of our ongoing quality control and data improvement measures for Worksheet S–10, we have updated the benchmarking analysis described in the report ''Improvements to Medicare Disproportionate Share Hospital (DSH) Payments Report: Benchmarking S–10 Data Using IRS Form 990 Data and Worksheet S–10 Trend Analyses'' posted with the FY 2017 IPPS/LTCH PPS proposed rule. A copy of the updated analysis was made available in conjunction with the FY 2018 IPPS/LTCH PPS proposed rule on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/FY2018-NPRM-Update-of-Benchmarking-S-10-Data.pdf*. As discussed in the FY 2017 IPPS/LTCH PPS proposed rule, the purpose of the benchmarking analysis was to determine if Worksheet S–10 uncompensated care data are becoming more stable over time (81 FR 25090). In the report issued in conjunction with the FY 2017 rulemaking, we conducted an analysis of 2010, 2011, and 2012 Worksheet S–10 data and IRS Form 990 data from the same years. Using IRS Form 990 data for tax years 2010, 2011, and 2012 (the latest available years at

that time) as a benchmark, we compared key variables derived from Worksheet S–10 and IRS Form 990 data, such as charity care and bad debt. The analysis was completed using data from hospitals that had completed both Worksheet S–10 and IRS Form 990 across all study years, yielding a sample of 788 not-for-profit hospitals (representing 668 unique Taxpayer Identification Numbers). Because Factor 3 is used to determine the Medicare uncompensated care payment amount for each hospital, we calculated the amounts for Factor 3 for the matched hospitals using charity care and bad debt, and compared the Factor 3 distributions calculated using data from IRS Form 990 and Worksheet S–10. Key findings indicated that the amounts for Factor 3 derived using the IRS Form 990 and Worksheet S–10 data were highly correlated. In addition, the correlation coefficient between the amounts for Factor 3 calculated from the IRS Form 990 and Worksheet S–10 had increased over time, from 0.71 in 2010 to 0.77 in 2011 and 0.80 in 2012, demonstrating an increasing convergence between the data sources.

As we discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19949), in the updated analysis performed for the FY 2018 rulemaking, we again compared Worksheet S–10 and IRS Form 990 data and assessed the correlation in Factor 3s derived from each of the data sources. We conducted an analysis of 2011, 2012, and 2013 Worksheet S–10 data and IRS Form 990 data from the same years. (The previous analysis used data from 2010 to 2012.) Using IRS Form 990 data for tax years 2011, 2012, and 2013 (again, the latest available years) as a benchmark, we utilized the same methodology as was used in the previous analysis, which yielded a sample of 1,061 not-for-profit hospitals (representing 918 unique Taxpayer Identification Numbers) and found that the amounts for Factor 3 derived using the IRS Form 990 and Worksheet S–10 data continue to be highly correlated and that, within the larger sample in the updated analysis, this correlation continues to increase over time, from 0.80 in 2011 to 0.85 in 2013. (The highest correlation found in the earlier analysis performed for the FY 2017 rulemaking was 0.80.)

The fact that this most recent analysis, which was performed after the issuance of the FY 2017 IPPS/LTCH PPS final rule, continues to demonstrate a high correlation between the amounts for Factor 3 derived using the IRS 990 data and the Worksheet S–10 data and that this correlation continues to increase over time leads us to believe that we have reached a tipping point with respect to the use of the Worksheet S–10 data. Specifically, we can no longer conclude that alternative data are available for FY 2014 that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured than the data on uncompensated care costs reported on the Worksheet S–10. However, we stated in the proposed rule that we continue to believe that it is appropriate to use low-income insured days as a proxy for uncompensated care costs for years prior to FY 2014. Hospitals did not have notice that the Worksheet S–10 data from these years might be used for purposes of computing uncompensated care payments and, as a result, may not have fully appreciated the importance of reporting their uncompensated care costs as completely and accurately as possible.

We found further evidence for this tipping point when we examined changes to the FY 2014 Worksheet S–10 data submitted by hospitals since the publication of the FY 2017 IPPS/LTCH PPS final rule. In the FY 2017 IPPS/LTCH PPS final rule, as part of our ongoing quality control and data improvement measures for the Worksheet S–10, we referred readers to Change Request 9648, Transmittal 1681, titled ''The Supplemental Security Income (SSI)/Medicare Beneficiary Data for Fiscal Year 2014 for Inpatient Prospective Payment System (IPPS) Hospitals, Inpatient Rehabilitation Facilities (IRFs), and Long Term Care Hospitals (LTCH),'' issued on July 15, 2016 (available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1681OTN.pdf*). In this transmittal, as part of the process for ensuring complete submission of Worksheet S–10 by all eligible DSH hospitals, we instructed MACs to accept amended Worksheets S–10 for FY 2014 cost reports submitted by hospitals (or initial submissions of Worksheet S–10 if none had been submitted previously) and to upload them to the Health Care Provider Cost Report Information System (HCRIS) in a timely manner. The transmittal stated that, for revisions to be considered, hospitals were required to submit their amended FY 2014 cost report containing the revised Worksheet S–10 (or a completed Worksheet S–10 if no data were included on the previously submitted cost report) to the MAC no later than September 30, 2016.

As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19949), we examined hospitals' FY 2014 cost reports to see if the Worksheet S–10 data on those cost reports have changed as a result of the opportunity for hospitals to submit revised Worksheet S–10 data for FY 2014. Specifically, we compared hospitals' FY 2014 Worksheet S–10 data as they existed in the first quarter of CY 2016 with data from the fourth quarter of CY 2016. We found that the FY 2014 Worksheet S–10 data had changed over that time period for approximately one quarter of hospitals that receive uncompensated care payments. As we discussed in the proposed rule, the fact that the Worksheet S–10 data changed for such a significant number of hospitals following a review of the cost report data they originally submitted and that the revised Worksheet S–10 information is available to be used in determining uncompensated care costs contributes to our belief that we can no longer conclude that alternative data are available that are a better proxy than the Worksheet S–10 data for the costs of subsection (d) hospitals for treating individuals who are uninsured.

Commenters have also provided equity arguments with respect to the relationship between uncompensated care payments and the expansion of Medicaid in certain States under the authority provided by the Affordable Care Act. The commenters have made a twofold argument. First, they have argued that hospitals in States that did not expand Medicaid treat a higher number of uninsured patients compared to hospitals in States that did expand Medicaid and, as a result, provide more uncompensated care. However, since the implementation of the new DSH payment methodology under section 3133 of the Affordable Care Act in FY 2014, these hospitals have experienced reductions in the payments for uncompensated care due to the national decline in the uninsured rate driven in large part by Medicaid expansions in other States. Second, they have argued that hospitals in nonexpansion States will be penalized a second time when Medicaid utilization is used as part of the basis for determining Factor 3 because their Medicaid utilization has not grown as much relative to hospitals in expansion States. Although CMS has not yet used data affected by Medicaid expansion when determining Factor 3, commenters are concerned that they will be penalized in future calculations when these data are used.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50639), we recognized that, in using Medicaid days as part of the proxy for uncompensated care, it would be possible for hospitals in States that choose to expand Medicaid to receive higher uncompensated care payments because they may have more Medicaid

patient days than hospitals in a State that does not choose to expand Medicaid. Because the earliest Medicaid expansions under the Affordable Care Act began in 2014, the 2011, 2012, and 2013 Medicaid days data used to determine Factor 3 for FY 2017 are the most recent available data on Medicaid utilization that do not reflect the effects of these Medicaid expansions. Accordingly, if we were to use only low-income insured days to estimate uncompensated care in FY 2018, we would need to hold the time period of these data constant and use data on Medicaid days from 2011, 2012, and 2013 in order to avoid the risk of any redistributive effects arising from the decision to expand Medicaid in certain States. As a result, we would be using older data that may provide a less accurate proxy for the level of uncompensated care being furnished by hospitals in FY 2018, contributing to our growing concerns regarding the continued use of low-income insured days as a proxy for uncompensated care costs in FY 2018.

In the proposed rule, we also noted that when weighing the new information that has become available to us regarding the Worksheet S–10 and the low-income days proxy since the FY 2018 rulemaking, we are not considering these developments in isolation, but rather in the context of the information that we previously considered as part our discussions of the Worksheet S–10 data in prior rulemaking. Part of this background is provided by the 2007 MedPAC analysis of data from the Government Accountability Office (GAO) and the American Hospital Association (AHA), which suggests that Medicaid days and low income Medicare days are not a good proxy for uncompensated care costs (80 FR 49525). Additional analyses performed by MedPAC showed that the correlation between audited uncompensated care data from 2009 and the data from the FY 2011 Worksheet S–10 was over 0.80, as compared to a correlation of approximately 0.50 between the audited uncompensated care data and 2011 Medicare SSI and Medicaid days. Based on this analysis, MedPAC concluded that use of Worksheet S–10 data was already better than using Medicare SSI and Medicaid days as a proxy for uncompensated care costs, and that the data on Worksheet S–10 would improve over time as the data are actually used to make payments (81 FR 25090). Furthermore, MedPAC in the past has raised concerns about the low-income days proxy we have used historically because it is an inpatient measure and much of the uncompensated care provided by certain hospitals, including rural hospitals, occurs in the emergency room or other outpatient areas. In its comments on the FY 2017 IPPS/LTCH PPS proposed rule, MedPAC again recommended that we start using the Worksheet S–10 data with a phase-in (81 FR 56962).

In summary, as we stated in the FY 2018 IPPS/LTCH PPS proposed rule, when weighing the new information that has become available to us since the FY 2017 rulemaking in conjunction with the information regarding Worksheet S–10 data and the low-income days proxy that we have analyzed as part of our consideration of this issue in prior rulemaking, we can no longer conclude that alternative data to the Worksheet S–10 are available for FY 2014 that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured.

Comment: Many commenters expressed disapproval that CMS ''backtracked'' on its decision in the FY 2017 IPPS/LTCH PPS final rule to postpone incorporating data from Worksheet S–10 into the calculation of Factor 3 and voiced their confusion and surprise over the apparent change in policy. These commenters noted that CMS' position in the FY 2017 IPPS/LTCH PPS final rule was that additional time was needed to make certain modifications and clarifications to the cost report instructions for Worksheet S–10, as well as to explore suggestions made by commenters in previous years for ensuring the consistent submission of Worksheet S–10 by hospitals when filing their cost reports (such as software edits to flag negative, unusual, or missing data or a missing Worksheet S–10). They added that CMS stated that this postponement also allowed time for hospitals to more accurately complete and submit the form. The commenters observed that CMS' stated intent in the FY 2017 IPPS/LTCH PPS final rule was to begin to incorporate Worksheet S–10 data into the computation of Factor 3 once these additional measures to ensure data quality and completeness are in place, and no later than FY 2021, yet CMS had reversed this decision by proposing to use Worksheet S–10 data from FY 2014 in the calculation of Factor 3 for FY 2018 in the FY 2018 IPPS/LTCH PPS proposed rule.

Response: We appreciate the comments regarding our proposal to begin using data from Worksheet S–10 in the calculation of Factor 3 in FY 2018. As stated in the FY 2018 IPPS/LTCH PPS proposed rule and explained in greater detail below, when weighing the new information that has become available to us since the FY 2017 rulemaking, in conjunction with the information regarding Worksheet S–10 data and the low-income days proxy that we have analyzed as part of our consideration of this issue in prior rulemaking, we can no longer conclude that alternative data to the Worksheet S–10 are available for FY 2014 that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured.

Comment: Several commenters approved of CMS' proposal to begin using data from Worksheet S–10 in the calculation of Factor 3 prior to FY 2021. MedPAC stated that using Worksheet S–10 data, in conjunction with select auditing of cost reports, will lead to better estimates of uncompensated care costs than the continued use of the current proxy of Medicaid and SSI days. Other commenters echoed MedPAC's statement, noting that the metrics from Worksheet S–10 appear to provide a better assessment of a hospital's uncompensated care costs than the current proxy data, which assess only low-income insured days and distribute the bulk of Medicare DSH payments based on the amount of inpatient care a hospital delivers to Medicaid patients and recipients of SSI payments. One commenter cited the December 2016 article in *Health Affairs* (Stensland, *et al.*), which estimated that Medicare payments on average are reduced by $20 for every additional uninsured patient a hospital treats, to support the argument that the distribution of uncompensated care payments according to a hospital's proportion of low-income insured days results in payments that are poorly correlated with a hospital's true uncompensated care burden. The commenter asserted that uncompensated care payments should compensate hospitals based on their delivery of care to the uninsured rather than based on a proxy that is poorly correlated with the costs of treating the uninsured.

As in previous years, commenters also believed that the proposed methodology for FY 2018 brings parity and equity across the States, regardless of their decision to expand Medicaid. Commenters stated that implementation of the proposal to use data from Worksheet S–10 will create more balance between Medicaid expansion and nonexpansion States, especially because hospitals in nonexpansion States are ''at a significant disadvantage'' under the current proxy methodology. The commenters noted that, under the current methodology used to calculate Factor 3, hospitals in

nonexpansion States bear a greater uncompensated care burden, yet are effectively penalized in Medicare DSH allocations twice: First, because they incur a reduction in the total amount available to be distributed as uncompensated care payments based on the national decline in the uninsured rate that largely reflects the experience of expansion States; and second, because their Medicaid utilization rates remain relatively flat compared to the increasing rates of hospitals in expansion States, resulting in lower uncompensated care payments. These commenters believed that FY 2018 is an appropriate time to transition to Worksheet S–10, as CMS proposed, using an average of 2 years of Medicaid and SSI days data in conjunction with 1 year of Worksheet S–10 data that eliminates the use of the low-income insured days proxy for FY 2014 when many States expanded Medicaid. Furthermore, as proposed, the amount available for uncompensated care payments would increase by approximately $1 billion in FY 2018, which helps mitigate the financial impact of transitioning to Worksheet S–10 data for hospitals treating higher numbers of Medicaid and SSI patients and fewer uninsured patients.

In response to arguments that further refinement of Worksheet S–10 is needed, one commenter pointed to separate evaluations performed by MedPAC and the consulting firm Dobson DaVanzo, which both found a high degree of correlation between data reported on Worksheet S–10 and audited uncompensated care data, as evidence that the information currently reported on Worksheet S–10 is satisfactory for purposes of allocating uncompensated care payments. The commenter argued that while CMS should continue to refine the instructions for Worksheet S–10, the transition from the proxy of low-income insured days to Worksheet S–10 as a method of allocating uncompensated care payments will never take place if CMS postpones the transition until the Worksheet S–10 data are perfect. The commenter stated that, despite years of refinements, Medicare has yet to achieve perfection in the Medicare cost report data; nevertheless, there are various examples throughout the Medicare inpatient PPS in which payments are made based on the best available information from the Medicare cost report. This commenter was troubled that CMS had delayed the implementation of Worksheet S–10 until no later than FY 2021 in the FY 2017 IPPS/LTCH PPS final rule, and encouraged CMS to finalize its proposal to begin incorporating Worksheet S–10 data in the calculation of Factor 3 for FY 2018.

Response: We appreciate the support for our proposal to begin to incorporate Worksheet S–10 data into the computation of Factor 3 for FY 2018. We agree with the commenters that FY 2018 is an appropriate time to begin using Worksheet S–10 data in the calculation of Factor 3 due to a confluence of factors, including evidence that the Worksheet S–10 data are improving over time and concerns that the proxy data for FY 2014 and subsequent years will reflect the effects of Medicaid expansion. As we stated in the FY 2018 IPPS/LTCH PPS proposed rule, we can no longer conclude that alternative data to the Worksheet S–10 are available for FY 2014 that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. We also acknowledge that the approximately $800 million increase in the total amount available to make uncompensated care payments will help to mitigate the impact of this change on hospitals that serve a large number of Medicaid and SSI patients and fewer uninsured patients.

Comment: Many commenters opposed the use of Worksheet S–10 to compute Factor 3 and allocate uncompensated care costs beginning in FY 2018. Most of these commenters maintained their position from previous years that, while Worksheet S–10 has the potential to serve as a more exact measure of hospital uncompensated care costs, the data reported are not presently a reliable and accurate reflection of these uncompensated care costs. These commenters disagree with CMS that the agency has reached a ''tipping point'' and shared observations that they believe refute each of the factors cited in the FY 2018 IPPS/LTCH PPS proposed rule as a reason to begin using Worksheet S–10 data. Overall, commenters stated that the rationale provided by CMS for transitioning to the use of data from Worksheet S–10—that the accuracy of the data has improved over time—was not sufficient to justify the transition.

With respect to the Dobson DaVanzo report, which showed a strong correlation between Factor 3 values derived from data reported on IRS 990 Schedule H and Worksheet S–10, several commenters noted limitations that they believe should be taken into consideration when using these findings to support the use of Worksheet S–10 data. Commenters noted that a simple correlation between two data sources that have not been reviewed for accuracy does not support the statistical validity of the uncompensated care data reported on Worksheet S–10. Furthermore, commenters noted that because the data from IRS 990 do not include for-profit and government hospitals, the sample used in the analysis is not representative of the universe of hospitals receiving Medicare DSH payments and therefore presents biased results. One commenter observed that the analysis overrepresents certain States and underrepresents other States. Another commenter noted some specific line items that illustrate inconsistencies between the IRS 990 data and the S–10 data. For example, the commenter stated that in tax year 2011, the IRS 990 Schedule H changed such that bad debt expense is no longer reported at cost, and filing organizations were no longer instructed to multiply bad debt expense by their CCR, a change that is not reflected in the Worksheet S–10 instructions and which the Dobson analysis does not take into consideration.

Commenters continued to express concerns about the lack of accurate and consistent data being reported on Worksheet S–10, primarily due to what they perceive as a lack of clear and concise line level instructions. Commenters pointed out that, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56963), CMS agreed to institute certain additional quality control and data improvement measures prior to moving forward with incorporating Worksheet S–10 data into the calculation of Factor 3. However, the commenters pointed out that, aside from a brief window in 2016 for hospitals to submit corrected data on their FY 2014 Worksheet S–10 by September 30, 2016, and the issuance of revised instructions (Transmittal 10) in November 2016 that are applicable to cost reports beginning on or after October 1, 2016, no additional quality control and data improvement measures have been implemented. Furthermore, commenters asserted that the clarifications and guidance with respect to the instructions for Worksheet S–10 issued by CMS are not sufficient to ensure consistent submission of uncompensated care data, and that the 25 percent of hospitals that either resubmitted their FY 2014 Worksheet S–10 or provided a missing FY 2014 Worksheet S–10 do not present significant evidence that the problems with Worksheet S–10 reporting have been resolved. One commenter took issue with CMS' statement in the proposed rule that it does not anticipate making any further modifications to the

instructions for completing Worksheet S–10 at this time, and asserted that hospitals should have the benefit of a final rule and instructions that can be referenced in completing Worksheet S–10 data for future cost reports, ensuring accuracy, consistency and completeness.

Because many commenters were concerned that unclear reporting instructions on Worksheet S–10 would result in inconsistent and inaccurate reporting of data, commenters requested that, after more precise instructions are provided, CMS apply a strict auditing process for information reported on the Worksheet S–10 before it is used to determine uncompensated care costs. The commenters believed that simply tying information reported on Worksheet S–10 to payment and requiring its regular use will not improve the accuracy of the data. In addition, commenters requested that CMS ensure that its contractors administer an auditing process consistently and make the instructions for such an audit public. To support their claim that auditing is needed, many commenters shared observations regarding anomalies they identified in data from Worksheet S–10 and associated concerns. A number of commenters shared their own analyses that looked at the small proportion of hospitals receiving a large share of uncompensated care payments, and the proportion of hospitals that reported aberrant data relating to uncompensated care costs. The commenters stated that the aberrant numbers reported by some hospitals illustrate some combination of misinterpretation of Worksheet S–10 instructions, lack of clarity of those instructions, and possible attempts by providers to maximize their Medicare DSH dollars.

MedPAC also commented that a hospital's charges may have errors that could result in overstating uncompensated care costs. To limit the effect of aberrant charges, MedPAC suggested that CMS could screen out Worksheet S–10 data where there were high levels of reported uncompensated care relative to total operating costs reported on the cost report (for example, 50 percent of operating costs). MedPAC expected that very few hospitals would report uncompensated care costs in excess of this threshold. For hospitals that did exceed this threshold, MedPAC suggested using 2015 Worksheet S–10 data if they were available. If the hospital insisted that the 2014 data were correct, MedPAC suggested that CMS require the hospital to provide support for the 2014 data. If the hospital did not provide audited financial statements supporting the uncompensated care reported, MedPAC suggested that the reported uncompensated care could be reduced down to a threshold of 50 percent of operating costs. Other commenters also discussed examining the ratio of the reported uncompensated care to total operating costs to identify aberrant data. They provided additional ratio examples such as uncompensated care costs relative to total revenue, operating budget, Worksheet C total costs, or Worksheet C total charges. Some commenters suggested that CMS adopt an empirically derived upper threshold for the ratio of uncompensated care costs to operating costs, and then prioritize those hospitals that exceeded the threshold for audit purposes. One commenter's example of an empirically derived threshold was 3 standard deviations from the mean for the ratio of uncompensated care costs to total operating costs.

The majority of the commenters who opposed the use of Worksheet S–10 in FY 2018 stated that the low-income insured days proxy is more accurate than Worksheet S–10 in its current form. They suggested that CMS should continue to use this proxy on a temporary basis to distribute uncompensated care payments until the data from Worksheet S–10 are more reliable, or CMS should consider using a methodology that utilizes a permanent blend of data from Worksheet S–10 and low-income insured days. Some commenters believed that the proposed methodology for calculating Factor 3 in FY 2018, which excludes Medicaid shortfalls from the calculation of uncompensated care costs, could lead to a huge inequity, as there would be a substantial redistribution of Medicare DSH payments from Medicaid expansion States to non-expansion States. While one commenter referred to CMS' potential legal concern about continuing to use low-income insured days as a proxy for uncompensated care for FY 2014 and subsequent years, several commenters and their outside counsel concluded that CMS has the authority to ''fashion an 'appropriate' calculation using proxy data as it has already been doing for three years, adjusted proxy data or blended data.''

Commenters stated that using uncompensated care data from Worksheet S–10 for computing uncompensated care payments would be highly redistributive, with many hospitals experiencing significant swings in their payments. Commenters noted that using data from Worksheet S–10 to calculate Factor 3, as opposed to using the current low-income insured days proxy, has serious implications for entire States. Many commenters noted that the States that would lose uncompensated care dollars are States that have expanded their Medicaid programs, as the current proxy captures Medicaid days and the Worksheet S–10 does not. One analysis showed that the Worksheet S–10 data would be highly redistributive to the extent that 10 percent of hospitals would receive 77 percent of total gains in uncompensated care payments among all hospitals, while other hospitals would experience significant losses. One commenter indicated that the losses it anticipates if the proposal to incorporate data from the Worksheet S–10 in FY 2018 is finalized will not only hamper its system's ability to provide care through different service lines, but will also affect its ability to participate in different types of value-based purchasing programs. Another commenter noted that the cuts CMS outlines also are far more redistributive than had been intended when the Affordable Care Act was enacted in 2010 prior to the Supreme Court ruling that rendered Medicaid expansion optional.

Response: We thank the commenters for their input. In previous rulemaking cycles, commenters, both in favor of and opposed to use of a proxy for calculation of Factor 3, requested that CMS provide a timeline and implementation process for when and how the Worksheet S–10 data would be used for determining uncompensated care costs (for example, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49524)). We note that we have been receiving such requests since the rulemaking for the FY 2014 IPPS/LTCH PPS final rule, and that hospitals have been on notice since FY 2014 that Worksheet S–10 could eventually become the data source for computing Factor 3. With this in mind, and based on the growing evidence that Worksheet S–10 is improving over time, we proposed to begin incorporating Worksheet S–10 data from FY 2014 cost reports into the calculation of Factor 3 for FY 2018.

We understand the commenters' concerns about the limitations of the IRS 990 correlation analysis and the shortcomings of using the study findings to support assertions about the validity of the Worksheet S–10 data. Notwithstanding those limitations, a few commenters supported the findings and the use of Worksheet S–10 in FY 2018. Although we acknowledge that the analysis was limited to not-for-profit hospitals, we believe it is relevant to our assessment of the overall quality of the data reported on Worksheet S–10.

Because many not-for-profit hospitals are eligible for empirically justified Medicare DSH payments and, therefore, uncompensated care payments, we believe they represent a suitable standard of comparison. Furthermore, as stated in the proposed rule, we did not make the decision to propose to begin Worksheet S–10 implementation in FY 2018 based on the correlation analysis alone. MedPAC also submitted an analysis that corroborated the results of the Dobson DaVanzo report, showing a high level of correlation between audited uncompensated care data and uncompensated care costs reported on Worksheet S–10 and a lower correlation between the audited uncompensated care data and Medicaid and SSI days.

After considering the comments submitted by MedPAC and others regarding the potential for aberrant data to be reported on the Worksheet S–10, we agree that using the ratio of uncompensated care costs to total operating costs to identify potentially aberrant data when determining the Factor 3 amounts for FY 2018 has merit. We acknowledge that it is not possible to determine a perfect threshold for when this ratio reflects potentially aberrant data. However, after a review of the comments received, we do not believe that it is appropriate to have no threshold, nor do we believe that it is appropriate to delay beginning to incorporate the Worksheet S–10 data in the calculation of Factor 3 in pursuit of a perfect threshold. It is relatively straightforward to identify the extreme end of the spectrum of possible threshold values: it does not appear to us to be reasonable for a hospital to have uncompensated care costs that exceed all of its operating expenses (that is, a threshold of 100 percent or more). Using the data currently available to us, we have attempted to determine the most appropriate threshold above which it would be reasonable to believe that aberrant uncompensated care data may have been reported. While we do not want to include aberrant data in the determination of Factor 3, we also do not want to inappropriately reduce FY 2018 uncompensated care payments to a hospital with a legitimately high ratio. Weighing all of these considerations, we believe it is appropriate to adopt MedPAC's suggestion that uncompensated care costs in excess of half a hospital's total operating expenses may be potentially aberrant. In the rare situations where a hospital has a FY 2014 ratio in excess of 50 percent, we also agree with MedPAC and other commenters that it would be appropriate to utilize 2015 data in some manner to address the potentially aberrant 2014 Worksheet S–10 data. As we have previously indicated, we do not believe it would be appropriate to use Worksheet S–10 data from years prior to FY 2014 in the determination of Factor 3. Therefore, the most widely available Worksheet S–10 data available to us if a hospital exceeds the threshold for its FY 2014 Worksheet S–10 data are the FY 2015 Worksheet S–10 data. We believe that when a hospital has reported uncompensated care costs in excess of 50 percent of operating costs, the issue is most likely its FY 2014 uncompensated care costs and not its FY 2014 total operating expenses. Accordingly, we will determine the ratio of FY 2015 uncompensated care costs to FY 2015 total operating expenses from the hospital's FY 2015 cost report and apply that ratio to the FY 2014 total operating expenses from the hospital's FY 2014 cost report to determine an adjusted amount of uncompensated care costs for FY 2014. Under this approach, if a hospital has a consistently high ratio across the 2 years, we are less likely to inappropriately reduce its uncompensated care payments.

However, if a hospital has a much lower ratio in FY 2015, we believe it is reasonable to believe that the data reported for FY 2014 were aberrant. Specifically, after considering the public comments received, for hospitals where the ratio of uncompensated care costs relative to total operating costs for the hospital's 2014 cost report (as reported on Worksheet G, Part 3, Line 4) exceeds 50 percent, we will determine the ratio of uncompensated care costs relative to total operating costs from the hospital's 2015 cost report (as of March 2017) and apply that ratio to the hospital's total operating costs from the 2014 cost report to determine an adjusted amount of uncompensated care costs for FY 2014. We will then substitute this amount for the FY 2014 Worksheet S–10 data when determining Factor 3 for FY 2018. We believe this approach, which affects the data from three hospitals, balances our desire to exclude potentially aberrant data from a small number of hospitals in the determination of Factor 3 with our concern regarding inappropriately reducing FY 2018 uncompensated care payments to a hospital that may have a legitimately high ratio. As discussed elsewhere in this section, we are developing audit protocols for the Worksheet S–10 data for use in future rulemaking. We will consider in future rulemaking whether continued use of this adjustment or an alternative adjustment is necessary for subsequent years.

We appreciate the commenters' concerns relating to the instructions for Worksheet S–10. In November 2016, we issued Transmittal 10, which clarified and revised the instructions for the Worksheet S–10, including the instructions regarding the reporting of charity care charges. Transmittal 10 is available for download on the CMS Web site at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2016-Transmittals-Items/R10P240.html*. In Transmittal 10, we clarified that hospitals may include discounts given to uninsured patients who meet the hospital's charity care criteria in effect for that cost reporting period. This clarification applied to cost reporting periods beginning prior to October 1, 2016, as well as cost reporting periods beginning on or after October 1, 2016. As a result, nothing prohibits a hospital from considering a patient's insurance status as a criterion in its charity care policy. A hospital determines its own financial criteria as part of its charity care policy. The instructions for the Worksheet S–10 set forth that hospitals may include discounts given to uninsured patients, including patients with coverage from an entity that does not have a contractual relationship with the provider, who meet the hospital's charity care criteria in effect for that cost reporting period. In addition, we revised the instructions for the Worksheet S–10 for cost reporting periods beginning on or after October 1, 2016, to provide that charity care charges must be determined in accordance with the hospital's charity care criteria/policy and written off in the cost reporting period, regardless of the date of service. We will continue to work with our stakeholders to address their concerns regarding the reporting of uncompensated care through provider education and refinement of the instructions to the Worksheet S–10.

We also understand the commenters' concerns regarding the effects on hospitals' payments of moving from calculating Factor 3 using a proxy based on low-income days to the use of uncompensated care data from Worksheet S–10. As discussed in prior rulemaking, in using Medicaid and Medicare SSI days as a proxy for uncompensated care, we recognize that it would be possible for hospitals in States that choose to expand Medicaid to receive higher uncompensated care payments because they may have more Medicaid patient days than hospitals in a State that does not choose to expand Medicaid. We believe that the

redistribution of payments from hospitals that serve a greater number of Medicaid patients to hospitals that serve more uninsured patients is consistent with the intent of the Affordable Care Act. However, as described below, we have proposed a methodology that would help to stabilize payments and protect hospitals from undue fluctuations by gradually incorporating Worksheet S–10 data into the calculation of Factor 3. In addition, the approximately $800 million increase in the amount available to be distributed as uncompensated care payments will also help to offset some of the redistributive effects of moving to Worksheet S–10 in FY 2018.

Regarding some commenters' recommendation that we continue to use low-income insured days to calculate Factor 3, either on their own or in a permanent blend with Worksheet S–10 data, we note that the earliest Medicaid expansions under the Affordable Care Act began in 2014. Therefore, in order to insulate the calculation of Factor 3 from the effects of Medicaid expansion, Medicaid days must be drawn from cost reporting periods prior to FY 2014. This prohibits the use of low-income insured days on a permanent basis, as the data will become too old to ensure accuracy. However, the methodology of using 3 years of data to estimate uncompensated care that we first adopted for FY 2017 and that we again proposed for FY 2018 would help to protect hospitals from undue payment fluctuations by using a blend of low-income insured days data and Worksheet S–10 data on a temporary basis.

When all of these factors are taken into consideration, we maintain that we can no longer conclude that alternative data to the Worksheet S–10 are available for FY 2014 that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. We believe that continued use of Worksheet S–10 will improve the accuracy and consistency of the reported data, especially in light of our concerted efforts to allow hospitals to review and resubmit their Worksheet S–10 data for past years and the use of select audit protocols to trim aberrant uncompensated care costs and replace them with more reasonable amounts.

Comment: Many commenters, whether supporting or opposing the eventual use of Worksheet S–10, believed that it was premature to use its data in the calculation of Factor 3 for FY 2018. The commenters noted that, given that data elements used for the distribution of uncompensated care payments must be ''historically publicly available, subject to audit, and used for payment purposes,'' CMS has not met its own criteria for using Worksheet S–10 data to determine the distribution of uncompensated care payments. They stated that this is particularly troublesome because CMS has stated that it does not anticipate completing desk audits of data from Worksheet S–10 until FY 2020.

Most commenters recommended that CMS delay the use of data from Worksheet S–10 for at least 1 year, and up to 3 years, or until CMS has put processes in place to ensure consistent submissions by all hospitals as discussed in the FY 2017 IPPS/LTCH PPS final rule. Specifically, the majority of commenters stated that before Worksheet S–10 data are used, CMS must improve and clarify the instructions for Worksheet S–10 to ensure consistent reporting, and also implement audits of the data from Worksheet S–10.

One commenter suggested that these audits be conducted outside of the regular cost report audit for FY 2014 cost reports to ensure consistency with the Worksheet S–10's cost reporting instructions. The commenter also indicated that CMS may need to develop separate audit protocols for different cost reporting periods, as there are differences between the Worksheet S–10 instructions for cost reporting periods beginning before October 1, 2016 and those beginning on or after that date. The commenter urged CMS to make proposed audit instructions to the MACs available in advance and to gather additional stakeholder input before finalizing an audit approach, and noted that making the instructions available in advance would help the agency to identify issues that need additional refinement. Several commenters suggested that the data be audited in a rigorous manner, similar to wage index data. One commenter provided a list of metrics for CMS to consider including in a guide for MACs for their audits of the Worksheet S–10 data. Several other commenters disagreed with CMS' decision not to share the audit criteria with hospitals, and asked that CMS also release the audit criteria for charity care and non-Medicare bad debt. Similarly, commenters asked that before data from Worksheet S–10 are used, CMS implement additional steps to eliminate outliers, including data that represent unreasonable uncompensated care costs. However, the commenters also noted that CMS must allow hospitals a way to appeal any adjustments made to their data, and that CMS needs to allow a grace period similar to the Medicaid DSH audits before the results of the audit have financial consequences.

Many commenters who urged CMS to delay the use of data from Worksheet S–10 also provided recommendations for CMS to address during the intervening time. Commenters requested that, before Worksheet S–10 data are put to use, CMS further educate hospitals about how to complete the Worksheet S–10 accurately and consistently and allow them to correct their data retroactively. This would include providing hospitals the opportunity to amend previously submitted worksheets for FY 2014 and FY 2015. The commenters emphasized the importance of providing this opportunity because the previous September 30, 2016 deadline for amending 2014 cost reports meant that the revised instructions for the Worksheet S–10 published in November 2016 could not be used because the deadline for resubmission had already passed. In addition, commenters recommended that CMS convene a stakeholder technical advisory group to make Worksheet S–10 data recommendations.

Response: We acknowledge the concerns raised by commenters regarding the use of data from Worksheet S–10 in the calculation of Factor 3 for FY 2018. However, as we stated in the FY 2018 IPPS/LTCH PPS proposed rule, when weighing the new information that has become available to us since the FY 2017 rulemaking in conjunction with the information regarding Worksheet S–10 data and the low-income days proxy that we have analyzed as part of our consideration of this issue in prior rulemaking, we can no longer conclude that alternative data to the Worksheet S–10 are available for FY 2014 that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. We also note that, as part of our ongoing quality control and data improvement measures to continue to improve the Worksheet S–10 data over time, we have revised the cost report instructions and are currently developing an audit process. With respect to the cost reporting instructions, on November 18, 2016, we issued Transmittal 10 which updated the instructions for Form 2552–10. Specifically, we updated the instructions in Section 4012 of Chapter 40 of the Provider Reimbursement Manual, Part II. The instructions clarify the reporting of charity care charges. Transmittal 10 is available for download on the CMS Web site at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2016-Transmittals-Items/R10P240.html*.

With respect to the audit process, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56964), we stated that we intended to provide standardized instructions to the MACs to guide them in determining when and how often a hospital's Worksheet S–10 should be reviewed. We indicated that we would not make the MACs' review protocol public, as all CMS desk review and audit protocols are confidential and are for CMS and MAC use only. The instructions for the MACs are still under development and will be provided to the MACs as soon as possible and in advance of any audit. We refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56964) for a complete discussion concerning the issues that we are considering in developing the instructions that will be provided to the MACs.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19955), we stated our belief that cost reports beginning in FY 2017 will be the first cost reports for which the Worksheet S–10 data will be subject to a desk review. In addition, due to the overwhelming feedback from commenters emphasizing the importance of audits in ensuring the accuracy and consistency of the Worksheet S–10 data, we expect cost reports beginning in FY 2014, FY 2015, and FY 2016 to be subject to further scrutiny after submission.

We will continue to work with our stakeholders to address their concerns through provider education and further refinement of the instructions to the Worksheet S–10 as appropriate.

In reference to allowing hospitals to amend or submit new data for Worksheet S–10 for FYs 2014 and 2015, we note that, as discussed in the FY 2017 IPPS/LTCH PPS final rule, hospitals were given the opportunity to revise and resubmit their data for FY 2014. For revisions to be considered, hospitals were required to submit their amended FY 2014 cost report containing the revised Worksheet S–10 (or a completed Worksheet S–10 if no data were included on the previously submitted cost report) to the MAC no later than September 30, 2016. Although commenters asserted that the September 30, 2016 deadline for amending 2014 cost reports meant that the revised instructions for Worksheet S–10 published in November 2016 could not be used because the deadline had already passed, the changes to the instructions for Worksheet S–10 did not apply to FY 2014 cost reports as they were limited to cost reporting periods beginning on or after October 1, 2016. However, we note that the clarification that only the charges of uninsured patients who do not meet the hospital's charity care criteria for a full or partial discount must be excluded from charity care could affect hospitals who provided discounts to uninsured patients who met the hospital's charity care policy in FY 2014. Accordingly, we are allowing hospitals another opportunity to resubmit data for FY 2014 Worksheets S–10, and they may include these charges if they were previously omitted. For revisions to be considered, hospitals must submit their amended FY 2014 cost report containing the revised Worksheet S–10 (or a completed Worksheet S–10 if no data were included on the previously submitted cost report) to the MAC no later than September 30, 2017. We note that these revised data will not be used to calculate Factor 3 for FY 2018, but will be available for use in future years if we propose and finalize a methodology for determining Factor 3 that uses FY 2014 Worksheet S–10 data.

We will provide hospitals with a similar opportunity for FY 2015 cost reports. We refer readers to Change Request 10026, Transmittal 1863, titled ''The Supplemental Security Income (SSI)/Medicare Beneficiary Data for Fiscal Year 2015 for Inpatient Prospective Payment System (IPPS) Hospitals, Inpatient Rehabilitation Facilities (IRFs), and Long Term Care Hospitals (LTCH),'' issued on June 30, 2017 (available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017-Transmittals-Items/R1863OTN.html*). In this transmittal, as a step in the process of ensuring complete submission of Worksheet S–10 by all DSH-eligible hospitals, we instruct MACs to accept amended Worksheets S–10 of FY 2015 cost reports submitted by hospitals (or initial submissions of Worksheet S–10 if none have been submitted previously) and to upload them to the Health Care Provider Cost Report Information System (HCRIS) in a timely manner. The transmittal states that, for revisions to be considered, hospitals must submit their amended FY 2015 cost report containing the revised Worksheet S–10 (or a completed Worksheet S–10 if no data were included on the previously submitted cost report) to the MAC no later than September 30, 2017.

After consideration of the public comments received, we are finalizing our proposal to begin incorporating Worksheet S–10 into the calculation of Factor 3 beginning in FY 2018. We discuss below our proposed methodology for how we would begin to incorporate Worksheet S–10 data into the calculation of Factor 3 of the uncompensated care payment methodology.

(3) Time Period for Calculating Factor 3 for FY 2018, Including Methodology for Incorporating Worksheet S–10 Data

Section 1886(r)(2)(C) of the Act not only governs the selection of the data to be used in calculating Factor 3, but also allows the Secretary the discretion to determine the time periods from which we will derive the data to estimate the numerator and the denominator of the Factor 3 quotient. Specifically, section 1886(r)(2)(C)(i) of the Act defines the numerator of the quotient as the amount of uncompensated care for such hospital *for a period selected by the Secretary.* Section 1886(r)(2)(C)(ii) of the Act defines the denominator as the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act *for such period.* In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50638), we adopted a process of making interim payments with final cost report settlement for both the empirically justified Medicare DSH payments and the uncompensated care payments required by section 3133 of the Affordable Care Act. Consistent with that process, we also determined the time period from which to calculate the numerator and denominator of the Factor 3 quotient in a way that would be consistent with making interim and final payments. Specifically, we must have Factor 3 values available for hospitals that we estimate will qualify for Medicare DSH payments and for those hospitals that we do not estimate will qualify for Medicare DSH payments but that may ultimately qualify for Medicare DSH payments at the time of cost report settlement.

In the FY 2017 IPPS/LTCH PPS final rule, in order to mitigate undue fluctuations in the amount of uncompensated care payments to hospitals from year to year and smooth over anomalies between cost reporting periods, we finalized a policy of calculating a hospital's share of uncompensated care based an average of data derived from three cost reporting periods instead of one cost reporting period. As explained in the preamble to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56957 through 56959), instead of determining Factor 3 using Medicaid days from a single cost reporting period and the most recent available data on Medicare SSI utilization, as we did in FY 2014, FY 2015, and FY 2016, we used Medicaid days from *three* cost reporting periods (FYs 2011, 2012, and 2013) and SSI days from the *three* most recent available years of SSI utilization

data (FYs 2012, 2013, and 2014) to compute Factor 3 for FY 2017. We continued to extract Medicaid days data from the most recent update of HCRIS, which for FY 2017 was the March 2016 update. Furthermore, instead of determining a single Factor 3 as we have done since the first year of the uncompensated care payment in FY 2014, we calculated an individual Factor 3 for each of the three cost reporting periods, which we then averaged by the number of cost reporting years with data to compute the final Factor 3 for a hospital. Under this policy, if a hospital had merged, we would combine data from both hospitals for the cost reporting periods in which the merger was not reflected in the surviving hospital's cost report data to compute Factor 3 for the surviving hospital.

Moreover, to further reduce undue fluctuations in a hospital's uncompensated care payments, if a hospital filed multiple cost reports beginning in the same fiscal year, we combined data from the multiple cost reports so that a hospital could have a Factor 3 calculated using more than one cost report within a cost reporting period. We codified these changes for FY 2017 by amending the regulations at § 412.106(g)(1)(iii)(C).

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19951), we proposed to continue to use the methodology finalized in FY 2017 and to compute Factor 3 for FY 2018 using an average of data from three cost reporting periods instead of one cost reporting period. Consistent with the methodology used to calculate Factor 3 for FY 2017, we proposed to advance the time period of the data used in the calculation of Factor 3 forward by 1 year and use data from FY 2012, FY 2013, and FY 2014 cost reports. For the reasons we described earlier, we explained our belief that it would not be appropriate to use Worksheet S–10 data for periods prior to FY 2014. Rather, for cost reporting periods prior to FY 2014, we indicated that we believe it would be appropriate to continue to use low-income insured days. Accordingly, with a time period that includes 3 cost reporting years consisting of FY 2014, FY 2013, and FY 2012, we proposed to use Worksheet S–10 data for the FY 2014 cost reporting period and the low-income insured days proxy data for the two earlier cost reporting periods. In order to perform this calculation, we will draw three sets of data (2 years of Medicaid utilization data and 1 year of Worksheet S–10 data) from the most recent available HCRIS extract, which was the December 2016 update of HCRIS for the FY 2018 IPPS/LTCH PPS proposed rule and is the March 2017 update of HCRIS for this final rule. Accordingly, for FY 2018, in addition to the Worksheet S–10 data for FY 2014, we proposed to use Medicaid days from FY 2012 and FY 2013 cost reports and FY 2014 and FY 2015 SSI ratios. We also proposed to continue to use FY 2012 cost report data submitted to CMS by IHS and Tribal hospitals to determine Medicaid days for those hospitals. (Cost report data from IHS and Tribal hospitals are included in HCRIS beginning in FY 2013, and are no longer submitted separately.) We also proposed to continue the policies that were finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50020) to address several specific issues concerning the process and data to be employed in determining Factor 3 in the case of hospital mergers as well as the policies finalized in the FY 2017 IPPS/LTCH PPS final rule concerning multiple cost reports beginning in the same fiscal year (81 FR 56957).

We stated in the proposed rule that we believe this approach, if we were to propose to continue it for FY 2019 and FY 2020, would have the effect of transitioning the incorporation of data from Worksheet S–10 into the calculation of Factor 3. Starting with 1 year of Worksheet S–10 data in FY 2018, an additional year of Worksheet S–10 data would be incorporated into the calculation of Factor 3 in FY 2019, and the use of low-income insured days would be phased out by FY 2020.

In addition, in the proposed rule we acknowledged the concerns regarding IHS/Tribal hospitals and subsection (d) Puerto Rico hospitals that some commenters expressed in response to the FY 2017 proposal to begin using Worksheet S–10 data to determine Factor 3 in FY 2018. According to some of these commenters, the use of data from Worksheet S–10 to calculate uncompensated care may jeopardize all of the IHS/Tribal hospitals' uncompensated care payments due to their unique funding structure. With respect to Puerto Rico, other commenters asserted that the use of Worksheet S–10 data may not be appropriate, given the historical treatment of subsection (d) Puerto Rico hospitals under the statutory provisions governing payments under Medicaid and Medicare Part A and its impact on the reporting of uncompensated care payments by these hospitals. After consideration of the concerns, we indicated that we believe the uncompensated care data reported by Puerto Rico and IHS/Tribal hospitals needs to be further examined and should not be used for FY 2018. For the reasons described earlier related to the impact of the Medicaid expansion beginning in FY 2014, we also stated that we do not believe it would be appropriate to calculate a Factor 3 for these hospitals using FY 2014 low-income insured days. Because we do not believe it is appropriate to use the FY 2014 uncompensated care data for these hospitals and we also do not believe it is appropriate to use the FY 2014 low-income insured days, we stated that we believe the best proxy for the costs of Puerto Rico and IHS/Tribal hospitals for treating the uninsured is the low income-insured days data for FY 2012 and FY 2013. Accordingly, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19951), we proposed for these hospitals that when we compute the individual Factor 3s for each of the three cost reporting periods that are used to determine Factor 3, rather than computing a Factor 3 using Worksheet S–10 data from the hospital's FY 2014 cost report, we would substitute the Factor 3 calculated using the hospital's FY 2013 low-income insured days. That is, in order to determine the Factor 3 for FY 2018, we would calculate an average of three individual Factor 3s using the Factor 3 calculated using FY 2013 cost report data twice and the Factor 3 calculated using FY 2012 cost report data once. We indicated that we believe it is appropriate to double-weight the Factor 3 calculated using FY 2013 data as it reflects the most recent available information regarding the hospital's low-income insured days before any expansion of Medicaid. We also noted that, as we were not making any proposals with respect to the calculation of Factor 3 for FY 2019 in the FY 2018 IPPS/LTCH PPS proposed rule, we would reexamine the use of the Worksheet S–10 data for Puerto Rico and IHS/Tribal hospitals as part of the FY 2019 rulemaking. In addition, we proposed to continue to use a proxy for SSI days consisting of 14 percent of a hospital's Medicaid days for Puerto Rico hospitals, as finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56953 through 56956).

Therefore, for FY 2018, we proposed to compute Factor 3 for each hospital by—

- *Step 1:* Calculating Factor 3 using the low-income insured days proxy based on FY 2012 cost report data and the FY 2014 SSI ratio;
- *Step 2:* Calculating Factor 3 using the insured low-income days proxy based on FY 2013 cost report data and the FY 2015 SSI ratio;
- *Step 3:* Calculating Factor 3 based on the FY 2014 Worksheet S–10 data (or

using the Factor 3 calculated in Step 2 for Puerto Rico and IHS/Tribal hospitals); and

• *Step 4:* Averaging the Factor 3 values from Steps 1, 2, and 3; that is, adding the Factor 3 values from FY 2012, FY 2013, and FY 2014 for each hospital, and dividing that amount by the number of cost reporting periods with data to compute an average Factor 3.

We invited public comments on our proposed methodology for calculating Factor 3 for FY 2018. We also noted that if this proposed methodology was adopted for FY 2018, we would expect to propose to use a similar methodology for calculating Factor 3 for subsequent years, meaning that for FY 2019 we would expect to incorporate data from the FY 2015 Worksheet S–10 into the methodology and drop the FY 2012 low-income insured day proxy data. However, we did not make any proposals with respect to the calculation of Factor 3 for FY 2019 in the FY 2018 IPPS/LTCH PPS proposed rule.

Comment: While many commenters supported CMS' proposal to use a 3-year average to calculate Factor 3 for FY 2018, some commenters also provided suggestions for modified or alternative methodologies to calculate Factor 3 in FY 2018 and beyond. Many of these commenters opposed the use of Worksheet S–10 data beginning in FY 2018 and recommended a delay of at least 1 year to allow for further refinement of the Worksheet S–10 instructions and audit protocols to identify and remove aberrant uncompensated care costs. Several commenters requested that, instead of adding Factor 3 values from FY 2012, FY 2013, and FY 2014 for each hospital, and dividing that amount by the number of cost reporting periods with data, CMS continue to use the same data that was used to calculate uncompensated care payments in FY 2017 (Medicaid days from FYs 2011, 2012, and 2013 cost reports and SSI days from FY 2012, FY 2013, and FY 2014 SSI ratios) for purposes of calculating uncompensated care payments to hospitals in FY 2018. The commenters noted that using these data during a 1-year delay in incorporating Worksheet S–10 data would avoid including post-Medicaid expansion data for FY 2014 in the Factor 3 calculation.

Many commenters asked that CMS implement a stop-loss policy to protect hospitals that lose more than 5 to 10 percent in DSH payments in any given year as a result of transitioning to use of Worksheet S–10 data. These commenters suggested that this stop-loss should extend beyond the transition to help hospitals with decreasing uncompensated care payments adjust to their new payment levels. However, other commenters noted that a permanent stop-loss would not be warranted, given that a 3-year phase-in is an appropriate way to temporarily reduce the impact of new provisions.

One commenter recommended that any measure of uncompensated care should account for the different sources of uncompensated care burden hospitals incur as they treat low income patients in a changing coverage landscape. The commenter suggested that CMS use a permanent hybrid methodology that includes both a hospital's low-income insured days and uncompensated care costs from Worksheet S–10 to calculate its Factor 3. This commenter recommended that instead of transitioning entirely to Worksheet S–10 data (presumably in FY 2020), CMS use a weighted average of low-income insured days and uncompensated care costs from Worksheet S–10, with low-income insured days weighted 25 percent and Worksheet S–10 data weighted 75 percent.

Another commenter suggested an alternative 5-year phase-in, beginning in FY 2019. This commenter recommended that the weight accorded to data from Worksheet S–10 from FY 2014 be limited in the first year to 10 percent, with the remaining 90 percent determined using data on low-income insured days for FYs 2012 and 2013. In the second year, the commenter suggested that 2 years of data from Worksheet S–10 (FY 2014 and FY 2015) would be averaged and would equal 20 percent, with the remaining 80 percent weight accorded to the data on low-income insured days from FYs 2012 and 2013. In the third year, the commenter suggested that Worksheet S–10 data from FYs 2016 and 2017 would be averaged and weighted at 40 percent, with 60 percent weight accorded to the data on low income insured days. The commenter added that the phase-in process would continue in Year 4, FY 2022, with the use of averaged FY 2017 and FY 2018 Worksheet S–10 data with 80 percent weight, the remainder accorded to the data on low-income insured days. According to the commenter, Year 5 of the phase-in would utilize Worksheet S–10 as the sole data source, with an average of audited data from FYs 2017 through 2019.

While many commenters expressed approval of the proposed 3-year phase-in approach to using data from Worksheet S–10, there were other varying opinions expressed regarding the length of the phase-in period. Many commenters agreed with the proposed 3-year phase-in following a period of delay, as outlined above. However, other commenters encouraged CMS to expedite the transition to Worksheet S–10 data with potentially no phase-in. Commenters who recommended no phase-in noted that Worksheet S–10 uses the most accurate information available on uncompensated care costs, and while it is not perfect, no cost report schedule or other source of information provided by individual hospitals will ever achieve perfection. Conversely, other commenters requested that CMS consider a longer phase-in period. These commenters recommended a minimum 5-year transition period to gradually phase-in the use of Worksheet S–10 data once the data have been audited. According to the commenters, this longer phase-in would mitigate the effect on hospitals of the redistribution in uncompensated care payments resulting from the inclusion of data from the Worksheet S–10.

One commenter did not agree with the use of a 3-year average in the computation of Factor 3 because it would result in the use of dated information and is not a reasonable solution to solve data anomalies. This commenter requested that CMS use both Medicaid and Medicare SSI days from the most recent available full year of cost report data to compute Factor 3 for FY 2018. However, most commenters supported the use of 3 years of data in the calculation of Factor 3 in FY 2018, regardless of whether they supported a 1-year delay prior to implementing the use of Worksheet S–10 data or the implementation of the use of Worksheet S–10 data in FY 2018, as proposed.

Response: We appreciate the commenters' support for the use of a 3-year average in the calculation of Factor 3 for FY 2018. We also appreciate the comments regarding alternative timelines for incorporating Worksheet S–10 data into the calculation of Factor 3 and alternative methods for computing proxies for uncompensated care costs. As we stated in the FY 2018 IPPS/LTCH PPS proposed rule, when weighing the new information that has become available to us since the FY 2017 rulemaking in conjunction with the information regarding Worksheet S–10 data and the low-income days proxy that we have analyzed as part of our consideration of this issue in prior rulemaking, we can no longer conclude that alternative data to the Worksheet S–10 are available for FY 2014 that are a better proxy for the costs of subsection (d) hospitals for treating individuals

who are uninsured. For these reasons, we believe that it is appropriate to begin to incorporate the Worksheet S–10 data in the calculation of Factor 3 starting in FY 2018. We note that the proposals in the FY 2018 IPPS/LTCH PPS proposed rule were limited to FY 2018, and that we did not make any proposals with respect to the data that would be used to calculate Factor 3 for subsequent years. As a result, it would be premature for CMS to establish policies for future years in this final rule. We will consider the commenters' suggestions for further incorporating Worksheet S–10 into the calculation of Factor 3, or computing proxies for uncompensated care costs using a blend of Worksheet S–10 data, low-income insured days, or other data sources, in future rulemaking.

With respect to the stop-loss policy that one commenter suggested, we believe that the use of 3 years of data instead of 1 year of data already provides assurance that hospitals' uncompensated care payments will remain reasonably stable and predictable, and would not be subject to unpredictable swings and anomalies in a hospital's low-income insured days or reported uncompensated care costs. As a result, because there is already a mechanism for smoothing the transition from the use of low-income insured days to the use of Worksheet S–10 data in place, we do not believe a stop-loss policy is necessary at this time.

Comment: One commenter requested that CMS consider using a proxy for Puerto Rico hospitals' SSI days in computing the empirically justified DSH payment amount, or 25 percent of the amount that would have been paid for Medicare DSH prior to implementation of section 3133 of the Affordable Care Act.

Response: In the FY 2018 IPPS/LTCH PPS proposed rule, we did not propose any changes to the methodology used to calculate empirically justified Medicare DSH payments. Therefore, we consider this comment to be outside the scope of the proposed rule. However, we note that while section 1886(r)(2)(C)(i) of the Act allows for the use of alternative data as a proxy to determine the costs of subsection (d) hospitals for treating the uninsured for purposes of determining uncompensated care payments, section 1886(r)(1) of the Act requires the Secretary to pay an empirically justified DSH payment that is equal to 25 percent of the amount of the Medicare DSH payment that would otherwise be made under section 1886(d)(5)(F) of the Act to a subsection (d) hospital for the fiscal year. Because section 1886(d)(5)(F)(vi) of the Act, which prescribes the disproportionate patient percentage used to determine empirically justified Medicare DSH payments, specifically calls for the use of SSI days in the Medicare fraction and does not allow the use of alternative data, we do not believe there is any legal basis for CMS to use a proxy for Puerto Rico hospitals' SSI days in the calculation of the empirically justified Medicare DSH payment under section 1886(r)(1) of the Act.

Comment: Several commenters supported the proposal to use 14 percent of Medicaid days as a proxy for Medicare SSI days when determining Factor 3 for Puerto Rico hospitals. These commenters stated that they appreciated the attention and effort by CMS to develop a fair and appropriate method to estimate SSI days for Puerto Rico hospitals, as the SSI program is statutorily unavailable to U.S. citizens residing in the Territories.

One commenter recommended that CMS examine data to evaluate future proxy alternatives for Puerto Rico hospitals, such as using data for Medicare beneficiaries with Medicaid eligibility (dual eligible beneficiaries). The commenter proposed that CMS initiate a plan to work with hospitals in Puerto Rico to formally review and define cost report data for recent years in relation to the documentation of hospital inpatient days for dual eligible beneficiaries. As a second step, the commenter recommended that CMS allow hospitals in Puerto Rico to resubmit the pertinent worksheets of the cost reports for past years, to appropriately document the inpatient days for dual-eligible beneficiaries.

Response: We appreciate the support for our continued use of 14 percent of a Puerto Rico hospital's Medicaid days as a proxy for SSI days. Because we are continuing to use insured low-income patient days as a proxy for uncompensated care as part of the Factor 3 calculation in FY 2018 and residents of Puerto Rico are not eligible for SSI benefits, we believe it is important to create a proxy for SSI days for Puerto Rico hospitals.

Regarding the comment recommending that we use inpatient days for Medicare beneficiaries receiving Medicaid as this proxy, we have examined this concept and have been unable to identify a systematic source for these data for Puerto Rico hospitals. Specifically, we note that inpatient utilization for Medicare beneficiaries entitled to Medicaid is not reported by hospitals on the Medicare cost report, either within or outside Puerto Rico. We expect to further address issues related to estimating the amount of uncompensated care for hospitals in Puerto Rico as part of the FY 2019 rulemaking.

Comment: A few commenters expressed concern that the use of data from Worksheet S–10 to calculate uncompensated care costs does not take into account the IHS's unique funding structure and therefore may jeopardize all uncompensated care payments for IHS hospitals. The commenters stated that, due to their unique funding structure, Indian Health Care Providers (IHCPs) do not have uncompensated care costs under Worksheet S–10. They indicated that because funding for the costs of patient care is provided through congressional appropriations, all care is considered compensated, even though appropriations fund only approximately 59 percent of the health care needs for American Indians/Alaska Natives. The commenters also stated that many Tribes and Tribal organizations invest non-Federal resources in their health care programs to furnish care that could easily be classified as uncompensated care because IHCPs may not charge beneficiaries to receive care and, thus, may not have the accounting methods to track these costs. As a result, the commenters stated that IHCP hospitals are currently unable to report charity care and non-Medicare bad debt consistent with the proposed definition of uncompensated care in the proposed rule. Therefore, the commenters requested that CMS consult with IHS and Tribal stakeholders to estimate the amount of uncompensated care furnished in IHCP hospitals. The commenters also stated that the opportunity to submit comments on the rulemaking process is not considered meaningful consultation in accordance with Executive Order 13175 or the CMS Tribal consultation policy approved December 5, 2015, and that additional Tribal consultation is necessary.

Response: We appreciate these comments and acknowledge that the use of data from Worksheet S–10 to calculate uncompensated care costs does not take into account the unique funding structure of IHS hospitals and therefore using these data to determine Factor 3 may have an unintended impact on the uncompensated care payments to these hospitals. Through consultation and communication with IHS and Tribal hospitals, including an All Tribes' Call on May 22, 2017, to discuss the FY 2018 IPPS/LTCH PPS proposed rule, we have confirmed that it would not be appropriate to use FY 2014 uncompensated care cost data from Worksheet S–10 to calculate Factor 3 for IHS and Tribal hospitals.

In the FY 2018 IPPS/LTCH PPS proposed rule, we proposed for IHS

hospitals that when we compute the individual Factor 3s for each of the three cost reporting periods that are used to determine Factor 3, rather than computing a Factor 3 using Worksheet S–10 data from the hospital's FY 2014 cost report, we would substitute the Factor 3 calculated using the hospital's FY 2013 low-income insured days. That is, in order to determine the Factor 3 for FY 2018, we would calculate an average of three individual Factor 3s using the Factor 3 calculated using FY 2013 cost report data twice and the Factor 3 calculated using FY 2012 cost report data once. We believe it is appropriate to double-weight the Factor 3 calculated using FY 2013 data as it reflects the most recent available information regarding the hospital's low-income insured days before any expansion of Medicaid. We note that we did not make any proposals with respect to the calculation of Factor 3 for FY 2019 in the FY 2018 proposed rule. We will reexamine the use of the Worksheet S–10 data for IHS/Tribal hospitals as part of the FY 2019 rulemaking.

Comment: Many commenters asked CMS to change, rescind, or otherwise edit methodologies with respect to all-inclusive rate providers, which several commenters called ''inappropriate'' and ''erroneous.'' Several commenters suggested a separate audit protocol to address the unique circumstances of all-inclusive billers, and to ensure that their uncompensated care is accurately captured. They observed that because all-inclusive rate providers do not use charges, the CCR on the Worksheet S–10 would be inaccurate. One commenter suggested the use of an audit protocol akin to the one that is used to audit charity care reported by CAHs for purposes of the meaningful use program.

One suggestion to ameliorate the issues regarding all-inclusive rate providers was to add a line to the Worksheet S–10 that asks hospitals ''Are you an all-inclusive biller?'' that would provide an alternative methodology for those hospitals to calculate their CCRs. Another suggestion was to allow all-inclusive rate providers to submit their own CCRs, so they could explain or correct their data prior to CMS substitution of the hospital-reported CCR with the statewide average. A third suggestion was to use the uncompensated care costs as reported by all-inclusive rate providers on Line 30 of Worksheet S–10 (as opposed to converting charges to costs using the CCR reported on Line 1 of Worksheet S–10 or a statewide average CCR as CMS proposed) or to use low-income days as a proxy for uncompensated care when calculating Factor 3 either for all all-inclusive rate providers or for public all-inclusive rate providers.

Response: We appreciate the concerns and suggestions raised by commenters with respect to the CCRs that will be used in determining the uncompensated care costs of all-inclusive rate providers. Given the unique charge structure of all-inclusive rate providers, we have determined that it would not be appropriate to use FY 2014 uncompensated care cost data from Worksheet S–10 to calculate Factor 3 for these hospitals, and we will instead use an alternate methodology that is consistent with the methodology that we proposed for IHS/Tribal hospitals and Puerto Rico hospitals, which also experience special circumstances that could potentially affect the validity of their Worksheet S–10 data. We note that we did not make any proposals with respect to the calculation of Factor 3 for FY 2019 or subsequent years in the FY 2018 proposed rule; we will reexamine the use of the Worksheet S–10 data for all-inclusive rate providers as part of the FY 2019 rulemaking.

After consideration of the public comments we received, we are finalizing our proposal to incorporate 1 year of Worksheet S–10 data into the calculation of Factor 3 in FY 2018 in conjunction with data on low-income insured days for FYs 2012 and 2013. We will continue to use data from three cost reports, which will gradually incorporate data from Worksheet S–10 into the calculation of Factor 3.

We also are finalizing our proposal not to incorporate Worksheet S–10 data for Puerto Rico hospitals and IHS and Tribal hospitals, but will double-weight the 2013 Factor 3 calculated for these hospitals. In addition, we will not use Worksheet S–10 data for all-inclusive rate providers, but will also double-weight the 2013 Factor 3 calculated for these hospitals. We believe that the uncompensated care data reported by Puerto Rico hospitals, IHS/Tribal hospitals, and all-inclusive rate providers on Worksheet S–10 need to be further examined and should not be used in determining Factor 3 for FY 2018. Because we do not believe it is appropriate to use the FY 2014 uncompensated care data for these hospitals and we also do not believe it is appropriate to use the FY 2014 low-income insured days due to the effects of Medicaid expansion, we believe that the best proxy for the costs of Puerto Rico hospitals, IHS/Tribal hospitals, and all-inclusive rate providers for treating the uninsured is the low-income insured days data for FY 2012 and FY 2013.

In addition, we are finalizing the proposed amendment to the regulation at § 412.106(g)(1)(iii)(C) to reflect the data that will be used to calculate Factor 3 for FY 2018. We have made a minor modification to the proposed text of the regulation in order to clarify that data on uncompensated care costs will not be used to determine Factor 3 for Puerto Rico hospitals, IHS and Tribal hospitals, and all-inclusive rate providers.

For new hospitals that do not have data for any of the three cost reporting periods used in the Factor 3 calculation, we will continue to apply the new hospital policy finalized in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50643). That is, the hospital will not receive either interim empirically justified Medicare DSH payments or interim uncompensated care payments. However, if the hospital is later determined to be eligible to receive empirically justified Medicare DSH payments based on its FY 2018 cost report, the hospital will also receive an uncompensated care payment calculated using a Factor 3, where the numerator is the uncompensated care costs reported on Worksheet S–10 of the hospital's FY 2018 cost report, and the denominator is the sum of uncompensated care costs reported on Worksheet S–10 of all DSH eligible hospitals' FY 2014 cost reports as prospectively determined during rulemaking. We note that, given the selected time period of the data used to calculate Factor 3, any hospitals with a CCN established after October 1, 2014 will be considered new and subject to this policy.

As we have done for each proposed and final rule beginning in FY 2014, in conjunction with this final rule, we will publish on the CMS Web site a table listing Factor 3 for all hospitals that we estimate will receive empirically justified Medicare DSH payments in FY 2018 (that is, those hospitals that will receive interim uncompensated care payments during the fiscal year), and for the remaining subsection (d) hospitals and subsection (d) Puerto Rico hospitals that have the potential of receiving a Medicare DSH payment in the event that they receive an empirically justified Medicare DSH payment for the fiscal year as determined at cost report settlement.

In conjunction with the proposed rule, we published a supplemental data file containing a list of the mergers that we were aware of and the computed uncompensated care payment for each merged hospital. Hospitals had 60 days from the date of public display of the FY 2018 IPPS/LTCH PPS proposed rule to review the table and supplemental data

file published on the CMS Web site and to notify CMS in writing of any inaccuracies. We stated in the proposed rule that we would address these comments as appropriate in the table and the supplemental data file that we publish on the CMS Web site in conjunction with the publication of this FY 2018 IPPS/LTCH PPS final rule. Hospitals will have until August 31, 2017, to review and submit comments on the accuracy of the table and supplemental data file published in conjunction with this final rule. Comments may be submitted to the CMS inbox at *Section3133DSH@cms.hhs.gov* through August 31, 2017, and any changes to Factor 3 will be posted on the CMS Web site prior to October 1, 2017.

Comment: Some commenters provided specific information regarding merger situations involving their hospitals and requested that CMS consider these mergers in determining Factor 3 for FY 2018 payments. A few commenters also pointed out that specific data for the calculation of Factor 3, such as Medicaid days, were incorrect due to missing cost report data in the HCRIS extract for the applicable year. In addition, a few commenters noted inaccuracies in the FY 2018 Proposed Rule Supplemental Data File, which, in some cases, had not been updated to reflect the most recent FY 2014 cost report filed in accordance with CMS Transmittal 1681. CMS Transmittal 1681 instructed MACs to accept amended Worksheets S–10 for FY 2014 cost reports submitted by hospitals (or initial submissions of Worksheet S–10 if none had been submitted previously) and to upload them to the Health Care Provider Cost Report Information System (HCRIS) in a timely manner if received no later than September 30, 2016.

Response: We thank the commenters for their input. We have updated our list of mergers based on information submitted by the MACs as of June 2017. In addition, we have reviewed the commenters' submissions of mergers not previously identified in the proposed rule and have updated our list accordingly. We also have reviewed the commenters' submissions regarding missing or incorrect Worksheet S–10 data from FY 2014 cost reports in the FY 2018 Proposed Rule Supplemental Data File and included those data that were submitted timely and inadvertently excluded from the March 2017 HCRIS extract due to MAC or CMS error. We will continue to pay diligent attention to data inaccuracies and work internally and with our contractors to resolve these issues in a timely manner.

(4) Methodological Considerations for Calculating Factor 3

• *Annualizing short cost reports.* As we explained in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56957 through 56959) and in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19953), we believe that for hospitals that file multiple cost reports beginning in the same year, combining the data from these cost reports has the benefit of supplementing the data of hospitals that filed cost reports that are less than 12 months, such that the basis of their uncompensated care payments and those of hospitals that filed full-year 12-month cost reports would be more equitable. In response to our original proposal in the FY 2017 IPPS/LTCH PPS proposed rule to combine data from multiple cost reports, many hospitals stated that while they were appreciative of CMS' efforts to provide a more equitable playing field for hospitals that filed short cost reports, they believed that expanding the time period of the data used to calculate Factor 3 as well as combining data across multiple cost reports would not remedy the fact that some hospitals are still disadvantaged by having less than 36 months of data in their Factor 3 calculation (81 FR 56959). Other commenters opposed the use of multiple cost reporting periods if it would result in a hospital having more than 12 months of data in the Factor 3 calculation for a year, and recommended that CMS prorate the data to a 12-month period. Similarly, other commenters recommended that CMS annualize cost report data for any cost reporting period that is less than 12 months. In the FY 2017 IPPS/LTCH PPS final rule, we acknowledged that, although we had not made any proposal in the FY 2017 IPPS/LTCH PPS proposed rule to annualize the cost reports used to calculate Factor 3, the situations presented by commenters, including both long and short cost reporting periods, pose unique challenges in the context of estimating Factor 3. We stated that we intended to consider the issue further and might address the issue in future rulemaking.

For the FY 2018 IPPS/LTCH PPS proposed rule, taking into consideration the feedback from hospitals that have been disadvantaged in the Factor 3 calculation due to cost reports that do not span a full year, we proposed to annualize Medicaid data if a hospital's cost report does not equal 12 months of data. We did not propose to annualize SSI days because we do not obtain these data from hospital cost reports in HCRIS. Rather, we obtain these data from the latest available SSI ratios posted on the Medicare DSH homepage (*https://www.cms.gov/medicare/medicare-fee-for-service-payment/AcuteInpatientPPS/dsh.html*), which are aggregated at the hospital level and do not have the information needed to determine if the data should be annualized.

Under this proposal, if the time between the start date of a hospital's cost reporting year and the end date of its cost reporting year is less than 12 months, we proposed that we would annualize the Medicaid days so that the hospital has 12 months of data included in its Factor 3 calculation. Conversely, if the time between the aforementioned start date and the end date is *greater* than 12 months, we would annualize the Medicaid days to achieve 12 months of Medicaid days data. If a hospital files more than one cost report beginning in the same fiscal year, we would first combine the data across the multiple cost reports before determining the difference between the start date and the end date to see if annualization is needed.

To annualize the Medicaid days for a long or short cost reporting year, we proposed that we would divide the length of a full year (365 or 366 calendar days, as applicable) by the length of the cost reporting year (the number of calendar days in the cost reporting year) and then multiply the quotient by the number of Medicaid days in the cost reporting year.

For instance, a cost reporting year that is 285 calendar days long with 1,200 Medicaid days would be annualized as follows: (365/285) * 1,200 = 1,537 days.

A cost reporting year that is 385 calendar days long with 1,200 Medicaid days would be annualized using the same formula: (365/385) * 1,200 = 1,137 days.

Likewise, because long and short cost reporting periods pose the same challenges in the context of estimating Factor 3 using hospital uncompensated care costs, we proposed to annualize the uncompensated care cost data reported on Worksheet S–10 for cost reports that do not equal 12 months of data, by dividing the length of a full year (365 or 366 calendar days, as applicable) by the length of the cost reporting year (number of calendar days in the cost reporting year) and then multiplying the quotient by the total reported uncompensated care costs for the cost reporting year.

For instance, a cost reporting year that is 285 calendar days long reporting $10,500,000 in uncompensated care costs would be annualized as follows: (365/285) * $10,500,000 = $13,447,368.

A cost reporting year that is 385 calendar days long reporting $10,500,000 in uncompensated care costs would be annualized using the same formula: (365/385) * $10,500,000 = $9,954,545.

If a hospital files more than one cost report beginning in the same fiscal year, we proposed that we would first combine the data across the multiple cost reports before determining the length of the cost reporting year to see if annualization is needed.

We invited public comment on our proposal to annualize the cost reports used to calculate Factor 3 for FY 2018. In addition, as noted earlier, our proposal to continue calculating a hospital's share of uncompensated care payments using a time period that includes 3 cost reporting years was also designed to mitigate undue fluctuations in the amount of uncompensated care payments to hospitals from year to year and smooth over anomalies between cost reporting periods. Given that our proposal to annualize the cost reports used to calculate Factor 3 for FY 2018 would also mitigate fluctuations in the amount of uncompensated care payments from year to year, we also sought public comment on the degree to which the use of three cost reporting years would still be necessary if we were to adopt our proposal to annualize the cost reports used to calculate Factor 3, or if instead the use of a single cost reporting year or two cost reporting years would be appropriate. In order to facilitate public comments, we indicated that we intend to post on our Web site a data file containing information similar to the information provided in section I.H.5., ''Effects of the Proposed Changes to Medicare DSH and Uncompensated Care Payments for FY 2018'' of Appendix A of the proposed rule. However, instead of reflecting our proposed approach of calculating Factor 3 using a time period that includes 3 cost reporting years, it would reflect an alternative approach of calculating Factor 3 using only the most recent year (FY 2014) of our proposed 3-year average. In all other respects, the calculation of Factor 3 would remain the same.

Comment: Many commenters supported CMS' proposal to annualize cost reports that do not reflect 12 months of data (short and long periods). One commenter specifically supported the proposal to annualize Medicare SSI days for the Factor 3 calculation, while another commenter supported the proposal to combine data from multiple cost reports beginning in the same fiscal year before annualization.

Response: We appreciate the support for the proposal to annualize cost reports that do not meet the 12-month threshold. However, we reiterate that the proposal did not apply to Medicare SSI days as these data are not obtained directly from cost reports in HCRIS (unlike Medicaid days and uncompensated care cost data), but rather from a file posted on the CMS Web site: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html*, where the data are aggregated at the hospital level and without the information to determine if annualization is needed. Therefore, we are unable to annualize Medicare SSI days as we proposed for Medicaid days from Worksheet S–2 and uncompensated care cost data from Worksheet S–10 of the Medicare cost report.

After consideration of the comments we received, we are finalizing our proposal to annualize cost reports that do not have 12 months of data. As stated in the FY 2018 IPPS/LTCH PPS proposed rule, if the time between the start date of a hospital's cost reporting year and the end date of its cost reporting year is less than 12 months, we will annualize the Medicaid days so that the hospital has 12 months of data included in its Factor 3 calculation. Conversely, if the time between the aforementioned start date and the end date is *greater* than 12 months, we will annualize the Medicaid days to achieve 12 months of Medicaid days data. If a hospital files more than one cost report beginning in the same fiscal year, we will first combine the data across the multiple cost reports before determining the difference between the start date and the end date to see if annualization is needed.

- *Scaling Factor.* Under the methodology adopted in the FY 2017 IPPS/LTCH PPS final rule and as we proposed to apply in FY 2018, if a hospital does not have data for one or more of the three cost reporting periods, we would compute Factor 3 for the periods available and average those. In other words, we would divide the sum of the individual Factor 3s by the number of cost reporting periods with data so as not to disadvantage hospitals that are missing data for one or more cost reporting periods. Following the publication of the FY 2017 IPPS/LTCH PPS final rule, several hospitals noted that this aspect of the methodology resulted in the Factor 3 values of DSH eligible hospitals in Table 18 and the Medicare DSH Supplemental Data File adding up to slightly greater than one, which resulted in total uncompensated care payments somewhat exceeding the estimate published in the FY 2017 final rule. Specifically, for hospitals that have fewer than 3 cost reporting years with data, dividing the individual Factor 3s by the number of cost reporting years with data (that is, 2 cost reporting years or 1 cost reporting year) results in a higher average Factor 3 than if the individual Factor 3s were divided by the number of cost reporting years, regardless of whether or not there is data (that is, 3 cost reporting years). For example, a hospital with no data for FY 2011 and a Factor 3 of 0.000051762 for FY 2012 and 0.000049852 for FY 2013 will have an average Factor 3 of 0.000050807 if divided by 2 but an average Factor 3 of only 0.000033871 if divided by 3. After reviewing the data in Table 18 and the Medicare DSH Supplemental Data File, which were published in conjunction with the FY 2017 IPPS/LTCH PPS final rule, we concluded that the hospitals' observations are correct and that an adjustment is needed so that total uncompensated care payments do not exceed the estimated amount available to make uncompensated care payments as discussed in section V.G.4.b of the preamble of this final rule.

Accordingly, to address the effects of averaging Factor 3s calculated for three separate fiscal years, we proposed to apply a scaling factor to the Factor 3 values of all DSH eligible hospitals so that total uncompensated care payments are consistent with the estimated amount available to make uncompensated care payments for FY 2018. We proposed to first compute Factor 3 and the uncompensated care payments for all hospitals that we anticipate qualifying for Medicare DSH payments in FY 2018. We proposed to then divide 1 (the *expected* sum of all eligible hospitals' Factor 3 values) by the *actual* sum of all eligible hospitals' Factor 3 values and multiply the quotient by each hospital's total uncompensated care payment to obtain scaled uncompensated care payment amounts whose sum is consistent with the estimate of the total amount available to make uncompensated care payments. The hospital-specific uncompensated care amount would then be divided by a 3-year claims average to obtain the amount of the interim uncompensated care payment the hospital will receive for each claim. As an illustration of the calculation of the scaling factor, applying this proposal to the FY 2017 uncompensated care payments would have resulted in a scaling factor of 0.9992 (1/1.0008). We noted that the FY 2017 uncompensated

care payments as calculated for the FY 2017 IPPS final rule exceeded the estimated amount by approximately $5 million due to the lack of a scaling factor.

We invited public comments on our proposal to apply a scaling factor to all DSH eligible hospitals' Factor 3 values for FY 2018.

Comment: One commenter supported applying a scaling factor to Factor 3 and noted that it would prevent artificial inflation of a hospital's amount of uncompensated care in the absence of 3 years of cost report data.

Response: We appreciate the commenter's support for the proposed scaling factor.

After consideration of the comments we received, we are finalizing our proposal to implement a scaling factor to all DSH eligible hospitals' Factor 3 values for FY 2018.

(5) Methodological Considerations for Incorporating Worksheet S–10 Data

• *Definition of uncompensated care.* In the FY 2014 IPPS/LTCH PPS rulemaking, we considered three potential definitions of uncompensated care: Charity care; charity care + bad debt; and charity care + bad debt + Medicaid shortfalls. As we explained in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50634), we considered proposing to define the amount of uncompensated care for a hospital as the uncompensated care costs of that hospital and considered potential data sources for those costs. We examined the literature on uncompensated care and the concepts of uncompensated care used in various public and private programs, and considered input from stakeholders and public comments in various forums, including the national provider call that we held in January 2013. Our review of the information from these sources indicated that there is some variation in how different States, provider organizations, and Federal programs define ''uncompensated care.'' However, a common theme of almost all these definitions is that they include both ''charity care'' and ''bad debt'' as components of ''uncompensated care.'' Therefore, a definition that incorporates the most commonly used factors within uncompensated care as reported by stakeholders would include charity care costs and bad debt costs. Worksheet S–10 employs the definition of charity care plus non-Medicare bad debt.

Specifically:

Cost of Charity Care (Line 23)
+ Cost of non-Medicare bad debt expanse (Line 29)
Cost of non-Medicare uncompensated care (Line 30)

Where:

- Cost of charity care = Cost of initial obligation of patients approved for charity care (line 21) minus partial payment by patients approved for charity care (line 22).
- Cost of non-Medicare bad debt expense = Cost to charge ratio (line 1) times non-Medicare and nonreimbursable bad debt expense (line 28).

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25092), we proposed to adopt a definition of uncompensated care costs that included charity care and non-Medicare bad debt. We explained that we believe there are compelling arguments for excluding Medicaid shortfalls from the definition of uncompensated care, including the fact that several government agencies and key stakeholders do not consider Medicaid shortfalls in their definition of uncompensated care and that excluding Medicaid shortfalls from the uncompensated care definition allows Medicare uncompensated care payments to target hospitals that have a disproportionate share of uncompensated care for patients with no insurance coverage. Although we did not finalize the proposed definition of uncompensated care costs as part of the FY 2017 rulemaking, we continue to believe a definition of uncompensated care that incorporates the most commonly used factors within uncompensated care as reported by stakeholders would include charity care costs and non-Medicare bad debt costs, which correlates to Line 30 of Worksheet S–10. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19954), we again proposed that, for purposes of calculating Factor 3 and uncompensated care costs beginning in FY 2018, ''uncompensated care'' would be defined as the amount on line 30 of Worksheet S–10, which is the cost of charity care (Line 23) and the cost of non-Medicare bad debt (Line 29). We invited public comments on this proposal.

Comment: Several commenters supported the proposed definition of uncompensated care as charity care plus non-Medicare bad debt. However, a common concern expressed by these commenters, as well as those commenters who disagreed with the proposed definition, was the inclusion of Medicaid shortfalls in the definition of uncompensated care as captured by Worksheet S–10. Commenters stated that excluding Medicaid shortfalls from the definition of uncompensated care severely penalizes hospitals that care for a large number of Medicaid patients because, while uninsured costs have declined as people have gained coverage through Medicaid, hospitals continue to lose money on Medicaid patients as the Medicaid payment rates are often below the cost of providing health care services. The commenters also stated that including Medicaid losses in the definition of uncompensated care would align with the Medicaid DSH program and the IRS method of calculating the community benefit provided by nonprofit hospitals. Some commenters also requested that shortfalls from CHIP and State and local indigent care programs be included in uncompensated care costs along with charity care and non-Medicare bad debt.

Other commenters supported the exclusion of Medicaid shortfalls from the definition of uncompensated care. One of these commenters pointed out that the current use of low-income insured days as a proxy for uncompensated care already penalizes hospitals in nonexpansion States as their Medicaid ratio is lower than hospitals in expansion States. The commenter believed that including Medicaid shortfalls in the definition of uncompensated care would exacerbate this impact. In addition, the commenter supported the exclusion of Medicaid shortfalls from the definition of uncompensated care because it believed that Medicaid programs vary by State, making the data on shortfalls less reliable. Commenters added that excluding Medicaid unreimbursed costs from non-Medicare uncompensated care will result in a more equitable distribution of uncompensated care payments. Another commenter believed that continuing to exclude Medicaid shortfalls from Factor 3 calculations will improve the accuracy and consistency of the data reported on Worksheet S–10. In addition, commenters noted that computing losses on Medicaid patients is operationally problematic because it is unclear how much Medicaid shortfalls are left after the Medicare DSH payment is made. That is, commenters noted that Medicare DSH payments may already be covering the Medicaid shortfalls.

In addition to comments about the Medicaid shortfalls, commenters observed that States differ in how they define uncompensated care costs, and that not all costs incurred by hospitals in treating the uninsured are categorized as charity care and bad debt, such as in the case of discounts to the uninsured who are unable to pay or unwilling to provide means-tested information. Specifically, commenters pointed out that Worksheet S–10 does not capture all of the information relevant to the

purposes of section 3133 of the Affordable Care Act. To this end, one commenter noticed definitional discrepancies in Worksheet S–10 that failed to recognize the requirement under section 3133 of the Affordable Care Act that the amount of uncompensated care costs of subsection (d) hospitals reflect the costs of treating the uninsured, which should include costs incurred through non-means tested uninsured discount programs. Commenters expressed concern for the disregard of uninsured discounts, which, according to them, results in uncompensated care being undercounted.

Several commenters stated that the uncompensated care definition should be expanded to include discounts to the uninsured and underinsured as well as those who self-pay. According to one commenter, such discounts should include ''self-pay imposed charge discounts,'' ''state mandated self-pay charge discounts,'' and ''means tested'' charge discounts. The same commenter stated that, despite CMS' concerns that adding self-pay discounts into uncompensated care may result in situations where payments exceed costs, overall self-pay patient payments are immaterial in the aggregate and would not be a significant factor in such a calculation.

Some commenters also argued that adopting a policy that excludes discounts would inappropriately penalize hospitals that offer uninsured discounts and disincentivize hospitals from offering this financial help to the uninsured. To this end, commenters noted that Worksheet S–10 does not adequately reflect discounts to the uninsured and expressed concern that hospitals that attempt to collect on a full debt with no discount receive the same or a higher uncompensated care total as hospitals that do provide discounts. Specifically, one commenter noted that the current policy for uninsured discounts is irrational because it gives special treatment to those hospitals unwilling to discount care for the uninsured. Another commenter argued that discounts offered to the uninsured are costs that hospitals incur in providing care for such patients; therefore, regardless of whether they are called ''discounts'' or some other term, they should be incorporated in the definition of uncompensated care in Worksheet S–10. One commenter also noted that it applies discounts according to its charity patients' liability, which includes both coinsurance and deductible for covered services, and the costs of services provided but not covered by the patient's insurance, stating that this practice is ''industry standard'' as well as allowable under IRS Form 990. Echoing calls from others, the commenter suggested that CMS revise the definitions for uncompensated care to reflect the entirety of costs to hospitals for providing charity care, including uninsured discounts.

In contrast to the support for the inclusion of discounts to the uninsured in the definition of uncompensated care, one commenter believed that expansion of the definition of uncompensated care to include discounts to the uninsured is flawed because these discounts are nonlegitimate ''costs'' for community health reporting. The commenter stated that hospitals in its State have a long history of discounts to the uninsured through an Attorney General's agreement, and that the State tends to have a higher-than-normal adoption rate of high-deductible health plans. Therefore, the commenter has come to this conclusion regarding these discounts based on its own significant experience.

Response: In general, we will attempt to address commenters' concerns in future cost report clarifications to ensure that Worksheet S–10 is an appropriate instrument to collect the information necessary to implement section 3133 of the Affordable Care Act. With regard to the comments regarding Medicaid shortfalls, we recognize commenters' concerns but continue to believe there are other compelling arguments for excluding Medicaid shortfalls from the definition of uncompensated care, including the fact that several key stakeholders do not consider Medicaid shortfalls in their definition of uncompensated care, and that it is most consistent with section 3133 of the Affordable Care Act for Medicare uncompensated care payments to target hospitals that incur a disproportionate share of uncompensated care for patients with no insurance coverage. Conceptual issues aside, we note that even if we were to adjust the definition of uncompensated care to include Medicaid shortfalls, this would not be a feasible option at this time due to computational limitations. Specifically, computing such losses is operationally problematic because Medicaid pays hospitals a single DSH payment that in part covers the hospital's costs in providing care to the uninsured and in part covers estimates of the Medicaid ''shortfalls.'' Therefore, it is not clear how CMS would determine how much of the ''shortfalls'' is left after the Medicaid DSH payment is made. In addition, in some States, hospitals return a portion of their Medicaid revenues to the State via provider taxes, making the computation of ''shortfalls'' even more complex. Accordingly, we continue to believe it is appropriate to apply a definition of uncompensated care costs that includes charity care and non-Medicare bad debt for FY 2018.

With regard to the comments that States differ in how they define uncompensated care costs, and that hospitals' costs of treating the uninsured are not always categorized as charity care and bad debt, such as in the case of discounts to the uninsured who are unable to pay or unwilling to provide income information, we believe the commenters are referring to the Worksheet S–10 instructions for Line 20, which state, in part, ''Do not include charges for either uninsured patients given discounts without meeting the hospital's charity care criteria or patients given courtesy discounts.'' We believe that hospitals have the discretion to design their charity care policies as appropriate, and may include discounts offered to uninsured patients as ''charity care.'' However, we will also further consider the concern raised by the commenter as to whether CMS' current instructions are inadvertently creating a disincentive to offer such discounts, and we may consider revisions to the instructions on Line 20 of Worksheet S–10 to further clarify when patient discounts would be considered charity care versus bad debt.

Comment: Many commenters expressed concerns relating to, and provided suggestions for, calculating charity care and bad debt as captured on Worksheet S–10:

- Commenters expressed confusion about what is identified as an indigent care program, and when charity care and Medicaid noncovered charges are components of charity care, pointing out that there are several areas of confusion and areas that might encourage individual interpretation. In addition, commenters believed that government providers are misreporting data related to charity care by including all charges for their indigent care/general relief patient populations as charity care while not accounting for offsetting payments. The commenters expressed their view that services furnished under these programs are not uncompensated, but are funded through State and local tax assessments. Therefore, the commenters requested that CMS require that patient charges cannot be included in the cost of charity care unless the related services are not covered by an indigent care program. More generally, commenters stated that hospitals have difficulty in identifying where to report

nonpatient-specific payments that are received to offset charity care and bad debt.

• Commenters raised a similar concern about Line 20 of Worksheet S–10 regarding a possible discrepancy between considering noncovered charges for Medicaid patients as eligible for charity care, but not allowing noncovered charges for patients that have some commercial coverage to be considered charity care. In particular, according to commenters, the current methodology used to calculate the cost of charity care for insured patients is incorrect because it asks hospitals to apply a CCR to deductibles and coinsurance in order to arrive at the cost, which will significantly understate the cost of charity care because coinsurance and deductibles are typically a function of the payment rate rather than the hospital's charges for the service. To this end, one commenter noted that waived deductibles and coinsurance for charity care insured patients would always be expected to be less than, and only a fraction of, full charges for charity care for uninsured patients. Commenters suggested that CMS develop a separate CCR applicable to deductible and coinsurance amounts to calculate the cost of charity care.

• One commenter requested that instructions for the Worksheet S–10 ensure that the dollar amount reported for Line 22, Column 2 represents payments from both patients and insurers for specific patient accounts that were granted charity care during the cost reporting period.

• A few commenters stated that any further revision to the instructions for Line 20 of Worksheet S–10 should reference a hospital's ''financial assistance policy'' for consistency with the terminology used in the regulations implementing section 501(r) of the Internal Revenue Code, which require hospitals to establish financial assistance policies and to reduce charges for services furnished to individuals who qualify for assistance under those policies. In addition, commenters suggested that CMS clarify that Federal law does not mandate eligibility criteria for a hospital's financial assistance policy.

• Commenters stated that hospitals report charity care amounts for patients that qualify for partial charity inconsistently, and requested that CMS clarify how amounts should be reported for patients that qualify for partial charity care, including both uninsured individuals as well as patients with financial responsibility after their insurance pays. In addition, one commenter asked CMS to provide guidance that protects facilities that expanded their tiered partial charity care programs in order to cover more individuals falling within a broader income scale.

• Many commenters believed that the definition of bad debt is unclear and that the methodology CMS uses to arrive at the cost of bad debt significantly understates the uncompensated care expense that hospitals incur as a result of uncollectable amounts. Commenters also asked for clarification on whether or not non-Medicare bad debt claimed on Line 26 of Worksheet S–10 should be netted of recoveries received during the cost report period.

• Commenters also expressed concern in regard to patients who have some form of insurance but are not able to meet their cost sharing responsibility, in particular coinsurance and deductibles. These commenters believed that applying the hospital's CCR to the amount on Line 26 of Worksheet S–10 understates the costs associated with deductibles and coinsurance for insured patients written off as bad debt. The commenters recommended that CMS revise Worksheet S–10 to require separate reporting for bad debt written off for the uninsured and for those who are insured but cannot afford their cost sharing, similar to the instructions for Line 20.

• Several commenters observed that the current Worksheet S–10 methodology may provide an incentive to hospitals to overstate charity care, compromising the fidelity of the information collected.

• One commenter stated that bad debt and charity care should be considered reductions to expected hospital payment and thus should not treated as hospital charges and adjusted by the CCR.

• One commenter believed that charity care and bad debt are not valid measures of a hospital's uncompensated care burden, as charity care may be offset with direct taxes, appropriations, and/or uncompensated care payments.

Response: We intend to consider the various issues raised by the commenters that directly relate to reporting of charity care and bad debt costs on Worksheet S–10 as we continue to review Worksheet S–10. We will continue to work with our stakeholders to address their concerns through provider education and further refinement of the instructions to the Worksheet S–10 as appropriate. We also clarify that the bad debt claimed on Line 26 of Worksheet S–10 must be net of bad debt recoveries received during the cost report period.

• *Trims to apply to CCRs on Line 1 of Worksheet S–10.* As we noted in the FY 2017 IPPS/LTCH PPS proposed and final rules (81 FR 25093 and 81 FR 56971), commenters have suggested that uncompensated care costs reported on Worksheet S–10 should be audited due to extremely high values consistently reported by some hospitals. In response to these comments, we reviewed the Worksheet S–10 data and identified approximately 10 to 20 hospitals that have anomalous uncompensated care costs. We note that many of these hospitals are public hospitals, which can have charging practices that are distinct from other hospital types. We believe that, just as we apply trims to hospitals' CCRs to eliminate anomalies when calculating outlier payments for extraordinarily high cost cases (§ 412.84(h)(3)(ii)), it is appropriate to apply statistical trims to the CCRs on Worksheet S–10, Line 1 that are considered anomalies. Specifically, § 412.84(h)(3)(ii) states that the Medicare contractor may use a statewide CCR for hospitals whose operating or capital CCR is in excess of 3 standard deviations above the corresponding national geometric mean (that is, the CCR ''ceiling''). This mean is recalculated annually by CMS and published in the proposed and final IPPS rules each year. To control for data anomalies, in the FY 2017 rulemaking, we considered approaches that would trim hospitals' CCRs to ensure reasonable CCRs are used to convert charges to costs for purposes of determining uncompensated care costs.

After considering the comments received in response to the FY 2017 IPPS/LTCH PPS proposed rule, which were discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56971 through 56973), in the FY 2018 IPPS/LTH PPS proposed rule (82 FR 19954 and 19955), for FY 2018, we proposed the following alternative methodology for trimming CCRs:

Step 1: Remove Maryland hospitals. In addition, we will remove all-inclusive rate providers, as they have charge structures that differ from other IPPS hospitals, and providers that did not report a CCR on Worksheet S–10, Line 1, and assign them the statewide average CCR in step 5 below.

Step 2: For hospitals with multiple cost reports included in the 2014 HCRIS data, (a) combine the amounts from Worksheet C, Part I, Line 202, Column 3 from each cost report to calculate total costs, (b) combine the amounts from Worksheet C, Part I, Line 202, Column 8 from each cost report to calculate total charges, and (c) divide the total costs by

the total charges to arrive at a recalculated CCR.

Step 3: Calculate a CCR ''ceiling'' using the CCRs reported on Worksheet S–10, Line 1, from all IPPS hospitals that were not removed in Step 1 (including non-DSH eligible hospitals), or the recalculated CCR described in Step 2. The ceiling is calculated as 3 standard deviations above the national geometric mean CCR. This approach is consistent with our calculation of the CCR ceiling used for high-cost outliers. Remove all hospitals that exceed the ceiling so that these aberrant CCRs do not skew the calculation of the statewide average CCR. Based on the information currently available to us during the development of this final rule, this trim would remove 9 hospitals that have CCRs above the calculated ceiling of 0.932.

Step 4: Using the CCRs for the remaining hospitals in Step 3, determine the urban and rural statewide average CCRs using Line 1 of Worksheet S–10 for hospitals within each State (including non-DSH eligible hospitals), weighted by the sum of total inpatient discharges and outpatient visits from Worksheet S–3, Part I, Line 14, Column 14.

Step 5: Assign the appropriate statewide average CCR (urban or rural) calculated in Step 4 to all hospitals with a CCR greater than 3 standard deviations above the corresponding national geometric mean (that is, the CCR ''ceiling''), as well as to providers that did not report a CCR on Worksheet S–10, Line 1. The statewide average CCR would therefore be applied to 27 hospitals, of which 18 did not report a CCR on Worksheet S–10, Line 1 and 9 had a CCR that exceeded the calculated ceiling of 0.932. (We note that the number of hospitals that are assigned the statewide average CCR has changed significantly from the estimates included in the proposed rule due to our decision not to incorporate Worksheet S–10 data into the calculation of Factor 3 for all-inclusive rate providers, as discussed above.)

After applying the applicable trims to a hospital's CCR as appropriate, we proposed to calculate a hospital's uncompensated care costs as being equal to Line 30, which is the sum of Line 23 and Line 29, as follows:

Hospital Uncompensated Care Costs = Line 30 (Line 23 + Line 29), which is equal to—

[(Line 1 CCR (as adjusted, if applicable) × charity care line 20) − (Payments received for charity care Line 22)]

+

[(Line 1 CCR (as adjusted, if applicable) × Non-Medicare and non-reimbursable Bad Debt Line 28)].

We invited public comments on our proposed trim methodology for FY 2018.

Comment: Many commenters expressed concern that the proposed trim methodology would improve neither the accuracy nor consistency of uncompensated care data. The commenters recommended that CMS further review the trim methodology or delay its application until an audit of the Worksheet S–10 is complete.

Several commenters suggested that high-cost outliers be entirely removed to avoid skewing the data instead of setting their CCRs as the statewide average. The commenters contended that automatically setting CCRs to the statewide average would be ''inappropriate,'' especially when performed without opportunities for explanation. One commenter stated that hospitals that have been identified as potential outliers should have the opportunity to explain their data and correct errors before the trim methodology is applied, which would facilitate data validity.

A few commenters requested that the trimming methodology should not be finalized until an audit of the data has been conducted, and that hospitals with extremely high CCRs should be audited and an appropriate CCR determined instead of applying an arbitrary trim to a statewide average. One commenter suggested that CMS develop a separate audit protocol for all-inclusive billers before application of the trimming methodology. Another commenter believed that it would be inappropriate to assume that reported amounts are incorrect and thus change State averages or other DSH calculations, especially without an auditing process in place. Others identified ''anomalies'' in data that would not be addressed by the proposed trims, such as a hospital with uncompensated care that equaled to four times total hospital charges. Another commenter requested that instead of applying the statewide average CCR, CMS instruct MACs to use 2015 Worksheet S–10 data if the 2014 data were incomplete or unusually high.

As noted above, several commenters expressed concern over the proposed trim methodology because hospitals that are considered ''all-inclusive rate providers'' are not required to complete Worksheet C, Part I, which is used for reporting the CCR on Line 1 of the Worksheet S–10. Commenters noted that, as a result, the proposed trim methodology inappropriately modifies their uncompensated care costs, and that a high CCR could be accurate if the hospital's charges are close to costs, as is usually the case for all-inclusive rate hospitals. One commenter suggested that, instead of applying a trim, CMS evaluate CCRs on cost reports to identify misreported, erroneous values and not penalize hospitals that are accurately reporting information under a CMS-sanctioned methodology.

Response: We appreciate the additional information provided by the commenters related to applying trims to the CCRs. We intend to further explore which trims are appropriate to apply to the CCRs on Line 1 of Worksheet S–10, including whether it is appropriate to apply a unique trim to certain subsets of hospitals, such as all-inclusive rate providers. We note that all-inclusive rate providers have the ability to compute and enter their appropriate CCR on Worksheet S–10, Line 1, by answering Yes to the question on Worksheet S–2, Part I, Line 115, and not have it computed using information from Worksheet C, Part I. We will give more consideration to the utilization of statewide averages in substituting outlier CCRs, and in future rulemaking, we intend to consider other approaches that would ensure validity of the trim methodology and not penalize hospitals that use alternative methods of cost apportionment. However, as we previously discussed, because all-inclusive rate providers have charge structures that differ from other IPPS hospitals, we will not use data from the Worksheet S–10 to determine Factor 3 for these hospitals for FY 2018. Instead, we will determine Factor 3 for these hospitals using an average of three individual Factor 3s, using the Factor 3 calculated using low-income insured days for FY 2013 twice and the Factor 3 calculated using low-income insured days for FY 2012 once.

Comment: Many commenters requested that the cost of graduate medical education (GME) be included within the CCR calculation to account for the costs associated with the training of interns and residents. One commenter stated that hospitals charges are based on ''all costs'' acquired in the provision of medical services, which would ''naturally'' include GME. The commenter indicated that exclusion of costs associated with GME would result in inaccurate reporting of costs and lower CCRs.

Several commenters observed that GME is included in the denominator but not the numerator of the Worksheet S–10 CCR and that this discrepancy should be rectified. One commenter observed that this inconsistency occurs

because Line 1 uses data from Worksheet C, Column 3 (''costs,'' which do not include GME) and Worksheet C, Column 8 (''charges,'' which do include GME). The commenter recommended using the ''costs'' definition from Worksheet B, Column 24, Line 118 to reconcile the discrepancy. One commenter noted that inclusion of GME costs in the numerator would ensure ''fairness'' in the calculation. Another commenter stated that modification of the calculation to include GME costs within the CCR should occur on Line 1 of the Worksheet S–10.

Response: As we have stated previously in response to this issue, we believe that the purpose of uncompensated care payments is to provide additional payment to hospitals for treating the uninsured, not for the costs incurred in training residents. In addition, because the CCR on Line 1 of Worksheet S–10 is pulled from Worksheet C, Part I, and is also used in other IPPS ratesetting contexts (such as high-cost outliers and the calculation of the MS–DRG relative weights) from which it is appropriate to exclude GME because GME is paid separately from the IPPS, we hesitate to adjust the CCRs in the narrower context of calculating uncompensated care costs. Therefore, we continue to believe that it is not appropriate to modify the calculation of the CCR on Line 1 of Worksheet S–10 to include GME costs in the numerator.

After consideration of the comments we received, we are finalizing our proposal to apply statistical trims to the CCRs on Worksheet S–10, Line 1 that are considered anomalies using the methodology outlined earlier, but are not applying the statewide average to all-inclusive rate providers as described earlier.

• *Cost report revisions and Worksheet S–10 audits.* While not directly relevant to our proposal to use FY 2014 Worksheet S–10 data beginning in FY 2018, in the proposed rule, we noted that, as part of our ongoing quality control and data improvement measures to continue to improve the Worksheet S–10 data over time, we have made revisions to the cost report instructions and developed an audit process.

With respect to the cost reporting instructions, on November 18, 2016, we issued Transmittal 10 which updated the instructions for Form 2552–10. Specifically, we updated the instructions in Section 4012 of Chapter 40 of the Provider Reimbursement Manual, Part II. The instructions clarify the reporting of charges for charity care. Transmittal 10 is available for download at the CMS Web site at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2016-Transmittals-Items/R10P240.html*.

With respect to the audit process, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56964), we stated that we intended to provide standardized instructions to the MACs to guide them in determining when and how often a hospital's Worksheet S–10 should be reviewed. We indicated that we would not make the MACs' review protocol public, as all CMS desk review and audit protocols are confidential and are for CMS and MAC use only. The instructions for the MACs are still under development and will be provided to the MACs as soon as possible. We refer readers to the FY 2017 IPPS/LTCH PPS final rule for a complete discussion concerning the issues that we are considering in developing the instructions that will be provided to the MACs. We note that, in addition to our stated belief in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19955) that cost reports beginning in FY 2017 will be the first cost reports for which the Worksheet S–10 data will be subject to a desk review, we expect cost reports beginning in FY 2014, FY 2015, and FY 2016, to be subject to further scrutiny after submission. We will continue to work with our stakeholders to address their concerns through provider education and further refinement of the instructions to the Worksheet S–10, as appropriate.

Comment: Many commenters expressed concern about confusing or unclear instructions in the Worksheet S–10, especially with regard to the definition of ''uncompensated care.'' The commenters expressed a general concern toward ''inconsistent reporting'' and ''inadequate and unreliable data'' abounded as a result of current Worksheet S–10 instructions. One commenter requested that CMS clarify the definition of ''uncompensated care'' specifically within the general instructions of the Worksheet S–10. Another commenter observed that issues with flawed data may be the result of inconsistent reporting that could be ameliorated by clarification of the Worksheet S–10 instructions, such as on Lines 20 and 21.

Several commenters expressed concern that, despite the clarifications discussed in the FY 2017 IPPS/LTCH PPS final rule, MACs lacked ''guidance, instruction, and training'' for the ''uniform and even application'' of the reporting requirements for the Worksheet S–10. One commenter recommended that CMS provide additional guidance and documentation to MACs and instruct them to accept amended and/or corrected cost reports. Another commenter expressed discontent that CMS allowed hospitals to amend data from FY 2014 in late FY 2016 but provided ''no education,'' guidance, or other ''insight'' that may have facilitated accurate and/or consistent hospital reporting. Many commenters provided a broad range of detailed suggestions related to reporting requirements for specific lines of Worksheet S–10. Commenters suggested the following general modifications to the manner in which uncompensated care costs are captured on Worksheet S–10:

• Commenters observed that the instructions for Worksheet S–10 are inconsistent with generally accepted accounting principles (GAAP) and differ from the accounting practices of the majority of hospitals. Therefore, the commenters requested that CMS amend the cost reporting instructions to require hospitals to report amounts based on GAAP. One commenter believed that using GAAP would make every hospital be under the same rules. Commenters also suggested that the Worksheet S–10 instructions be amended to require hospitals to report the same bad debt and charity care amounts they report on their financial statements, which are GAAP appropriate. In particular, one commenter asked that CMS clarify whether the 35 percent residual of Medicare bad debts recorded as bad debt expense should be included in the determination of uncompensated care costs (currently, based on GAAP, a hospital will record 100 percent of the unpaid Medicare deductible and coinsurance as bad debt; however, only 65 percent is reimbursed by Medicare).

• Commenters noted that because Worksheet S–10 data is derived from data reported on the Medicare cost report, charges and payments for physician services are currently excluded. However, the commenters stated that hospitals provide physician services to patients with little or no access to private physicians. They noted that safety-net hospitals in low-income communities particularly provide these services. As a result, several commenters argued the Worksheet S–10 should include uncompensated care costs related to employed physician services.

• Commenters requested clarification of whether charity care charges should be reported for inpatient hospital services, outpatient hospital services, or both. The commenters requested the ability to report these charges on separate lines and to apply separate CCRs to these separate sets of costs. One commenter noted that because ''aggregate outpatient CCRs are usually

higher than aggregate inpatient CCRs, application of an overall CCR to uncompensated care charges will generally underestimate UC costs.''

• Commenters noted that the instructions for Line 26 include Medicare bad debts for services provided beyond the inpatient and outpatient setting, and interpreted this to mean that hospitals should include non-Medicare bad debts for services provided in the following settings for which expenses are included on the hospital cost report: Skilled nursing beds (both swing beds and distinct part facilities); distinct part inpatient rehabilitation units; distinct part LTCHs; distinct part psychiatric units; dialysis centers; CMHCs; RHCs; and FQHCs. The commenters asked CMS to confirm in the final rule that this interpretation is correct. Similarly, commenters requested that CMS define any additional distinct part units or services that are not listed in the instructions for Line 26 but should be included in that line when reporting non-Medicare bad debt.

• Commenters advised requiring Medicaid DSH payments and Medicaid supplemental payment information to be reported on separate lines, and to offset all of these payments against Medicaid costs reported on Worksheet S–10. In addition, according to one commenter, the current Worksheet S–10 provides an incomplete picture of Medicaid shortfall and should be revised to allow hospitals to deduct intergovernmental transfers, certified public expenditures, and provider taxes from their Medicaid revenues. Specifically, some commenters also requested separate reporting of a number of such payments, including direct payments to hospitals, Medicaid DSH, and supplementary payments including upper payment limits, intergovernmental transfers, certified government expenditures, provider taxes, other government payments, and payments for local or state indigent care.

• One commenter suggested that CMS integrate payer mix into Worksheet S–10, as providers with a substantial commercial payer mix often have operating margins that help offset uncompensated care costs. The commenter recommended that CMS examine methods to adjust the uncompensated care amount for payer mix.

• One commenter noted that CCRs in Worksheet S–10 are reported with Reasonable Compensation Equivalency (RCE) limits applied. The commenter cited the discussion in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50161), which states that RCE limits have no effect on IPPS provider payments. Therefore, the commenter believed that if the CCR in Worksheet S–10 is used, IPPS hospitals' payments would be affected by RCE limits, and RCE disallowances should therefore be removed from the CCR on Line 1 of Worksheet S–10.

• Commenters observed that CCRs for ''parts of hospitals'' such as facility-based skilled nursing facilities and inpatient rehabilitation facilities are very different from the CCRs for acute care hospitals paid under the IPPS. The commenters questioned the appropriateness of including parts of hospitals in the CCR in Worksheet S–10. In particular, one commenter noted that the initial instructions on the Worksheet S–10 ask hospitals to report costs ''incurred by the hospital for providing inpatient and outpatient hospital services.'' However, later instructions for Line 20 ask hospitals to report gross charity care costs for the ''entire facility,'' which could lead to IPPS and OPPS payments to parts of the hospital that should not have been covered, such as skilled nursing facilities and rehabilitation facilities. The commenter recommended that CMS either use consistent language or list the subparts of hospitals that should be included.

Response: Some of the commenters express concerns and raise questions that have not been raised before, while others have been raised in previous rulemaking. We believe that a number of these questions and concerns are addressed by the updated instructions for the Worksheet S–10 that were issued in November 2016, which clarify the reporting of charges for charity care. We will continue to work with our stakeholders to address their concerns through provider education and further refinement of the instructions to the Worksheet S–10, as appropriate.

With regard to the comments asking for clarification of which inpatient and outpatient services should be included in the uncompensated care costs reported on the Worksheet S–10, we note that the cost report instructions at Section 4012 of CMS Pub. 15–2, state: ''Worksheet S–10—Hospital Uncompensated and Indigent Care Data—Section 112(b) of the Balanced Budget Refinement Act (BBRA) requires that short-term acute care hospitals (§ 1886(d) of the Act) submit cost reports containing data on the cost incurred by the hospital for providing *inpatient and outpatient hospital services for which the hospital is not compensated*'' (emphasis added). In a similar vein, the CCR used on Worksheet S–10, Line 1 is from Worksheet C, Part I, Line 202. This CCR reflects costs and charges of all hospital inpatient departments and outpatient department and clinics. Thus, Worksheet S–10 is designed to capture uncompensated care costs associated with the hospital under all of the hospital's Medicare provider agreements, including provider-based facilities. However, Worksheet S–10 is not intended to capture uncompensated care costs related to physician services. We note that at various points on Worksheet S–10, the instructions state, ''Include payments for all covered services except *physician or other professional services*'' (emphasis added).

Finally, with regard to the comment that the CCRs on Worksheet S–10 are reported with the RCE limits applied, we believe the commenter is mistaken. Line 1 of Worksheet S–10 instructs hospitals to compute the CCR by dividing the costs from Worksheet C, Part I, Line 202, Column 3, by the charges on Worksheet C, Part I, Line 202, Column 8. The RCE limits are applied in Column 4, not in Column 3; thus, the RCE limits do not affect the CCR on Line 1 of Worksheet S–10.

H. Medicare-Dependent, Small Rural Hospital (MDH) Program (§ 412.108)

1. Background for the MDH Program

Section 1886(d)(5)(G) of the Act provides special payment protections, under the IPPS, to a Medicare-dependent, small rural hospital (MDH). (For additional information on the MDH program and the payment methodology, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51683 through 51684).) As discussed in section V.B.1. of the preamble of the FY 2018 IPPS/LTCH PPS proposed rule and this final rule, the MDH program provisions at section 1886(d)(5)(G) of the Act will expire at the end of FY 2017. Beginning with discharges occurring on or after October 1, 2017, all hospitals that previously qualified for MDH status will be paid based on the Federal rate.

Since the extension of the MDH program through FY 2012 provided by section 3124 of the Affordable Care Act, the MDH program had been extended by subsequent legislation as follows: Section 606 of the ATRA (Pub. L. 112–240) extended the MDH program through FY 2013 (that is, for discharges occurring before October 1, 2013). Section 1106 of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) extended the MDH program through the first half of FY 2014 (that is, for discharges occurring before April 1, 2014). Section 106 of the PAMA (Pub. L. 113–93) extended the MDH program

through the first half of FY 2015 (that is, for discharges occurring before April 1, 2015). Section 205 of the MACRA (Pub. L. 114–10) extended the MDH program through FY 2017 (that is, for discharges occurring before October 1, 2017). For additional information on the extensions of the MDH program after FY 2012, we refer readers to the following **Federal Register** documents: The FY 2013 IPPS/LTCH PPS final rule (77 FR 53404 through 53405 and 53413 through 53414); the FY 2013 IPPS notice (78 FR 14689); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50647 through 50649); the FY 2014 interim final rule with comment period (79 FR 15025 through 15027); the FY 2014 notice (79 FR 34446 through 34449); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50022 through 50024); the August 2015 interim final rule with comment period (80 FR 49596); and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57054 through 57057).

b. Expiration of the MDH Program

Because section 205 of the MACRA extended the MDH program through FY 2017 only, beginning October 1, 2017, the MDH program will no longer be in effect. Because the MDH program is not authorized by statute beyond September 30, 2017, beginning October 1, 2017, all hospitals that previously qualified for MDH status under section 1886(d)(5)(G) of the Act will no longer have MDH status and will be paid based on the IPPS Federal rate.

When the MDH program was set to expire at the end of FY 2012, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53404 through 53405), we revised our sole community hospital (SCH) policies to allow MDHs to apply for SCH status in advance of the expiration of the MDH program and be paid as such under certain conditions. We codified these changes in the regulations at §§ 412.92(b)(2)(i) and (b)(2)(v). Specifically, the existing regulations at §§ 412.92(b)(2)(i) and (b)(2)(v) allow for an effective date of an approval of SCH status that is the day following the expiration date of the MDH program. We note that these same conditions apply to MDHs that intend to apply for SCH status with the expiration of the MDH program on September 30, 2017. Therefore, in order for an MDH to receive SCH status effective October 1, 2017, the MDH must apply for SCH status at least 30 days before the expiration of the MDH program; that is, the MDH must apply for SCH status by September 1, 2017. The MDH also must request that, if approved as an SCH, the SCH status be effective with the expiration of the MDH program; that is, the MDH must request that the SCH status, if approved, be effective October 1, 2017, immediately after its MDH status expires with the expiration of the MDH program on September 30, 2017. We emphasize that an MDH that applies for SCH status in anticipation of the expiration of the MDH program would not qualify for the October 1, 2017 effective date for SCH status if it does not apply by the September 1, 2017 deadline. If the MDH does not apply by the September 1, 2017 deadline, the hospital would instead be subject to the usual effective date for SCH classification; that is, 30 days after the date of CMS' written notification of approval as specified at § 412.92(b)(2)(i).

We note that the regulations governing the MDH program are found at § 412.108 and the MDH program is also cited in the general payment rules in the regulations at § 412.90. As stated earlier, under current law, the MDH program will expire at the end of FY 2017, which is already reflected in § 412.108. As such, we did not propose to make specific amendments to the regulations at § 412.108 to reflect the expiration of the MDH program. However, it has come to our attention that, with the various extensions of the MDH program as noted earlier, we neglected to make conforming changes to the regulation text at § 412.90. Therefore, we proposed to revise the general payment rules under § 412.90 to reflect the expiration of the MDH program. We did not receive any public comments on our proposed conforming changes to the regulation text at § 412.90 and are finalizing these changes as proposed. However, we also proposed that if the MDH program were to be extended by law, similar to how it was extended through legislation set forth above, including most recently through FY 2017, by the MACRA (Pub. L. 114–10), we would make conforming changes to the regulations governing the MDH program at § 412.108(a)(1) and (c)(2)(iii) and the general payment rules at § 412.90(j) to reflect such an extension of the MDH program. We stated that these conforming changes would only be made if the MDH program were to be extended by statute beyond September 30, 2017. As of the time of the development of this final rule, there has been no change in law to extend the MDH program beyond FY 2017. Therefore, in this final rule, we are not making any additional changes to the regulations governing the MDH program at § 412.108, and, as stated above, the revisions we are finalizing to the general payment rules under § 412.90 reflect the current expiration of the MDH program on September 30, 2017.

Comment: Several commenters indicated that hospitals in their States would experience payment decreases as a result of the expiration of the MDH program. One commenter urged CMS to work with Congress to permanently extend the MDH program. Another commenter indicated that it would continue supporting congressional efforts to protect the MDH program.

Response: We appreciate the commenters' concerns about the expiration of the MDH program. However, CMS does not have the authority under current law to continue the MDH program beyond the September 30, 2017 statutory expiration date. These comments are similar to comments we received previously, prior to the statutory extensions of the MDH program for FYs 2013 and 2014 provided by subsequent legislation, and discussed in both the FY 2013 IPPS/LTCH PPS final rule (77 FR 53413 through 53414) and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50647 through 50649). Therefore, under current law, beginning October 1, 2017, all hospitals that previously qualified for MDH status will no longer have MDH status.

I. Hospital Readmissions Reduction Program: Updates and Changes (§§ 412.150 Through 412.154)

1. Statutory Basis for the Hospital Readmissions Reduction Program

Section 3025 of the Patient Protection and Affordable Care Act, as amended by section 10309 of the Patient Protection and Affordable Care Act, added section 1886(q) to the Act, which establishes the ''Hospital Readmissions Reduction Program'' effective for discharges from ''applicable hospitals'' beginning on or after October 1, 2012. Under the Hospital Readmissions Reduction Program, payments to applicable hospitals may be reduced to account for certain excess readmissions. We refer readers to section IV.E.1. of the FY 2016 IPPS/LTCH PPS final rule (80 FR 49530 through 49531) for a detailed discussion and additional information on of the statutory history of the Hospital Readmissions Reduction Program.

On December 13, 2016, the 21st Century Cures Act (Pub. L. 114–255) was enacted. Section 15002 of Public Law 114–255 added subparagraphs (D) and (E) to section 1886(q)(3) of the Act. These subparagraphs direct the Secretary to assign hospitals to peer groups, develop a methodology that allows for separate comparisons for hospitals within these groups, and

allows for changes in the risk adjustment methodology. Section 15002 of Public Law 114–255 also directs MedPAC to conduct a review of overall hospital readmissions and whether such readmissions are related to any changes in outpatient and emergency services furnished. A report on the study is required to be submitted in the MedPAC's Report to Congress no later than June 2018.

Section 1886(q)(3)(D) of the Act directs the Secretary to develop a transitional methodology that accounts for the percentage of full-benefit dual-eligible patients treated by a hospital to determine a hospital's payment adjustment factor. Section 1886(q)(3)(D)(i) of the Act sets forth the requirement that the Secretary assign hospitals to groups and apply a methodology ''that allows for separate comparison of hospitals within each such group.'' This applies to discharges that occur during and after FY 2019 and before the application of section 1886(q)(3)(E)(i) of the Act, which allows the Secretary to take into account the recommendations in the reports required by the IMPACT Act (Pub. L. 113–185) related to risk adjustment and social risk factors. The first of two reports required in the IMPACT Act was released in December 2016 (available at: *https://aspe.hhs.gov/system/files/pdf/253971/ASPESESRTCfull.pdf*), and the second report is required to be completed by October 2019.

The hospital groups in section 1886(q)(3)(D)(ii) of the Act are described as being based on their overall proportion of the inpatients who are entitled to, or enrolled for, benefits under Medicare Part A and who are full-benefit dual-eligible individuals (as defined in section 1935(c)(6) of the Act). The Secretary is further required to consult with MedPAC when defining groups and may consider analysis done by MedPAC in preparation for its June 2013 report submitted to Congress. Section 1886(q)(3)(D)(iii) of the Act prevents the imposition of additional reporting requirements in order to carry out subparagraph (D). Section 1886(q)(3)(D)(iv) of the Act requires that the estimated total amount of reductions in payments using the methodology should equal the estimated total amount of reductions in payments if subparagraph (D) did not apply.

Section 1886(q)(3)(E) of the Act outlines the considerations the Secretary may take into account with respect to the risk adjustment methodology. Section 1886(q)(3)(E)(i) of the Act allows the Secretary to take into account studies conducted and recommendations made by the Secretary under section 2(d)(1) of the IMPACT Act in the application of risk adjustment methodologies. This does not preclude the consideration of the use of groupings of hospitals. The Secretary is also allowed under section 1886(q)(3)(E)(ii) of the Act to consider the use of ''V'' or other ICD-related codes for removal of a readmission with respect to discharges occurring after FY 2018. Section 1886(q)(3)(E)(iii) of the Act outlines the considerations the Secretary may make in the removal of certain readmissions. For discharges occurring after FY 2018, the Secretary may consider the removal as a readmission of an admission that is classified within one or more of the following: Transplants; end-stage renal disease; burns, trauma; psychosis; or substance abuse.

2. Regulatory Background

We refer readers to the following past final rules for detailed discussions of the regulatory background and descriptions of the current policies for the Hospital Readmissions Reduction Program: The FY 2012 IPPS/LTCH PPS final rule (76 FR 51660 through 51676); the FY 2013 IPPS/LTCH PPS final rule (77 FR 53374 through 53401); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50649 through 50676); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50024 through 50048); the FY 2016 IPPS/LTCH PPS final rule (80 FR 49530 through 49543); and the FY 2017 IPPS/LTCH PPS final rule (81 FR 56973 through 56979). These policies describe the general framework for the implementation of the Hospital Readmissions Reduction Program, including: (1) The selection of and measures for the applicable conditions; (2) the calculation of the excess readmission ratio, which is used, in part, to calculate the readmissions adjustment factor; (3) the current calculation of the hospital readmission payment adjustment factor, specifically addressing the base operating DRG payment amount, aggregate payments for excess readmissions, and aggregate payments for all discharges; (4) the opportunity for hospitals to review and submit corrections using a process similar to what is currently used for posting results on *Hospital Compare;* (5) the adoption of an extraordinary circumstances exception policy to address hospitals that experience a disaster or other extraordinary circumstance; (6) the clarification that the public reporting of excess readmission ratios will be posted on an annual basis to the *Hospital Compare* Web site as soon as is feasible following the preview period; and (7) the specification that the definition of ''applicable hospital'' does not include hospitals and hospital units excluded from the IPPS, such as LTCHs, cancer hospitals, children's hospitals, IRFs, IPFs, CAHs, and hospitals in Puerto Rico.

We also have codified certain requirements of the Hospital Readmissions Reduction Program at 42 CFR 412.152 through 412.154.

CMS strives to put patients first, ensuring that they are empowered to make decisions about their own healthcare along with their clinicians, using information from data-driven insights that are increasingly aligned with meaningful quality measures. We support technology that reduces burden and allows clinicians to focus on providing high-quality health care for their patients. We also support innovative approaches to improve quality, accessibility, and affordability of care while paying particular attention to improving clinicians' and beneficiaries' experience when interacting with CMS programs. We believe the Hospital Readmissions Reduction Program in combination with other efforts across the Department of Health and Human Services encourages hospitals to improve health care quality and value, while giving patients and providers the tools and information needed to make the best decisions for them. We recognize that the Hospital Readmissions Reduction Program represents a key component of the way that we bring quality measurement and improvement together with payment, we have taken efforts to review existing policies to identify how to move the program forward in the least burdensome manner possible while continuing to encourage improvement in the quality of care provided to patients.

3. Maintenance of Technical Specifications for Quality Measures

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50039) for a discussion of the maintenance of technical specifications for quality measures for the Hospital Readmissions Reduction Program. Technical specifications of the readmission measures are provided on our Web site in the Measure Methodology Reports at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. Additional resources about the Hospital Readmissions Reduction Program and measure technical specifications are on the QualityNet Web site on the Resources page at: *http://*

www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772412995.

4. Policies for the Hospital Readmissions Reduction Program

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19957 through 19967), we proposed the following policies for the Hospital Readmissions Reduction Program: (1) The applicable time period for FY 2018; (2) the calculation of aggregate payments for excess readmissions for FY 2018; (3) changes to the payment adjustment factor in accordance with section 15002 of Public Law 114–255 for FY 2019; and (4) updates to the Extraordinary Circumstance Exception policy beginning in FY 2018 as related to extraordinary circumstances that occur on or after October 1, 2017. These proposals are described in more detail below.

5. Applicable Period for FY 2018

Under section 1886(q)(5)(D) of the Act, the Secretary has the authority to specify the applicable period with respect to a fiscal year under the Hospital Readmissions Reduction Program. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51671), we finalized our policy to use 3 years of claims data to calculate the readmission measures. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53675), we codified the definition of ''applicable period'' in the regulations at 42 CFR 412.152 as the 3-year period from which data is collected in order to calculate excess readmissions ratios and adjustments for the fiscal year, which includes aggregate payments for excess readmissions and aggregate payments for all discharges used in the calculation of the payment adjustment.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56974 through 56975), for FY 2017, consistent with the definition specified at § 412.152, we established an ''applicable period'' for the Hospital Readmissions Reduction Program to be the 3-year period from July 1, 2012 through June 30, 2015. In other words, the excess readmissions ratios and the payment adjustment (including aggregate payments for excess readmissions and aggregate payments for all discharges) for FY 2017 are calculated using data from the 3-year time period of July 1, 2012 through June 30, 2015.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19957), for FY 2018, consistent with the definition specified at § 412.152, we proposed that the ''applicable period'' for the Hospital Readmissions Reduction Program would be the 3-year period from July 1, 2013 through June 30, 2016. In other words, we proposed that the excess readmissions ratios and the payment adjustment (including aggregate payments for excess readmissions and aggregate payments for all discharges) for FY 2018 would be calculated using data from the 3-year time period of July 1, 2013 through June 30, 2016. We invited public comment on this proposal.

Comment: Many commenters expressed concern about the proposed Hospital Readmissions Reduction Program performance period for FY 2018 because it combines data collected under both ICD–9 and ICD–10. Commenters requested that CMS provide further empirical analysis in the final rule to show that measure reliability and validity are not compromised by using two different coding systems and ensure that the ICD–10 versions of the measures in the Hospital Readmissions Reduction Program are endorsed by the National Quality Forum (NQF). One commenter also recommended that CMS analyze performance differences resulting from the transition to ICD–10 for all the measures used in all its public reporting and pay-for-performance programs to determine if there are any unintended biases and measure performance changes because of the change. One commenter disagreed with the use of the three-year performance period for FY 2018 because commenter believes it is too long and combines data from ICD–9 and ICD–10. The commenter suggested that a one-year performance period would be more appropriate.

Response: The readmission measures in the Hospital Readmissions Reduction Program all completed ''maintenance of endorsement,'' a periodic evaluation of measures to assess impact and potential unintended consequences, in December 2016 and are NQF-endorsed. The NQF requires developers to submit all ICD–9 and ICD–10 diagnosis and procedure codes used to define the measure cohorts. We identified all ICD–10 codes that corresponded with ICD–9 codes used in the measure cohort definitions using the General Equivalence Mappings tool (GEMs). The ICD–10 codes identified using GEMs were reviewed by measure and clinical experts and made public as a part of the maintenance of endorsement process. However, because the ICD–10 code system was implemented in October 2015, there were insufficient claims coded with ICD–10 to provide any testing results to NQF during the endorsement maintenance process. We will submit testing results in claims data coded with ICD–10 in future cycles of NQF endorsement maintenance.

In addition to identifying ICD–10 codes used to define the measures' cohorts using the GEMs tool and completing a review of those codes by clinical and measure experts, we also examined the frequency of the use of these codes in the first 6-months of ICD–10 coded claims for Medicare fee-for-service (FFS) patients who were 65 years and older. As a part of calculating measure results that will be made public in July 2017, we completed extensive testing of measure specifications and of measure performance. For the most recent measurement period from July 2013 through June 2016, there are 9 months, from October 2015 through June 2016, of ICD–10 coded claims. Results of some of this testing is described in the publicly available 2017 Annual Updates and Specifications reports for all readmission measures, including a description of the ICD–10 measure specifications, a description of measure cohort sizes, the number of acute care hospitals included in the measure, risk-standardized readmission rates in the national sample, risk variable frequencies and risk model coefficients, as well as overall model performance for each year and for the 3-year measurement period with the combined ICD–9 and ICD–10 codes. The results of these analyses demonstrate stability in the measure cohort, in the number of hospitals included in the measure, in the performance of the measure risk model, and in trends of modest reductions in risk-standardized readmission rates across the country.

We have decided to continue to use a three-year measurement period rather than a one-year measurement period despite the implementation of ICD–10. We use a 3-year measurement period because some small and rural hospitals do not have at least 25 admissions for Medicare FFS patients who are 65 years and older for each of the measure conditions in a single year or even over the course of two years. The three-year period allows us to include the maximum possible number of hospitals in public reporting.

In addition, we have examined the average change in risk-standardized readmission rates at the hospital-level and the distribution of changes in rates for all readmission measures comparing the results of the 2015, 2016, and 2017 reporting periods. We found that differences in average hospital-level performance comparing the 2016 performance year, which included only ICD–9 claims, and the 2017 performance year, which included 9 months of ICD–

10 claims, were similar to differences in performance observed between the 2015 and 2016 performance years. We are currently evaluating and considering the feasibility of publicly releasing these analyses. We believe the results show that our conversion process is maintaining a high level of accuracy.

After consideration of the public comments we received, we are finalizing as proposed, without modification, the applicable period of the 3-year time period of July 1, 2013 through June 30, 2016 to calculate readmission payment adjustment factor for FY 2018 under the Hospital Readmissions Reduction Program.

6. Calculation of Aggregate Payments for Excess Readmissions for FY 2018

Section 1886(q)(3)(B) of the Act specifies the ratio used to calculate the adjustment factor under the Hospital Readmissions Reduction Program. It states that the ratio is equal to 1 minus the ratio of—(i) the aggregate payments for excess readmissions and (ii) the aggregate payments for all discharges. For a detailed discussion on the methodology for the calculation of aggregate payments for excess readmissions, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53387 through 53397). We also have codified the definition of ''aggregate payments for excess readmissions'' and ''aggregate payments for all discharges,'' as well as a current methodology for calculating the numerator of the ratio (aggregate payments for excess readmissions) and the denominator of the ratio (aggregate payments for all discharges) at 42 CFR 412.152 through 412.154.

The Hospital Readmissions Reduction Program currently includes the following six applicable conditions: Acute myocardial infarction (AMI); heart failure (HF); pneumonia (PN); total hip arthroplasty/total knee arthroplasty (THA/TKA); chronic obstructive pulmonary disease (COPD); and Coronary Artery Bypass Graft (CABG) Surgery.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56975 through 56977), we adopted the methodology to include CABG in the calculation of the readmissions payment adjustment for FY 2017. Specifically, we discussed how the addition of CABG applicable conditions would be included in the calculation of the aggregate payments for excess readmissions (the numerator of the readmissions payment adjustment). We note that this policy did not alter our established methodology for calculating aggregate payments for all discharges (that is, the denominator of the ratio).

When calculating the numerator (aggregate payments for excess readmissions), we determine the base operating DRG payments for the applicable period. To determine the base operating DRG payment amount for an individual hospital for such applicable period for such condition, we use Medicare inpatient claims from the MedPAR file with discharge dates that are within the same applicable period to calculate the excess readmissions ratio. We use MedPAR claims data as our data source for determining aggregate payments for excess readmissions and aggregate payments for all discharges, as this data source is consistent with the claims data source used in IPPS rulemaking to determine IPPS rates.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19957 through 19959), for FY 2018, we proposed to use MedPAR claims with discharge dates that are on or after July 1, 2013, and no later than June 30, 2016, consistent with our historical use of a 3-year applicable period. Under our established methodology, we use the update of the MedPAR file for each Federal fiscal year, which is updated 6 months after the end of each Federal fiscal year within the applicable period, as our data source (that is, the March updates of the respective Federal fiscal year MedPAR files) for the final rules.

In the proposed rule, for FY 2018, we proposed to determine aggregate payments for excess readmissions and aggregate payments for all discharges using data from MedPAR claims with discharge dates that are on or after July 1, 2013, and no later than June 30, 2016. However, we noted that, for the purpose of modeling the proposed FY 2018 readmissions payment adjustment factors for the proposed rule, we used excess readmissions ratios for applicable hospitals from the FY 2017 Hospital Readmissions Reduction Program applicable period. For the FY 2018 IPPS/LTCH PPS final rule, applicable hospitals will have had the opportunity to review and correct data from the proposed FY 2018 applicable period of July 1, 2013 to June 30, 2016, before they are made public under our policy regarding the preview and reporting of hospital-specific information, which we discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53374 through 53401).

In the proposed rule, for FY 2018, we proposed to use MedPAR data from July 1, 2013 through June 30, 2016. Specifically, for the proposed rule, we used the following MedPAR files:

- March 2014 update of the FY 2013 MedPAR file to identify claims within FY 2013 with discharges dates that are on or after July 1, 2013;
- March 2015 update of the FY 2014 MedPAR file to identify claims within FY 2014;
- March 2016 update of the FY 2015 MedPAR file to identify claims within FY 2015;
- December 2016 update of the FY 2016 MedPAR file to identify claims within FY 2016 with discharge dates no later than June 30, 2016.

For the final rule, we proposed to use the same MedPAR files as listed above for claims within FY 2013, FY 2014 and FY 2015, and for claims within FY 2016, we proposed to use the March 2017 update of the FY 2016 MedPAR file.

For a discussion of how we identified the applicable conditions to calculate the aggregate payments for excess readmissions for FY 2017, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56975 through 56977).

Under our current methodology, in identifying the applicable conditions to calculate the aggregate payments for excess readmissions, we apply the same exclusions to the claims in the MedPAR file as are applied in the measure methodology for each of the applicable conditions. In the proposed rule, for FY 2018, we proposed to continue to apply the same exclusions to the claims in the MedPAR file as we applied for FY 2017 for the AMI, HF, PN, THA/TKA, CABG and COPD applicable conditions. We refer readers to the FY 2016 IPPS/LTCH PPS and FY 2017 IPPS/LTCH PPS final rules (80 FR 49539; 81 FR 56976) for a list of these exclusions. Updates to these exclusions will be posted on the QualityNet Web site at: *http://www.QualityNet.org* > Hospital-Inpatient > Claims-Based Measures > Readmission Measures > Measure Methodology.

Furthermore, under our current methodology we only identify Medicare FFS claims that meet the criteria described above for each applicable condition to calculate the aggregate payments for excess readmissions (that is, claims paid for under Medicare Part C or Medicare Advantage, are not included in this calculation). This policy is consistent with the methodology to calculate excess readmissions ratios based solely on admissions and readmissions for Medicare FFS patients. Therefore, consistent with our established methodology, for FY 2018, we proposed to continue to exclude admissions for patients enrolled in Medicare Advantage as identified in the Medicare Enrollment Database.

Under our existing policy, we identify eligible hospitalizations and readmissions of Medicare patients discharged from an applicable hospital having a principal diagnosis for the measured condition in an applicable period (76 FR 51669). As described above, the proposed 3-year applicable period for FY 2018 of July 1, 2013 through June 30, 2016 includes discharges occurring in four Federal FYs (FY 2013, FY 2014, FY 2015, and FY 2016). Diagnoses and procedure codes for discharges occurring prior to October 1, 2015 were reported under the ICD–9–CM code set. Effective with discharges occurring on or after October 1, 2015 (FY 2016), diagnoses and procedure codes are reported under the ICD–10–CM and ICD–10–PCS code sets. Thus, for the proposed FY 2018 applicable period, the discharge diagnoses for each applicable condition would be based on a list of specific ICD–9–CM or ICD–10–CM and ICD–10–PCS code sets, as applicable, for that condition.

In the proposed rule, to identify the discharges for each applicable condition for FY 2018 to calculate the aggregate payments for excess readmissions for an individual hospital, we proposed to identify each applicable condition, using, for FY 2013, FY 2014 and FY 2015, the appropriate ICD–9–CM codes, and for FY 2016, the appropriate ICD–10–CM and ICD–10–PCS code sets. This proposal is consistent with our established policy for identifying the discharges for each applicable condition to calculate the aggregate payments for excess readmissions (76 FR 51673 through 51676). The ICD–9–CM codes for the AMI, HF, PN, THA/TKA, COPD, and CABG applicable conditions can be found on the QualityNet Web site at: *http://www.QualityNet.org* > Hospital-Inpatient > Claims-Based Measures > Readmission Measures > Measure Methodology. For a complete list of the ICD–9–CM codes we proposed to use to identify the applicable conditions, we refer readers to the following tables of the measure methodology reports on the QualityNet Web site:

• 2016 Measure Updates: AMI, HF, Pneumonia, COPD, Stroke Readmission (*AMI-Version 8.0, HF-Version 8.0, Pneumonia-Version 8.0, COPD-Version 4.0, and Stroke-Version 4.0: 2016 Condition-Specific Readmission Measures Updates and Specifications Report*)—

++ Table D.1.1—ICD–9–CM Codes for AMI Cohort (page 79).

++ Table D.2.1—ICD–9–CM Codes for COPD Cohort (page 83).

++ Table D.3.1—ICD–9–CM Codes for Inclusion in HF Cohort (page 89).

++ Table D.4.1—ICD–9–CM Codes for Pneumonia Cohort (page 94).

• 2016 Measure Updates: THA/TKA and CABG Readmission (*THA and/or TKA-Version 4.0, CABG-Version 2.0: 2016 Procedure-Specific Readmission Measures Updates and Specifications Report*)—

++ Table D.1.1—ICD–9–CM Codes Used to Identify Eligible CABG Procedures (page 49).

++ Table D.2.1—ICD–9–CM Codes Used to Identify Eligible THA/TKA Procedures (page 58).

The ICD–10–CM codes for the AMI, HF, PN, THA/TKA, COPD, and CABG applicable conditions for the period from October 1, 2015 to June 30, 2016 can be found on the QualityNet Web site at: *http://www.QualityNet.org* > Hospital-Inpatient > Claims-Based Measures > Readmission Measures > Measure Methodology. For a complete list of the ICD–10–CM codes we are proposing to use to identify the applicable conditions, we refer readers to the following tables of the measure methodology reports on the QualityNet Web site:

• 2017 Measure Updates: AMI, HF, Pneumonia, COPD, Stroke Readmission (*AMI-Version 10.0, HF-Version 10.0, Pneumonia-Version 10.0, COPD-Version 6.0, and Stroke-Version 6.0: 2017 Condition-Specific Readmission Measures Updates and Specifications Report*)—

++ Table D.1.1—ICD–10–CM Codes for AMI Cohort (page 77).

++ Table D.2.1—ICD–10–CM Codes for COPD Cohort (page 81).

++ Table D.3.1—ICD–10–CM Codes for Inclusion in HF Cohort (page 87).

++ Table D.4.1—ICD–9–CM Codes for Pneumonia Cohort (page 93).

• 2016 Measure Updates: THA/TKA and CABG Readmission (*THA and/or TKA-Version 6.0, CABG-Version 4.0: 2017 Procedure-Specific Readmission Measures Updates and Specifications Report*)—

++ Table D.1.1—ICD–10–CM Codes Used to Identify Eligible CABG Procedures (page 49).

++ Table D.2.1—ICD–10–CM Codes Used to Identify Eligible THA/TKA Procedures (page 63).

In summary, for FY 2018, we proposed to calculate aggregate payments for excess readmissions, using MedPAR claims from July 1, 2013 through June 30, 2016, to identify applicable conditions based on the same ICD–9–CM codes or ICD–10–CM and ICD–10–PCS code sets, as applicable, used to identify the conditions for the readmissions measures, and to apply the proposed exclusions for the types of admissions (as previously discussed). We did not propose any changes to our existing methodology for calculating ''aggregate payments for excess readmissions'' for each hospital (the numerator of the ratio). Specifically, to calculate aggregate payments for excess readmissions for each hospital, we proposed to calculate the base operating DRG payment amounts for all claims in the 3-year applicable period for each applicable condition (AMI, HF, PN, COPD, THA/TKA, and CABG) based on the claims we have identified as described above. Once we have calculated the base operating DRG amounts for all the claims for the six applicable conditions, we proposed to sum the base operating DRG payments amounts by each condition, resulting in six summed amounts, one amount for each of the six applicable conditions. We proposed to then multiply the amount for each condition by the respective excess readmissions ratio minus 1 when that excess readmissions ratio is greater than 1, which indicates that a hospital has performed, with respect to readmissions for that applicable condition, worse than the average hospital with similar patients. Each product in this computation represents the payments for excess readmissions for that condition. We proposed to then sum the resulting products which represent a hospital's proposed ''aggregate payments for excess readmissions'' (the numerator of the ratio). Because this calculation is performed separately for each of the six conditions, a hospital's excess readmissions ratio must be less than or equal to 1 on each measure to avoid CMS' determination that there were payments made by CMS for excess readmissions (resulting in a payment reduction under the Hospital Readmissions Reduction Program). In other words, in order to avoid a payment reduction a hospital's excess readmissions ratio must be less than or equal to 1 on each measure. We note that we did not propose any changes to our existing methodology to calculate ''aggregate payments for all discharges'' (the denominator of the ratio).

Section 1886(q)(3)(A) of the Act defines the ''adjustment factor'' for an applicable hospital for a fiscal year as equal to the greater of: (i) The ratio described in subparagraph (B) for the hospital for the applicable period (as defined in paragraph (5)(D)) for such fiscal year; or (ii) the floor adjustment factor specified in subparagraph (C).

Section 1886(q)(3)(B) of the Act, in turn, describes the ratio used to calculate the adjustment factor. Specifically, it states that the ratio is equal to 1 minus the ratio of—(i) the

aggregate payments for excess readmissions and (ii) the aggregate payments for all discharges. The calculation of this ratio is codified at § 412.154(c)(1) of the regulations and the floor adjustment factor is codified at § 412.154(c)(2) of the regulations. Section 1886(q)(3)(C) of the Act specifies the floor adjustment factor at 0.97 for FY 2015 and subsequent fiscal years.

Consistent with section 1886(q)(3) of the Act, codified at § 412.154(c)(2), for FY 2018, the adjustment factor is either the greater of the ratio or the floor adjustment factor of 0.97. Under our established policy, the ratio is rounded to the fourth decimal place. In other words, for FY 2018, a hospital subject to the Hospital Readmissions Reduction Program would have an adjustment factor that is between 1.0 (no reduction) and 0.9700 (greatest possible reduction).

We did not receive public comments related to this proposal. Therefore, we are finalizing as proposed, without modification, the calculation of aggregate payments for excess readmissions for FY 2018.

7. Background and Current Payment Adjustment Methodology

a. Background

As described above, section 1886(q)(3)(D) of the Act requires the Secretary to group hospitals and apply a methodology that allows for separate comparisons of hospitals within groups in determining a hospital's adjustment factor for payments applied to discharges beginning in FY 2019.

b. Current Payment Adjustment Methodology

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53374 through 53401), we finalized policies that relate to the portions of section 1886(q) of the Act that at that time addressed the calculation of the hospital readmissions payment adjustment factor. Section 1886(q)(3)(A) of the Act defines the ''adjustment factor'' for an applicable hospital for a fiscal year as equal to the greater of: (i) The ratio described in subparagraph (B) for the hospital for the applicable period (as defined in paragraph (5)(D)) for such fiscal year; or (ii) the floor adjustment factor specified in subparagraph (C). Section 1886(q)(3)(B) of the Act, in turn, describes the ratio used to calculate the adjustment factor. Specifically, it states that the ratio is equal to 1 minus the ratio of—(i) the aggregate payments for excess readmissions and (ii) the aggregate payments for all discharges.

Consistent with section 1886(q)(3)(C) of the Act, codified at § 412.154(c)(2), for FY 2015 and subsequent years, the adjustment factor is either the greater of the ratio or the floor adjustment factor of 0.9700. In other words, a hospital subject to the Hospital Readmissions Reduction Program will have an adjustment factor that is between 1.0000 (no reduction) and 0.9700 (greatest possible reduction). Under our established policy, the ratio is rounded to the fourth decimal place.

8. Provisions for the Payment Adjustment Methodology for FY 2019: Methodology for Calculating the Proportion of Dual-Eligible Patients

a. Background

As described above, section 1886(q)(3)(D) of the Act requires the Secretary to group hospitals and apply a methodology that allows for separate comparisons of hospitals within groups in determining a hospital's adjustment factor for payments of discharges beginning in FY 2019. Furthermore, section 1886(q)(3)(D)(ii) of the Act directs the Secretary to define groups of hospitals, based on their overall proportion, of the inpatients who are entitled to, or enrolled for, benefits under part A, and who are full-benefit dual-eligible individuals (as defined in section 1935(c)(6) of the Act).[23] Under these statutory requirements, hospitals are grouped based on the proportion or ratio of full-benefit dual-eligible patients (numerator) to the hospital's Medicare inpatient stays (denominator). The Act specifies that in defining groups, the Secretary shall consult the MedPAC and may consider the analysis done by MedPAC in preparing the portion of its report submitted to Congress in June 2013 relating to readmissions.

b. Data Sources Used To Determine Dual Eligibility

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19960), we proposed to identify full-benefit dual status (numerator) using dual eligibility status data, where the original data source is the State Medicare Modernization Act (MMA) file of dual eligibility, which States submit to CMS monthly. The State MMA file is considered the most current and most accurate source of data for identifying dual-eligible beneficiaries since it is also used for operational purposes related to the administration of Part D benefits. Under our proposal, an individual would be counted as a full-benefit dual patient if the beneficiary was identified as full-benefit dual status in the State MMA files for the month he/she was discharged from the hospital.

We invited public comment on this proposal.

Comment: Many commenters supported the preferred approach of using the State Medicare Modernization Act (MMA) files as the source to identify full-benefit dual-eligible individuals, noting this approach adheres to the statutory requirement and does not impose any additional reporting burden on providers.

Response: We thank commenters for their support and agree with commenters.

Comment: A few commenters expressed support for comparing hospitals based on their proportion of patients who are dual-eligible patients. One commenter believed that this approach helps hospitals that have a disproportionate number of dual-eligible patients and specifically cited safety net hospitals as key beneficiaries.

Response: We thank commenters for their support and agree with commenters. We proposed to finalize approaches to implement policy options that change the payment formula to reduce the financial burden on safety-net hospitals without disproportionately increasing the penalty for non-safety-net hospitals to address stakeholder concerns and meet the implementation requirement of Public Law 114–255, which included grouping hospitals based on their proportion of dual-eligible beneficiaries.

Comment: A few commenters expressed concern with using the proportion of dual-eligible beneficiaries because it is an inappropriate mechanism for determining socioeconomic status. One commenter cautioned that dual-eligible peer groups exclude several at-risk and socioeconomically stressed patients that are not part of the data set. One commenter suggested that CMS should use the community distress index for the community where a hospital is located or a patient resides. One commenter expressed concern that dual eligibility was insufficient to identify socio-demographic risk. Another commenter suggested that CMS consider whether it should continue to use dual-eligibility as the adjustment variable, and whether to move from the current peer grouping approach to one that

[23] Section 1935(c)(6)(A) of the Act defines ''full-benefit dual-eligible individual'' as, ''for a State for a month, an individual who—(i) has coverage for the month for covered part D drugs under a prescription drug plan under part D of title XVIII, or under an MA–PD plan under part C of such title; and (ii) is determined eligible by the State for medical assistance for full benefits under this title for such month under section 1902(a)(10)(A) or 1902(a)(10)(C) [of the Act], by reason of section 1902(f) [of the Act], or under any other category of eligibility for medical assistance for full benefits under this title, as determined by the Secretary.''

incorporates one or more socioeconomic variables into the readmission measures risk-adjustment models of the Hospital Readmissions Reduction Program measures (that is, direct risk adjustment of the readmission measures). One commenter cautioned CMS against stating on *Hospital Compare* that dual eligibility denotes poverty.

Response: We thank commenters for their input and agree that we should be cautious in not stating on *Hospital Compare* that dual-eligibility denotes poverty. While we agree that many socioeconomically stressed patients are not dual eligible and therefore not accounted for when stratifying hospitals based on dual proportion, Public Law 114–255 requires that we use the proportion of dual-eligible beneficiaries to stratify hospitals into peer groups for the purpose of determining payments. Section 15002 of Public Law 114–255 added subparagraphs (D) and (E) to section 1886(q)(3) of the Act, which directs the Secretary to assign hospitals to peer groups, develop a methodology that allows for separate comparisons for hospitals within these groups, and allows for changes in the risk adjustment methodology. Specifically, section 1886(q)(3)(D) of the Act directs the Secretary to develop a transitional methodology that accounts for the percentage of full-benefit dual-eligible patients treated by a hospital to determine a hospital's payment adjustment factor. Section 1886(q)(3)(D)(i) of the Act sets forth the requirement that the Secretary assign hospitals to groups and apply a methodology that allows for separate comparison of hospitals within each such group.

Section 1886(q)(3)(E)(i) of the Act does not preclude the inclusion of additional risk factors. We will continue to monitor the impact of accounting for dual-eligible beneficiaries in the Hospital Readmissions Reduction Program and assess the appropriateness and feasibility of future changes to include other variables or adjustments.

Comment: One commenter expressed concern over the impact of risk adjustment for non-safety net facilities, arguing that facilities should be rewarded for outreach to at-risk populations instead of penalized with risk adjustment which may not reflect their actual readmission rates or patient's risk for readmissions at the facility, and which has the potential to reduce transparency.

Response: As required by Public Law 114–255, we are stratifying hospitals based on dual-eligible proportion and modifying the payment adjustment factor formula to assess a hospital's performance relative to other hospitals in its peer group. To clarify, we are not changing the measure methodology for calculating of the excess readmission ratios, rather we are stratifying hospitals based on the proportion of dual-eligible beneficiaries to set the threshold used to assess hospital performance. Because quality assessment is determined based on a hospital's performance relative to all other Hospital Readmissions Reduction Program eligible hospitals, and therefore allows for comparison between peer groups of hospitals, this approach is transparent. At the same time, by stratifying hospitals and determining the payment adjustment factors based on performance relative to the peer group median, we can reduce the penalty for safety-net hospitals, hence avoiding a reduction in the resources available to safety-net hospitals to provide high quality care for their at-risk patients. Because peer groups are based on proportion of dual-eligible patients served, the same would also be true for non-safety net facilities that do outreach to at-risk patients and thus have a higher proportion of dual-eligible patients than other non-safety net facilities.

We believe the proposed approach achieves both the goal of holding all hospitals to a high standard while also ensuring we are not disproportionally penalizing hospitals serving an at-risk population. Section 1886(q)(3)(E)(i) of the Act allows the Secretary to consider studies conducted and recommendations made by the Secretary under section 2(d)(1) of the IMPACT Act in the application of risk adjustment methodologies. We will continue to monitor the progress and findings of research the Assistant Secretary for Planning and Evaluation (ASPE) is conducting as part of its IMPACT Act study and the National Quality Forum's trial period and will consider their recommendations. We will continue to monitor the impact of accounting for dual-eligible patients in the Hospital Readmissions Reduction Program and evaluate if future changes to include other variables or adjustments are needed.

Comment: One commenter requested that CMS develop an adjustment for the variability in Medicaid eligibility across states for the calculations of the proportion of dual-eligible patients, citing its belief that the variation distorts the population measure of poverty that in fact may be representative of patients under treatment. The commenter also stated that Medicare Advantage data should only be included in the denominator if it is included in State reporting. Another commenter expressed concern with using quintiles based on the proportion of Medicare FFS and Medicare Advantage patients that are full-benefit, dual-eligible patients because it does not consider differences in States' health care program eligibility and if a State has expanded Medicaid under the Patient Protection and Affordable Care Act.

Response: We acknowledge the commenter's concern about using the proportion of Medicare FFS and Medicare Advantage patients that are full-benefit, dual-eligible patients when there is variability in Medicaid eligibility across states. However, Public Law 114–255 requires hospitals be stratified based on the proportion of Medicare patients who are eligible for full-benefit Medicaid. Although Medicaid eligibility is defined on a State-by-State basis, it varies much less across States for the over 65 and people with disabilities populations, the population covered under Medicare.[24] [25] In addition, the Patient Protection and Affordable Care Act did not expand Medicaid eligibility to patients enrolled in Medicare Part A or Part B. Because the dual proportion is calculated among Medicare beneficiaries only, there is much less variability in dual proportion than if it was calculated as the percentage of all hospital patients who were eligible for Medicaid. We will continue to monitor the impact of changes to Medicaid eligibility for the Medicare population and evaluate if future changes to include other variables or adjustments are needed.

Comment: Commenters supported the inclusion of a socioeconomic adjustment in the readmissions reduction program but recommended that the Secretary expand the conditions excluded from the readmission measures used in the Hospital Readmissions Reduction Program. Commenters also asked CMS to continue to find ways to adjust for social risk factors that capture variation

[24] For over-65 and people with disabilities populations in 40 States plus the District of Columbia, Medicaid eligibility in the Medicare population is connected to receipt of SSI, which sets an income standard for eligibility at roughly 75 percent of the Federal Poverty Level (FPL). However, about one third of States set their eligibility levels at 100 percent FPL or higher. There are also ten States, known as 209(b) States, in which eligibility rules for dually eligible populations can be set lower than the SSI standards.

[25] United States Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation. ''Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs: A Report Required by the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014''. Washington, DC: December, 2016.

in the complexity of patients across hospitals.

Response: We thank the commenters for their input and plan to investigate the impact on the readmission measures and appropriateness of categorizing additional diagnoses as planned readmissions as directed by Public Law 114–255. We will also continue to monitor the work being done by the Assistant Secretary for Planning and Evaluation (ASPE) as part of its study required by the IMPACT Act. The first of two reports on the study was released in December of 2016 and the second report is required to be completed by October 2019. The study analyzed the effects of certain social risk factors in Medicare beneficiaries on quality measures and measures of resource use used in one or more of nine Medicare value-based purchasing programs. The report also included considerations for strategies to account for social risk factors in these programs. We will continue to consider the analyses and recommendations from this report.

Comment: Numerous commenters expressed concern that they were unable to comment on the proposals due to the lack of publicly available data. To evaluate proposals and confirm estimates, commenters requested that CMS publicly provide a summary file providing hospital-level data consistent with the data used by CMS to derive the results reported in the tables and Readmission Proposal Supplemental files for each of the alternative approaches providing the data necessary to duplicate the CMS estimates that are reported in the tables.

Commenters further requested that dual-eligible summary files be released publicly since they reside with the States. Commenters also requested that CMS release patient population lists, quarterly, to identify this population for improvement activities and to allow for replication. Commenters asked CMS to make more data available on the proposed payment adjustment methodology to ensure full transparency on the various aspects of the agency's determinations. In addition, commenters recommended that CMS prepare a dry-run using this year's data so that hospitals can familiarize themselves with the new methodology. Commenters also suggested that CMS include hospital peer group assignments in future proposed rules, allow for review and corrections and asked CMS to continually evaluate its adjustment approach, and to engage with the field on ensuring its adjustment approach keeps up with the science.

Response: We thank commenters for their input and we agree with the need for transparency and providing stakeholders with data to confirm their dual proportion assignment. However, we also have a responsibility to safeguard patient information and comply with the federal regulations governing data. To ensure CMS upholds data security standards, we established the CMS Data Request Center through the Research Data Assistance Center (ResDAC) to review requests for data. To obtain the full MBSF data file a request can be submitted to ResDAC at: *https://www.resdac.org/cms-data/request/cms-data-request-center*. Such a request will be reviewed and approved based on ResDAC's established criteria. We are considering methods for publicly releasing this data. We are also considering different options to provide hospitals with early individualized feedback regarding their peer grouping and payment adjustment.

After consideration of the public comments we received, we are finalizing, without modification, our proposal that an individual would be counted as a full benefit dual-eligible patient if the beneficiary was identified as full-benefit dual status in the State MMA files for the month he/she was discharged from the hospital.

In the proposed rule, we considered two alternative definitions of total number of Medicare patients (denominator) that could be used to calculate each hospital's proportion of dual-eligible patients. We proposed to define the proportion of full-benefit dual-eligible beneficiaries as the proportion of dual-eligible patients among all Medicare FFS and Medicare Advantage stays. This is our preferred approach because using the proportion of dual-eligible patients calculated among all Medicare FFS and managed care patients more accurately represents the proportion of dual-eligible patients served by the hospital, particularly for hospitals in States with high managed care penetration rates. For example, Hospital A located in Arizona has a high managed care penetration rate. When stratified based on the proportion of dual-eligible patients, calculated among Medicare FFS and managed care patients, Hospital A was assigned to the top quintile of proportion of dual-eligible patients and its payment adjustment calculated based on its ERR relative to the threshold for the top quintile. When stratified based on the proportion of dual-eligible patients among only Medicare FFS patients, Hospital A was assigned to the second quintile and its payment adjustment calculated relative to the threshold of the second quintile. Its classification when managed care patients are included more accurately identifies the social risk of the patients Hospital A serves, compared to its classification if only the FFS population is included.

However, because the Hospital Readmissions Reduction Program payment adjustment is only applied to Medicare FFS payments, and is based on excess readmissions among Medicare FFS patients only, we included an alternative to define the proportion of full-benefit dual-eligible beneficiaries as only Medicare FFS stays. Under both approaches, we proposed to use the MedPAR files, the same data source used to calculate the payment adjustment factors, to identify total hospital stays as this is the best available claims data that are readily publicly available. However, in developing our proposal, we also considered using other data sources such as the CMS integrated data repository (IDR), which may incorporate managed care claims more consistently to calculate total hospital stays, but it is currently not readily available to the public. We invited stakeholder input on the most appropriate data source to identify total hospital stays and whether such stays should include all Medicare FFS and Medicare Advantage stays or only Medicare FFS stays.

We invited public comment on our preferred proposals and alternative considerations.

Comment: Many commenters supported using both Medicare Advantage and Medicare FFS patients to determine the total number of Medicare stays as the denominator because it accurately represents the proportion of dual-eligible patients a hospital serves. One commenter recommended including Medicaid enrollees under 100 percent of federal poverty level in addition to dual-eligibility status to improve accuracy. One commenter requested that CMS should monitor for any unintended consequences among hospitals in states with high managed care penetration, compared with those that have low penetration, and modify the methodology to adjust for future growth in managed care.

Response: We thank commenters for their support and we will continue to monitor the impact of stratifying hospitals based on the proportion of full-benefit dual-eligible beneficiaries in the Hospital Readmissions Reduction Program and evaluate if future changes to include other variables or adjustments are needed.

Comment: Several commenters recommended stratifying hospitals based on the share of full-benefit Medicaid patients among Medicare FFS patients only and not all FFS and MA

patients. One commenter stated that the share of Medicare FFS patients that are full dual-eligible beneficiaries should be used because penalties will not apply to MA readmissions. Another commenter expressed concerned that because penalties will not apply to MA readmissions, MA patients would distort the risk profiles of hospitals because their income characteristics may differ from FFS patients in certain hospitals.

Response: We thank the commenters for the input. In selecting a proposal, we considered calculating the proportion of dual-eligible patients (dual proportion) among Medicare FFS and managed care patients as well as Medicare FFS patients only. We agree that determining this proportion among Medicare FFS beneficiaries instead of all Medicare beneficiaries more accurately reflects the incidence of these factors among patients eligible for inclusion in the Hospital Readmissions Reduction Program measures. However, calculating the dual proportion among all Medicare FFS and managed care patients more accurately represents the dual status of the hospital, particularly for hospitals in States with high managed care penetration rates. This approach enables more accurate and complete risk profiles for hospitals. There is a strong relationship between dual proportion and penalties under both the current methodology and proposed approaches whether hospitals are stratified based on Medicare FFS patients only or based on both Medicare FFS and managed care patients. In general, this relationship is similarly positive; hospitals with higher dual proportions by either definition incur larger penalties on average. However, the relationship between the penalty share of payments and dual proportion among FFS and managed care patients exhibits a slightly stronger upward trend.

Comment: One commenter supported using both the Medicare Advantage and Medicare FFS patients identified through the CMS Integrated Data Repository (IDR) to determine the dual-eligible population, and supported calculating the dual proportion among both MA and FFS beneficiaries because it provides an accurate representation of a hospital's dual-eligible population.

Response: We thank the commenter for the support of calculating the dual proportion among both MA and FFS beneficiaries. Both the IDR and the Master Beneficiary Summary File (MBSF) are sourced from the State Medicare Modernization Act (MMA) file. Many commenters supported using data sourced from the State MMA file as it is considered the most current and most accurate source of data for identifying dual-eligible beneficiaries since it is also used for operational purposes related to the administration of Part D benefits. We will assess the feasibility of different datasets with dual status information sourced from the State MMA files as part of implementation.

After consideration of the public comments we received, we are finalizing, without modification, our proposal to define the proportion of full benefit dual-eligible beneficiaries as the proportion of dual-eligible patients among all Medicare FFS and Medicare Advantage stays.

c. Data Period Used To Define Dual Eligibility

Consistent with the requirement of the statute, we proposed to group or stratify hospitals based on the proportion of full-benefit dual-eligible patients determined under the proposals discussed above and proposed to define the proportion of full-benefit dual-eligible beneficiaries as the number of dual-eligible patients discharged during the 3-year applicable period under the Hospital Readmissions Reduction Program. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19960), we considered two alternatives for the data period used to define dual eligibility, a 3-year period corresponding to the performance period, and a 1-year period, which would be calculated over the most recent year for which complete data is available.

While both data periods would include the most recently available data to define dual eligibility, our proposal to use a 3-year period accounts for the influence of social risk factors on the excess readmissions ratio (ERR) because the proportion of dual-eligible patients is measured over the full period when they influenced the likelihood of excess readmissions. However, the most recent 1-year period would capture the most recent population served by the hospital and may enable a more accurate stratification to calibrate the impact of payment adjustments to the proportion of dual-eligible patients that the hospital currently serves.

We invited public comment on our preferred proposal and alternative considerations.

Comment: Many commenters supported using the 3-year data period because it aligns the adjustment for the proportion of dual-eligible patients with the established measurement period. Commenters stated that using a 3-year period will guard against the effects of recent shifts in year-to-year patient population changes. One commenter noted that both the 3-year data period and the 1-year data period provide similar information about the current patient population because both programs rely on data that will not be current at the time that payment penalty adjustment is applied.

Response: We thank commenters for their support and agree that the proposed 3-year data period is appropriate.

Comment: A few commenters supported the use of the 1-year data period. Commenters stated that a 1-year data period would provide the most recent population served by the hospitals and enable a more accurate stratification by proportion of dual-eligible patients for payment adjustments.

Response: While we understand commenters' support of using a 1-year data period, we agree with the many commenters who supported using the 3-year data period because it accounts for the influence of social risk factors on the excess readmission ratios (ERR) since the proportion of dual-eligible patients is measured over the full period when they influenced excess readmissions. We recognize that the 1-year data period may better represent a hospital's current patient population. However, the 3-year data period corresponds to the performance period; therefore, it more accurately reflects the influence of social risk factors on the ERRs and payment adjustments. We will continue to monitor the impact of accounting for dual-eligible patients in the Hospital Readmissions Reduction Program and evaluate if future changes to include other variables or other adjustments are needed.

After consideration of the public comments we received, we are finalizing the 3-year data period corresponding to the performance period as the data period used to define dual eligibility.

9. Provisions for the Payment Adjustment Methodology for FY 2019: Methodology for Assigning Hospitals to Peer Groups

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19960 through 19961), we considered three alternative methodologies for assigning hospitals to peer groups. For the reasons discussed below, our preferred approach is to stratify hospitals into quintiles (five peer groups). However, we also sought public comment on stratifying hospitals into two and 10 peer groups.

To understand the impact on payment adjustments of stratifying hospitals into different numbers of peer groups, we conducted an analysis that estimated

payment adjustments when stratifying hospitals into 2, 5 (quintiles), or 10 (deciles) peer groups. Two and 10 peer groups were considered to align with previous research conducted by MedPAC and ASPE that assessed impacts from stratifying hospitals into 2 or 10 groups. MedPAC's analysis stratified hospitals into 10 peer groups when setting the target rate used to compare hospital performance. ASPE's analysis stratified hospitals into 2 and 10 peer groups to calculate payment adjustments. Our analysis showed that using five peer groups allows for more precisely defined peer groups than is possible with a grouping of two, while ensuring that the number of hospitals is sufficient to represent a peer group, even for measures, like CABG, in which only a minority of hospitals are subject to a payment adjustment.

We note, as the number of groupings increase, hospitals became more similar within their peer groups with respect to proportion of dual-eligible patients in their patient population. Hence, payment adjustments are more closely related to the proportion of dual-eligible patients, and to the possible influence on the likelihood of readmission resulting from small variations in patient populations. We also observed that increasing the number of peer groups also increases the likelihood that hospitals with similar exposure to dual-eligible patients will be compared to different thresholds in the payment adjustment formula. Deciles cover a narrow range of dual-eligible patient proportions in each peer group; therefore, small differences in proportion are likely to result in differences in peer group assignment and corresponding comparison thresholds used in the payment adjustment formula. This problem is compounded by the small number of hospitals in deciles. When the number of hospitals is small, peer group thresholds or distributions and the resulting payment adjustments are less predictable.

Stratifying hospitals into two peer groups is a simpler method and reduces the likelihood that similar hospitals are assigned different payment adjustments. However, this approach yields peer groups with a more heterogeneous mix of hospitals assigned to each group and weakens the relationship between the payment adjustment and the hospital's patient population. When the impact on payments of different peer group definitions was tested using the various methods of incorporating stratification into the payment formula, we found a substantial reduction in penalties (measured as the share of payment adjustments as a percentage of total payments) to safety-net hospitals, defined as hospitals in the highest quintile for disproportionate share hospital (DSH) patient percentage, from stratification into quintiles compared to stratification into two groups. Furthermore, our analysis found a similar impact on the share of total payments borne as payment adjustments by safety-net hospitals from stratifying hospitals into quintiles and deciles, suggesting that the benefit to safety-net hospitals from increasing the number of strata would be small. For example, using the preferred modified payment formula, proposed below, across the current set of six conditions, we found that for safety-net hospitals, payment adjustment as a proportion of total payments decreased from a baseline of 0.64 percent to 0.59 percent with two groups, 0.55 percent with quintiles and 0.54 percent with deciles.

Based on the analysis described above, we proposed to stratify hospitals into quintiles (five peer groups) because it creates peer groups that accurately reflect the relationship between the proportion of dual-eligible patients in the hospital's population without the disadvantage of establishing a larger number of peer groups.

We invited public comment on our preferred proposal and alternative considerations.

Comment: Many commenters supported using quintiles because it creates peer groups that more accurately reflect the relationship between the proportion of dual-eligible patients in the hospital's population, while mitigating the disadvantages of establishing a larger number of peer groups. One commenter, using its data, found that 2 groups did not adequately differentiate among hospitals and 10 groups resulted in too many nonmonotonic excess readmission ratios. However, commenters urged CMS to be mindful of unintended consequences and be open to future changes if issues do rise.

Response: We thank commenters for their support.

Comment: One commenter stated that, while using quintiles is reasonable, there was no compelling reason for having the groups all have the same number of hospitals in them. One commenter suggested that many hospitals with relatively low proportions of ''duals'' could be grouped together, with the peer-grouping done to create several smaller groups at the high end of the distribution. Some commenters agreed that neither 2 nor 10 peer groups are adequate. However, commenters believed that the ideal number of groups could be improved. Commenters cited the use of continuous data, the introduction of additional covariates, and the use of statistical modeling as ways to produce a better method of grouping hospitals. One commenter also provided an example of a method it previously used to determine cut points (that is, performance thresholds or peer groupings).

Response: As the commenter noted, the upper part of the distribution is where the choice of peer groups has the greatest impact. This means the choice of the number of peer groups is most strongly influenced by hospitals with high dual proportions. Thus, the benefits of smaller peer groups among these hospitals were considered in establishing the number of peer groups. In our proposal, we considered how different numbers of peer groups influenced the yearly variation in peer group assignment. This is one of the reasons we proposed quintiles. The quintile-based approach is based on larger peer groups, thereby producing less arbitrary variation and yearly fluctuation in hospital assignments.

We considered many factors in developing peer groups to calculate payment adjustments for the Hospital Readmissions Reduction Program. These factors included: (1) The legislative requirements of Public Law 114–255, such as stratification by the proportion of dual-eligible beneficiaries in the patient census, budget neutrality, and the need for immediate implementation; (2) constructing peer groups that are consistent across six current measures and future additional measures, and are defined consistently over time; (3) the intent of the program to encourage efficient, high quality care; and (4) the impact of peer group definitions on the distribution of payments to hospital groups, such as safety-net or rural hospitals. The goodness of fit of the readmission measure models with hospitals' dual proportion is a contributory factor among these others factors. Preselecting peer groups of equal size and choosing the size that best meets these objectives is transparent and effective. In the future, more flexible methods for peer group formation may be considered for implementation. Any approach must be evaluated based on multiple criteria including those described above and proposed through the rulemaking process.

We need to consider both hospital performance on multiple measures and the program's impact on the distribution of payments. The most salient criterion for evaluating approaches is the impact

of stratification on the penalty share of payments in groups defined both by the stratifying variable and other relevant hospital characteristics. Preselecting peer groups of equal size and choosing the size that best meets these objectives is transparent and effective. Our use of cut-point evaluation techniques within the context described above helps to establish the relative benefit of choosing quintile or decile peer groups. In the future, a more flexible method for peer group formation may be developed and considered for implementation. However, this approach must still be evaluated based on multiple criteria, including those described above, and proposed through the rulemaking process.

Comment: One commenter discouraged the use of two peer groups because it does not adequately differentiate between hospitals' payer mixes and will continue to unfairly penalize urban safety net hospitals. The commenter noted the use of two peer groups would overgeneralize hospital SDS groupings.

Response: We agree with commenter that the use of two peer groups does not allow for meaningful comparison of hospitals.

Comment: One commenter recommended CMS use deciles rather than quintiles because hospitals in the highest decile of low-income shares tended to have higher readmissions than those in the eighth or ninth decile. Therefore, the commenter believed deciles would do a better job of acknowledging the challenges of the hospitals with the highest share of low-income patients.

Response: Our analyses found the relationship between hospital dual proportion decile and ERR is not consistent among the six readmission measures included in the Hospital Readmissions Reduction Program. However, the median ERR for the top decile is higher than that of the ninth decile for all six measures. When considering a final policy option, we assessed the strengths and weaknesses of both quintiles and deciles. While we agree that, compared to quintiles, stratification into deciles more completely accounts for the challenges faced by hospitals with the highest share of dually-eligible patients, both deciles and quintiles substantially reduce the share of penalties paid by safety-net hospitals (defined as the top DSH quintile), to a level below that paid by non-safety-net hospitals. The quintile-based approach is also based on larger peer groups and produces less arbitrary variation in hospital assignments and penalty changes from year to year. Using deciles causes hospitals to face more uncertainty in the standard from year to year.

Comment: One commenter expressed concern that the individual penalty amount for hospitals may be increased in a way that disproportionately shifts to a small group of outlier providers, citing its own analysis of the proposed methodology for quintile assignment.

Response: When considering the different approaches for adjusting the payment factor formula, one of our goals was to avoid disproportionally increasing the penalty for any hospital. Compared to other approaches, the use of the peer group median as the threshold for payment adjustment calculation results in smaller changes for individual hospitals. Our analysis found the proportion of hospitals estimated to have an increased penalty under the proposed approach slightly exceeds the proportion with decreased penalties. Because Public Law 114–255 requires total Medicare savings under the stratified methodology be equivalent to total Medicare savings under the current methodology (that is, budget neutrality), the mean penalty increase for hospitals with an increased penalty will be smaller than the mean penalty decrease for hospitals with a decreased penalty. The largest penalty increase projected under the preferred approach compared to the current methodology is substantially less than projected by the commenter, perhaps due to differences in the peer groups formed by DSH and dual proportions. We will continue to monitor the impact of these program changes on hospital penalties, including their impact on individual hospitals and consider changes to mitigate undesirable effects.

Comment: One commenter recommended that the peer groups account for academic status, citing studies that have shown a strong correlation between provider academic status and readmissions rates. In addition, one commenter recommended hospital groupings per other features, with special consideration for designated safety net hospitals, Level 1 Trauma centers, hospitals affiliated with schools of medicine and nursing, hospitals with in-house neonatal and pediatric intensive care units, and hospitals with solid organ transplant programs that include liver transplantation.

Response: We thank commenters for their recommendations, and we will continue to monitor the impact of accounting for dual-eligible beneficiaries in the Hospital Readmissions Reduction Program and evaluate if future changes to include other variables or adjustments are needed.

Comment: One commenter supported the development of peer groups for the purposes of payment but disagreed with accounting for social risk factors for the purposes of calculating readmission rates for public reporting.

Response: We will take this commenter's input into consideration as we continue to assess the appropriateness and feasibility of publicly and/or confidentially reporting information related to certain social risk factors, such as a hospital's proportion of dual-eligible beneficiaries. Public Law 114–255 requires the development of peer groups based on the number of dual-eligible patients served by each hospital for the purposes of scoring performance. In addition, as we are required under 1886(q)(6)(A) of the Act, we will continue to report the readmission rate data on *Hospital Compare* as we always have.

After consideration of the public comments we received, we are finalizing our proposal to stratify hospitals into quintiles.

10. Provisions for the Payment Adjustment Methodology for FY 2019: Payment Adjustment Formula Calculation Methodology

a. Background

As described above, section 1886(q)(3)(D)(iv) of the Act requires the Secretary to design the methodology to implement this subparagraph so that the estimated total amount of Medicare savings under this subsection (stratified methodology) equals the estimated total amount of Medicare savings that would otherwise occur under this subsection (current methodology) if this subparagraph did not apply (that is, maintain budget neutrality).

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19961 through 19966), we analyzed several modifications of the payment adjustment formula to assess payment reductions based on a hospital's performance compared to performance of other hospitals in its peer group. The current readmissions payment adjustment can be written as

[26] ''Payment'' refers to the base operating DRG payment.

$$1 - \min\{.03, \sum_{dx} \frac{Payment(dx) * \max\{(\mathrm{ERR(dx)} - 1.0000), 0\})}{All\ payments}\}$$ [26]

where dx is AMI, HF, pneumonia, COPD, THA/TKA or CABG. In our analyses, we modified the payment adjustment formula by replacing the current threshold ERR of 1.0000 with a peer group specific threshold.

In adopting a methodology for achieving budget neutrality, our priority is to adopt a simplified and well-known metric that allows us to be more transparent in our methodology and reduces the penalty on safety-net hospitals, while not disproportionality increasing the penalty to non-safety-net hospitals. In developing policy options to implement the budget neutrality requirement, we analyzed the following alternatives to evaluate the financial impacts:

- Using the median ERR for the hospital's peer group in place of 1.0000 in the payment adjustment formula and applying a uniform modifier to maintain budget neutrality;
- Using the mean ERR for the hospital's peer group in place of 1.0000 in the payment adjustment formula and applying a uniform modifier to maintain budget neutrality;
- Using the ''budget neutralizing'' ERR for each peer group in place of 1.0000 in the payment adjustment formula. The budget neutralizing ERR is defined as the ERR corresponding to the percentile (for example, 52nd) of the peer group distributions that would maintain budget neutrality for each peer group; and
- Using a standardized ERR for each individual hospital's ERR in place of the hospital's current calculated ERR and applying a uniform modifier to maintain budget neutrality. Each hospital's ERR is transformed to create a distribution of ERRs within each stratum with the same mean and standard deviation as the original mean and standard deviation across all hospitals.

b. Proposals

In the proposed rule, we discussed four alternative budget neutral methodologies for calculating the payment adjustment factor. Our preferred approach is assessing performance compared to the peer group median ERR, rather than the current threshold of 1.0000, and scaling hospital payment adjustments by a neutrality modifier. However, we are seeking public comment on three additional approaches—using the mean ERR plus a neutrality modifier, a budget neutralizing ERR, and a standardized ERR plus a neutrality modifier.

(1) Median ERR Plus a Neutrality Modifier

As we stated in the proposed rule, our preferred approach is using the median ERR plus a neutrality modifier. We would use the median ERR for the hospital's peer group in place of 1.0000, which is the approximate mean and median of the baseline distribution, in the current payment adjustment formula. The payment adjustment formula would then be:

$$P = 1 - \min\{.03, \sum_{dx} \frac{NM_M * Payment(dx) * \max\{(\mathrm{ERR(dx)} - \text{Median peer group ERR(dx)}), 0\})}{All\ payments}\}$$

The payment reduction (1 − P) resulting from use of the median ERR for the peer group is scaled by a neutrality modifier (NM_M) to achieve budget neutrality. To calculate the neutrality modifier, we estimate total Medicare savings across all hospitals under the current method and under the proposed stratified method, in the absence of a modifier. We then calculate a multiplicative factor that, when applied to each hospital's adjustment calculated using the stratified method, would equate total Medicare savings from that method to total Medicare savings under the current method. Total Medicare savings and the neutrality modifier will be calculated using the same payment data. These data will consist of the most recently available full year of MedPAR data. For example, if the payment reduction for a hospital (1 − P) equals 0.00748 when using the median threshold, then under the median plus neutrality modifier method it would equal NM * 0.00748 = 0.9545 * 0.00748 = 0.00714, where the neutrality modifier was equal to 0.9545. Thus, the hospital's payment adjustment factor (P) would equal 0.9925 (1 − 0.00748) in the absence of the neutrality modifier, and 0.9929 (1 − 0.00714) when the modifier is added.

(2) Mean ERR Plus a Neutrality Modifier

We also analyzed the use of the mean ERR plus a neutrality modifier to calculate the readmissions adjustment factor. Just like the median ERR plus neutrality modifier approach mentioned above, the mean ERR for the hospital's peer group would be used in place of 1.0000 in the payment adjustment formula. The payment adjustment formula would then be:

$$\mathrm{P} = 1 - \min\{.03, \sum_{\mathrm{dx}} \frac{K_\mu * \mathrm{Payment(dx)} * \max\{(\mathrm{ERR(dx)} - \text{Mean peer group ERR(dx)}), 0\}}{\text{All payments}}\}$$

(3) Budget Neutralizing ERR

We also analyzed using a budget neutralizing ERR in which penalties are assessed based on the difference between the hospital's ERR and the budget neutralizing ERR. The payment adjustment formula would be:

$$P = 1 - min\{.03, \sum_{dx} \frac{Payment(dx) * \max\{(ERR(dx) - budget\ neutralizing\ ERR\ (dx), 0\})}{All\ payments}\}$$

(4) Standardized ERR Plus a Neutrality Modifier

We also analyzed using a standardized ERR in which penalties are assessed by determining the mean and standard deviation of the ERRs across all hospitals. The payment adjustment formula would be calculated by dividing hospitals into strata based on a hospital's proportion of dual-eligible patients. The current ERRs would then be transformed to create a new standardized distribution of ERRs within each stratum with the same mean and standard deviation as the original mean and standard deviation across all hospitals.

$$P = 1 - min\{.03, \sum_{dx} \frac{NM_S * Payment(dx) * \max(S_B(dx)/S_p(dx)\{ERR(dx) + \mu_B(dx) - \mu_p(dx)\} - 1.0000, 0\})}{All\ payments}\}$$

where S_B (dx) and μ_B (dx) are the standard deviation and mean of the current ERR distribution for a condition (dx), and S_p (dx) and μ_p (dx) are the standard deviation and mean of the peer group ERR distribution for that dx. The standardized ERRs has a mean of 1 and a standard deviation equal to the standard deviation of ERRs across all hospitals in the peer group for that condition. The standardized ERRs are compared to 1.0000 in the payment adjustment formula to determine excess readmissions. The payment reduction (1 − P) resulting from use of the standardized ERR is then scaled by a neutrality modifier (NM_S) to achieve budget neutrality.

c. Analysis

As mentioned above, in adopting a methodology for achieving budget neutrality, our priority is to adopt a simplified and well-known metric that allows us to be more transparent in our methodology and reduces the penalty on safety-net hospitals, while not disproportionality increasing the penalty to non-safety-net hospitals. To assess the expected impact on hospital payment adjustments resulting from the changes to the formula, we simulated hospitals' readmission adjustment factors under different stratified thresholds. Readmissions adjustment factors were calculated using total base operating DRG payment amounts for each hospital as well as total base DRG payment amounts for each of the six measure cohorts (AMI, HF, pneumonia, COPD, CABG, THA/TKA) included in the FY 2018 program. We used DRG payment information for the period July 1, 2012 through June 30, 2015. Furthermore, to estimate the dollar amount of the penalty and the share of payments the penalty represents, we used total base operating DRG payments among Medicare FFS claims from the FY 2015 MedPAR data file.

All four methods support the agency's efforts to reduce the payment adjustment for safety-net hospitals. We proposed to use the median ERR plus a neutrality modifier because it creates a standard where a hospital's ERR is subject to payment reduction when a hospital's performance as measured by the ERR is worse than that of half the other hospitals in its peer group. The median ERR plus neutrality modifier is preferred to the mean ERR plus neutrality modifier because the median represents a consistent standard (that is, 50th percentile) for the hospital's rank within its peer group, while the rank corresponding to the mean changes between years, cohorts and peer groups. The median ERR plus neutrality modifier substantially reduces the penalty as a share of total payments (from 0.64 percent to 0.55 percent with quintile peer groups) and penalty per discharge (from $157 to $135) for safety-net hospitals while not disproportionately increasing the payment reduction amount for non-safety-net hospitals (from 0.61 percent to 0.63 percent as share of total payments). The median ERR plus neutrality modifier is also preferred because it achieves more precise budget neutrality than the budget neutralizing ERR. Below we show the estimated total Medicare savings under the current and stratified methodology used to assess budget neutrality.

Method	Estimated total medicare savings	Difference between stratified and current methodology	Percentage difference between stratified and current methodology
Current methodology	$532,948,318	N/A	N/A
Mean plus neutrality modifier (neutrality modifier=1.0135 when using quintiles)	532,949,006	688	<0.00
Median plus neutrality modifier (neutrality modifier=0.9546 when using quintiles)	532,946,272	($2,046)	<0.00
Budget neutralizing ERR	533,199,304	250,985	0.05
Standardized ERR plus neutrality modifier (neutrality modifier=0.9710 when using quintiles)	532,948,288	($30)	<0.00

Source: FY 2017 Hospital Readmissions Reduction Program Final Rule Results. Results are based on July 1, 2012, through June 30, 2015, discharges among subsection (d) and Maryland hospitals only. Although data from all subsection (d) and Maryland hospitals are used in calculations of each hospital's Excess Readmission Ratio (ERR), this table does not include results for Maryland hospitals. Hospital Characteristics are based on the FY 2017 final rule Impact File. Hospitals are stratified into quintiles based on the proportion of dual-eligible beneficiaries among Medicare FFS and managed care patients discharged between July 1, 2012, through June 30, 2015.

When we analyzed the other options, we found that the mean threshold permits a higher standard to be set if hospitals in the peer group have performance well above the midpoint but not far below, or a lower standard if hospitals are more likely to have very high rates. In our testing, the mean plus modifier resulted in lower penalties for safety-net hospitals (0.52 percent as a share of total payments compared to 0.55 percent for the median plus modifier). However, our preferred approach of the median is based on the judgment that the standard reflected by the threshold should not be affected by hospitals with unusually strong or weak performance in the peer group. Like the median, the budget neutralizing ERR threshold approach imposes a consistent rank-based standard across peer groups. However, this method is not preferred since it is more complex, less intuitive and results in greater

divergence between total payment adjustments under the stratified and current methodologies than approaches using a neutrality modifier (differing from the current methodology by approximately 0.05 percent of total payments when simulated with quintile peer groups). The median uses the original distribution of hospital ERR estimates, based on their relationship to a national standard, and represents the most precise possible measures of their performance under that standard. Using a standardized ERR within each peer group compares a hospital's performance to other hospitals in the peer group. In contrast, using the mean or median threshold adjusts penalties based on a hospital's relative performance within the peer group, but the performance indicator of the ERR retains the comparison to the mean performance of all hospitals across all peer groups. However, comparing the ERR to the mean or median for each peer group is a more straightforward methodology than re-standardizing ERRs. The median is preferred to the standardized ERR because, as with the budget neutralizing ERR, the median is less complex and more intuitive. Using a less complex and well-known metric, will create a more transparent methodology since it will be easier for hospitals and other stakeholders to replicate the calculation of the median ERRs.

The impact of the proposed changes to the payment adjustment formula for the budget neutral considered methods, by peer group options, for safety-net and non-safety-net hospitals is shown in the table below. The table includes three penalty metrics: average payment reduction, total Medicare savings, and share of payment adjustments as a percentage of total payments. The average payment reduction shows the average reduction in Medicare DRG payments for safety-net and non-safety-net hospitals. The total Medicare savings column shows the total estimated penalties borne by safety-net and non-safety-net hospitals under each approach. Because the payment reduction is applied to hospitals' base DRG payments, hospitals with more discharges will contribute a larger amount of Medicare savings to the group total of Medicare savings.

Furthermore, because there are fewer safety-net than non-safety-net hospitals, as safety-net is defined as hospitals in the top quintile of DSH patient percentage, the total Medicare savings for non-safety-net hospitals are inherently much larger than for safety-net hospitals. Therefore, to compare the financial impact of the program on hospitals in each group, we calculated the payment adjustment as a proportion of DRG payments. Using this metric allows comparison across the different methodologies where the total base operating DRG payments are different between different groups of hospitals and is a more accurate indication of the financial impact on the group. For example, under the current methodology, the payment adjustment as a proportion of all DRG payments among safety-net hospitals is 0.64 percent.

COMPARISON OF PENALTY METRICS BY THRESHOLD METHODS AND PEER GROUP OPTIONS FOR ALL HOSPITALS, SAFETY-NET, AND NON-SAFETY-NET HOSPITALS

Stratification approach and payment formula methodology	Average payment reduction (1 − P) [a] (%)	Total Medicare savings	Payment adjustment as a proportion of all DRG payments (%)
Current methodology:			
Safety-net hospitals	0.62	$109,142,525	0.64
Non-safety-net hospitals	0.61	$423,805,793	0.61
Approach 1: Two equal peer groups based on the proportion of dual-eligible beneficiaries			
Median plus neutrality modifier (neutrality modifier = 0.9558):			
Safety-net hospitals	0.56	100,205,115	0.59
Non-safety-net hospitals	0.61	432,741,958	0.62
Mean plus neutrality modifier (neutrality modifier = 1.0191):			
Safety-net hospitals	0.54	97,837,278	0.57
Non-safety-net hospitals	0.61	435,112,491	0.63
Budget neutralizing ERR:			
Safety-net hospitals	0.55	98,208,670	0.58
Non-safety-net hospitals	0.61	435,216,961	0.63
Standardized ERR plus neutrality modifier (neutrality modifier = 0.9796):			
Safety-net hospitals	0.55	98,468,430	0.58
Non-safety-net hospitals	0.61	434,478,852	0.63
Approach 2: Quintiles based on the proportion of dual-eligible beneficiaries			
Median plus neutrality modifier (neutrality modifier = 0.9546)			
Safety-net hospitals	0.52	93,878,536	0.55
Non-safety-net hospitals	0.62	439,067,736	0.63
Mean plus neutrality modifier (neutrality modifier = 1.0135)			
Safety-net hospitals	0.49	89,182,424	0.52
Non-safety-net hospitals	0.62	443,766,582	0.64
Budget neutralizing ERR			
Safety-net hospitals	0.49	88,510,157	0.52
Non-safety-net hospitals	0.62	444,689,147	0.64
Standardized ERR plus neutrality modifier (neutrality modifier = 0.9710)			
Safety-net hospitals	0.50	91,686,964	0.54
Non-safety-net hospitals	0.62	441,261,324	0.64

COMPARISON OF PENALTY METRICS BY THRESHOLD METHODS AND PEER GROUP OPTIONS FOR ALL HOSPITALS, SAFETY-NET, AND NON-SAFETY-NET HOSPITALS—Continued

Stratification approach and payment formula methodology	Average payment reduction (1 − P) [a] (%)	Total Medicare savings	Payment adjustment as a proportion of all DRG payments (%)
Approach 3: Deciles based on the proportion of dual-eligible beneficiaries			
Median plus neutrality modifier (neutrality modifier = 0.9555)			
Safety-net hospitals	0.51	91,881,047	0.54
Non-safety-net hospitals	0.62	441,068,999	0.64
Mean plus neutrality modifier (neutrality modifier = 1.0148)			
Safety-net hospitals	0.48	87,289,962	0.51
Non-safety-net hospitals	0.62	445,653,065	0.64
Budget neutralizing ERR			
Safety-net hospitals	0.47	86,671,374	0.51
Non-safety-net hospitals	0.62	446,299,280	0.64
Standardized ERR plus neutrality modifier (neutrality modifier = 0.9713)			
Safety-net hospitals	0.49	90,058,433	0.53
Non-safety-net hospitals	0.62	442,888,696	0.64

Notes: Results based on July 1, 2012 through June 30, 2015 discharges among subsection (d) and Maryland hospitals only. Although data from all subsection (d) and Maryland hospitals are used in calculations of each hospital's ERR, this table does not include results for Maryland hospitals. Hospitals are stratified based on the proportion of duals calculated among Medicare FFS and managed care patients for the FY 2017 performance period. Safety-net hospitals are defined as hospitals in the top quintile of DSH patient percentage. DSH patient percentage was calculated among all hospitals with a positive DSH value (including hospitals not eligible for DSH payments).

[a] The payment reduction shows what percentage of DRG payments hospitals will lose as a result of the program. This is slightly different than the adjustment factor that CMS applies, which is 1 minus the number reported here (that is, ranges from 0.97 to 1).

[b] Total Medicare savings is estimated by multiplying the payment reduction by total base operating DRG payments from July 1, 2014 through June 30, 2015.

[c] The group share of payment adjustments as a percentage of all DRG payments is calculated as the sum of total Medicare savings for the group of hospitals (that is, safety-net hospitals or non-safety-net hospitals) divided by total base operating DRG payments from July 1, 2014 through June 30, 2015 for the group of hospitals.

Our analysis also assesses the impact of the proposed changes to the payment adjustment formula on additional groups of hospitals. Variation in the impact of the proposed changes by hospital characteristics on the share of payment adjustments as a percentage of all DRG payments for the FY 2019 Hospital Readmissions Reduction Program, is shown in the table below. The table is based on results when hospitals are stratified into quintiles based on the proportion of dual-eligible beneficiaries among Medicare FFS and managed care patients discharged between July 1, 2012, and June 30, 2015, our preferred approaches. The table shows the average share of payment adjustments as a percentage of all DRG payments for each group of hospitals. The group average is calculated as the sum of penalties for all hospitals with that characteristic over the sum of all DRG payments for those hospitals between July 1, 2014 and June 30, 2015. For example, under the current methodology, the average share of payment adjustments as a percentage of all DRG payments for urban hospitals is 0.61 percent. This means that total penalties for all urban hospitals is 0.61 percent of total payments for urban hospitals (that is the ratio of total penalties to total DRG payments is 0.61 percent). This metric allows us to compare the financial impact of the different methods for assessing penalties between hospitals with different number of beds even though larger hospitals tend to generate higher total Medicare savings because their payment reduction is applied to more DRG payments. Measuring the financial impact on hospitals as a proportion of total DRG payments allows us to account for differences in the amount of DRG payments for hospitals when comparing the financial impact of the program on different groups of hospitals, and allows comparison across the different methodologies between groups of hospitals with different numbers of eligible hospitals.

AVERAGE SHARE OF PAYMENT ADJUSTMENTS AS A PERCENTAGE OF ALL DRG PAYMENTS FOR CONSIDERED APPROACHES FOR THE HOSPITAL READMISSIONS REDUCTION PROGRAM, BY HOSPITAL CHARACTERISTIC

Hospital characteristics	Number of hospitals with characteristic	Current methodology (%)	Median plus neutrality modifier (neutrality modifier = 0.9546) (%)	Mean plus neutrality modifier (neutrality modifier = 1.0135) (%)	Budget neutralizing ERR (%)	Standardized ERR plus neutrality modifier (neutrality modifier = 0.9710) (%)
All Hospitals	3,096	0.62	0.62	0.62	0.62	0.62
Geographic Location:						
Urban	2,304	0.61	0.62	0.62	0.62	0.62
Rural:	792	0.65	0.62	0.60	0.60	0.60
Bed size:						
1–99 beds	1,113	0.57	0.57	0.56	0.56	0.57
100–199 beds	886	0.70	0.70	0.70	0.70	0.70

AVERAGE SHARE OF PAYMENT ADJUSTMENTS AS A PERCENTAGE OF ALL DRG PAYMENTS FOR CONSIDERED APPROACHES FOR THE HOSPITAL READMISSIONS REDUCTION PROGRAM, BY HOSPITAL CHARACTERISTIC—Continued

Hospital characteristics	Number of hospitals with characteristic	Current methodology (%)	Median plus neutrality modifier (neutrality modifier = 0.9546) (%)	Mean plus neutrality modifier (neutrality modifier = 1.0135) (%)	Budget neutralizing ERR (%)	Standardized ERR plus neutrality modifier (neutrality modifier = 0.9710) (%)
200–299 beds	453	0.65	0.66	0.66	0.66	0.66
300–399 beds	278	0.64	0.63	0.63	0.63	0.63
400–499	155	0.53	0.54	0.54	0.54	0.54
500 or more beds	211	0.57	0.57	0.57	0.57	0.56
By DSH Payment Eligibility:						
Not eligible	474	0.55	0.61	0.65	0.64	0.64
DSH payment eligible	2,622	0.63	0.62	0.61	0.61	0.61
By Teaching Status:						
Non-teaching	2,076	0.66	0.67	0.67	0.67	0.67
Teaching	1,020	0.59	0.58	0.58	0.58	0.58
Fewer than 100 residents	772	0.59	0.60	0.60	0.61	0.60
100 or more residents	248	0.57	0.55	0.54	0.54	0.55
By Type of Ownership:						
Government	490	0.54	0.53	0.53	0.53	0.53
Proprietary	779	0.79	0.79	0.80	0.80	0.79
Voluntary	1,827	0.59	0.59	0.59	0.59	0.59
DSH patient percentage:						
1st	547	0.54	0.60	0.63	0.63	0.63
2nd	635	0.66	0.71	0.72	0.72	0.72
3rd	646	0.60	0.61	0.62	0.62	0.61
4th	642	0.61	0.60	0.59	0.59	0.59
5th	626	0.64	0.55	0.52	0.52	0.54
MCR Percent:						
0–24	410	0.42	0.40	0.39	0.39	0.39
25–49	2,081	0.63	0.63	0.63	0.63	0.63
50 and over	590	0.72	0.73	0.74	0.74	0.74
Region:						
New England	130	0.68	0.64	0.63	0.63	0.64
Middle Atlantic	354	0.86	0.83	0.83	0.83	0.83
South Atlantic	512	0.74	0.76	0.78	0.78	0.77
East North Central	482	0.63	0.63	0.63	0.63	0.63
East South Central	290	0.76	0.79	0.80	0.80	0.79
West North Central	252	0.39	0.41	0.41	0.41	0.41
West South Central	487	0.46	0.48	0.48	0.48	0.47
Mountain	223	0.36	0.39	0.40	0.40	0.39
Pacific	366	0.42	0.37	0.34	0.34	0.36

Source: FY 2017 Hospital Readmissions Reduction Program Final Rule Results. Results are based on July 1, 2012, through June 30, 2015, discharges among subsection (d) and Maryland hospitals only. Although data from all subsection (d) and Maryland hospitals are used in calculations of each hospital's Excess Readmission Ratio (ERR), this table does not include results for Maryland hospitals. This table only includes results for hospitals who are eligible for a penalty under the program on the basis of having at least 25 eligible discharges for at least one measure. Hospital Characteristics are based on the FY 2017 final rule Impact File. There were 15 hospitals that did not have MCR percentages in the FY 2017 final rule Impact File. To calculate the payment adjustment as a proportion of total base operating DRG payments, this analysis used MedPAR data to calculate the total base operating DRG payments from July 1, 2014 through June 30, 2015. The group average share of payment adjustments as a percentage of all DRG payments is calculated as the sum of all Medicare savings for the group of hospitals divided by total base operating DRG payments for all hospitals in that group.

We invited public comment on our preferred proposal and alternative considerations.

Comment: Many commenters supported using the median ERR plus neutrality modifier because a homogenous group of hospitals are included in each peer group, the approach is simple and accurate, it is not skewed by extreme values, and provides a more robust threshold. However, one commenter argued that budget neutrality should be done at the national level rather than using a budget-neutralizing ERR at the peer group level.

Response: We thank commenters for their support. We agree that the peer group median ERR is a strong threshold. To clarify, the budget neutralizing ERR is not calculated only among hospitals in the peer group. The budget neutralizing ERR is the ERR corresponding to the percentile within each peer group's distribution of ERRs that will ensure budget neutrality across all applicable hospitals.

Comment: One commenter asked CMS to reconsider the budget neutrality requirement for the payment adjustment methodology because it disincentivizes the overall goal of the program.

Response: While we understand commenters' concerns, one of the requirements of Public Law 114–255 is to maintain budget neutrality. For this reason, we have proposed using the median ERR as the threshold and scaling payment adjustments by a neutrality modifier. Many commenters expressed support for using the median ERR plus neutrality modifier. We believe that adopting the median ERR plus neutrality modifier methodology meets our priority to adopt a simplified and well-known metric that allows us to be more transparent in our methodology and reduces the penalty on safety-net

hospitals. We will continue to monitor the impact of accounting for dual-eligible patients in the Hospital Readmissions Reduction Program and evaluate if future changes to include other variables or adjustments are needed.

Comment: One commenter noted that, to calculate the difference between each hospital's excess readmission ratio and the quintile average, CMS must divide the former by the latter and then subtract 1 rather than simply subtracting the latter from the former. The commenter also argued that it was essential that CMS modify the quintile medians to ensure monotonicity to adhere to the intent of the statute.

Response: We considered many factors in developing peer groups to calculate payment adjustments for the Hospital Readmissions Reduction Program in response to Public Law 114–255. These factors included: (1) The legislative requirements of Public Law 114–255 such as stratification by dual proportion, budget neutrality, and immediate implementation; (2) constructing peer groups that were consistent across six current measures and future additional measures, and were defined consistently over time; (3) the intent of the program to encourage efficient, high quality care; and (4) the impact of peer group definitions on the distribution of payments to hospital groups, such as safety-net or rural hospitals.

The modification to the formula recommended in the proposed rule, to use the peer group median to assess hospital performance, meets these objectives. The proposed approach transforms the distribution of excess readmission ratios by subtracting from it the difference between the median of the peer group and the overall median. The commenter's proposed alternative modification, of dividing the excess readmission ratio by the peer group median, is consistent with the formulation of the payment adjustment as the proportion by which the hospital's readmission rate exceeds a standard rate multiplied by the cost of admissions. However, we do not agree that the formula modification must be performed in this way to be consistent with the requirements of the legislation and our objectives. Though monotonicity is desirable, the proposed approach, preselecting peer groups of equal size and choosing the size that best meets the objectives above with an unmodified median, is transparent and effective.

Comment: One commenter recommended that CMS delay implementing the payment adjustment methodology based on proportion of dual-eligible patients while better measures are developed.

Response: We thank the commenter for its recommendation. However, Public Law 114–255 requires the implementation of these changes to apply to discharges that occur during and after FY 2019. Public Law 114–255 added section 1886(q)(3)(D) to the Act, which directs the Secretary to develop a transitional methodology that accounts for the percentage of full-benefit dual-eligible patients treated by a hospital to determine a hospital's payment adjustment factor. Section 1886(q)(3)(D)(i) of the Act sets forth the requirement that the Secretary assign hospitals to groups and apply a methodology that allows for separate comparison of hospitals within each such group. This applies to discharges that occur during and after FY 2019, until and unless the system is revised under the authority of section 1886(q)(3)(E)(i) of the Act.

After consideration of the public comments we received, we are finalizing, without modification, our proposal to use the median ERR plus neutrality modifier.

11. Accounting for Social Risk Factors in the Hospital Readmissions Reduction Program

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19966 through 19967), we discussed the accounting for social risk factors in the Hospital Readmissions Reduction Program. Although the program has made steps to account for social risk factors in this year's rule, we understand that social risk factors such as income, education, race and ethnicity, employment, disability, community resources, and social support (certain factors of which are also sometimes referred to as socioeconomic status (SES) factors or socio-demographic status (SDS) factors) play a major role in health. One of our core objectives is to improve beneficiary outcomes, including reducing health disparities, and we want to ensure that all beneficiaries, including those with social risk factors, receive high quality care. In addition, we seek to ensure that the quality of care furnished by providers and suppliers is assessed as fairly as possible under our programs while ensuring that beneficiaries have adequate access to excellent care.

We have been reviewing reports prepared by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) [27] and the National Academies of Sciences, Engineering, and Medicine on the issue of accounting for social risk factors in CMS' quality measurement and payment programs, and considering options on how to address the issue in these programs. On December 21, 2016, ASPE submitted a report to Congress on a study it was required to conduct under section 2(d) of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. The study analyzed the effects of certain social risk factors in Medicare beneficiaries on quality measures and measures of resource use used in one or more of nine Medicare value-based purchasing programs, including the Hospital Readmissions Reduction Program.[28] The report also included considerations for strategies to account for social risk factors in these programs. In a January 10, 2017 report released by the National Academies of Sciences, Engineering, and Medicine, that body provided various potential methods for measuring and accounting for social risk factors, including stratified public reporting.[29]

As noted in the FY 2017 IPPS/LTCH PPS final rule, the NQF undertook a 2-year trial period in which certain new measures, measures undergoing maintenance review, and measures endorsed with the condition that they enter the trial period were assessed to determine whether risk adjustment for selected social risk factors is appropriate for these measures. This trial entailed temporarily allowing inclusion of social risk factors in the risk-adjustment approach for these measures. We await the recommendations of the NQF trial on risk adjustment for quality measures.

As we continue to consider the analyses and recommendations from these reports and await the results of the NQF trial on risk adjustment for quality measures, we are continuing to work with stakeholders in this process. As we have previously indicated, we are concerned about holding providers to different standards for the outcomes of their patients with social risk factors because we do not want to mask potential disparities or minimize incentives to improve the outcomes for disadvantaged populations. Keeping this concern in mind, while we sought input on this topic previously, we continue to seek public comment on

[27] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[28] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[29] National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

whether we should account for additional social risk factors in the Hospital Readmissions Reduction Program and, if so, what method or combination of methods, in addition to the method of stratification based on proportion of dual-eligible beneficiaries in the facility that we are finalizing in this rule, would be most appropriate for accounting for social risk factors. We believe that the path forward should incentivize improvements in health outcomes for disadvantaged populations while ensuring that beneficiaries have access to excellent care. Examples of methods include: Confidential reporting of stratified measure rates to providers; public reporting of stratified measure rates; risk adjustment of a particular measure as appropriate based on data and evidence; developing readmission measures or statistical approaches that are suitable for the reporting of performance on readmissions; providing financial incentives for achievement of low readmission rates for beneficiaries with social risk factors; and using a hospital-wide readmissions measure. While we consider whether and to what extent we currently have statutory authority to implement one or more of the above-described methods, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19966), we sought comments on whether any of these methods should be considered, and if so, which of these methods or combination of methods would best account for social risk factors in the Hospital Readmissions Reduction Program.

In addition, in the proposed rule, we sought public comment on which social risk factors might be most appropriate for stratifying measure scores and/or potential risk adjustment of a particular measure. Examples of social risk factors include, but are not limited to, dual eligibility/low-income subsidy, race and ethnicity, and geographic area of residence. We also sought comments on which of these factors, including current data sources where this information would be available, could be used alone or in combination, and whether other data should be collected to better capture the effects of social risk. We will take commenters' input into consideration as we continue to assess the appropriateness and feasibility of accounting for social risk factors in the Hospital Readmissions Reduction Program. We note that any such changes would be proposed through future notice-and-comment rulemaking.

We look forward to working with stakeholders as we consider the issue of accounting for social risk factors and reducing health disparities in CMS programs. Of note, implementing any of the above methods would be taken into consideration in the context of how this and other CMS programs operate (for example, data submission methods, availability of data, statistical considerations relating to reliability of data calculations, among others); therefore, we also welcomed comment on operational considerations. CMS is committed to ensuring that its beneficiaries have access to and receive excellent care, and that the quality of care furnished by providers and suppliers is assessed fairly in CMS programs.

Comment: Numerous commenters supported adjusting for social risk factors and recommended that any methodology support equitable care delivery while not disproportionately penalizing certain hospitals. Commenters cited the importance of transparency in risk factors related to any risk adjustment methodology to meet both aims and discourages the use of unadjusted data in public reporting and pay-for-performance. Commenters agreed with CMS' approach to stratify hospitals into peer groups and recommended that CMS consider additional social risk factors in addition to the peer grouping requirements using dual-eligibility data required by Public Law 114–255. Commenters recommended that CMS closely examine the considerations provided by National Academy of Medicine (NAM) for risk adjustment, which recommend four domains of risk indicators: Income, education, and dual eligibility; race, ethnicity, language, and nativity; marital/partnership status and living alone; and neighborhood deprivation, urbanicity, and housing.

Commenters also recommended that CMS study the relationship between a hospital's readmission rates and the surrounding area's Health Professional Shortage Area (HPSA), Type II Diabetes, hypertension, arthritis, heart disease and depression to determine if these factors should be accounted for. Commenters also suggested focusing on: Continuing refinement of performance scoring and measurements to end any bias to major teaching providers; continuing development of appropriate peer groups; develop and apply appropriate socio-demographic status adjustments to all the quality risk programs; and ensuring efficiency in data reporting. Commenters requested that CMS lay out a longer-term effort for testing and refining additional variables when accounting for social risk factors due to the wide range of variables that impact a person's health outcomes. A few commenters suggested that CMS use census data on poverty rates and education levels of patients in a hospital's service area, two key indicators of population health per Healthy People 2020, to adjust a hospital's measure score.

Some commenters recommended the use of confidential patient-reported data as self-reports offer a reasonably valid estimate of differences in utilization of health care between socioeconomic groups. Commenters requested that CMS consider providing hospitals with confidential reports of performance on accountability measures stratified by dual-eligible status or other nationally available data elements. Once hospitals have had sufficient opportunity to review and understand their performance on these stratified measures, CMS should work with stakeholders to publicly report this data in an appropriate fashion. Commenters further recommend the implementation of demonstration projects to encourage hospitals to collect data on social risk factors through their electronic health records (EHR).

Some commenters recommended that CMS start with standard patient admission information and use the information from NQF and other sources to gather additional data, provide appropriate metrics, risk models, and risk adjustment strategies. One commenter suggested that CMS should consider concurrently quality and disparities using a two-stage reimbursement strategy because it can mitigate unintended consequences while reducing disparities and improving quality.

A few commenters recommended that CMS not use social risk factors to adjust quality measures and recommended that CMS first evaluate and learn from the use of peer groups before additional adjustment to either the program or program measures. Commenters noted that adjusting for social risk factors does not address the underlying disparities that are often associated with poor health outcomes and would mask potential disparities or minimize incentives to improve the outcomes for disadvantaged populations.

Commenters expressed concern regarding the potential use of a hospital-wide readmission measure to account for social risk factors, citing the uncertainty that CMS has the legal authority to do so and government reports indicating that it would increase penalties for all hospitals and increase the disparity between safety-net and other hospitals. Commenters stated that if CMS incorporated the hospital-wide readmission measure in the Hospital Readmissions Reduction Program, it would need to remove the existing six

measures and do it in a budget-neutral manner.

One commenter believed that the readmission measures used in the Hospital Readmissions Reduction Program should be risk adjusted for social risk factors that are associated with higher readmission rates. The commenter recommended CMS undertake analysis that would directly measure those factors and make appropriate risk adjustments as part of the measure calculation.

Response: We thank commenters for the extensive responses to our request for public comments on whether we should account for social risk factors in the Hospital Readmissions Reduction Program, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors. We recognize that social risk factors impact health, and one of our core objectives is to improve beneficiary outcomes including reducing health disparities. In addition, we seek to ensure that the quality of care furnished by providers and suppliers is assessed as fairly as possible under our programs while ensuring that beneficiaries receive high quality care. To this end, we have closely reviewed reports by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academies of Sciences, Engineering, and Medicine on the issue of accounting for social risk factors in CMS' value-based purchasing and quality reporting programs. We also await the recommendations of the recently concluded NQF trial on risk adjustment for quality measures. As we have previously stated, we are concerned about holding providers to different standards for the outcomes of their patients with social risk factors, because we do not want to mask potential disparities or minimize incentives to improve the outcomes for disadvantaged populations.

Commenters were generally supportive of how the Hospital Readmissions Reduction Program is adopting a methodology for accounting for dual-eligible patients. However, commenters also stated concerns such as the need to: Continue refinement of performance scoring and measurements to end any bias to major teaching providers; continue development of appropriate peer groups; and work to develop and apply appropriate socio-demographic status adjustments. Some recommendations, such as the use of a hospital-wide readmission measure, would require a statutory change. We will consider all suggestions as we continue to assess each measure and the overall program. We intend to explore options including but not limited to measure stratification by social risk factors in a consistent manner across programs, informed by considerations of stratification methods described in section IX.A.13. of the preamble of this final rule. We thank commenters for this important feedback and will continue to consider options to account for social risk factors that would allow us to view disparities and potentially incentivize improvement in care for patients and beneficiaries. We will also consider providing feedback to providers on outcomes for individuals with social risk factors in confidential reports.

12. Extraordinary Circumstance Exception (ECE) Policy

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19967), we noted that many of our quality reporting and value-based purchasing programs share a common process for requesting an exception from program reporting due to an extraordinary circumstance not within a provider's control. The Hospital IQR, the Hospital OQR, the IPFQR, the Ambulatory Surgical Center Quality Reporting (ASCQR), and the PCHQR Programs, as well as the HAC Reduction Program, and the Hospital Readmissions Reduction Program, share common processes for ECE requests. In reviewing the policies for these programs, we recognized that there are five areas in which these programs have variance regarding ECE requests. These are: (1) Allowing the facilities or hospitals to submit a form signed by the facility's or hospital's CEO versus CEO or designated personnel; (2) requiring the form be submitted within 30 days following the date that the extraordinary circumstance occurred versus within 90 days following the date the extraordinary circumstance occurred; (3) inconsistency regarding specification of a timeline for us to provide our formal response notifying the facility or hospital of our decision; (4) inconsistency regarding specification of our authority to grant ECEs due to CMS data system issues; and (5) referring to the program as ''extraordinary extensions/exemptions'' versus as ''extraordinary circumstances exceptions.'' We believe addressing these five areas, as appropriate, can improve administrative efficiencies for affected facilities or hospitals.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49542 through 49543), we adopted an ECE policy for the Hospital Readmissions Reduction Program beginning in FY 2016. This policy was similar to the ECE policy for the Hospital IQR Program, as finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651), modified in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836) (designation of a non-CEO hospital contact), and further modified in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277) (amended 42 CFR 412.140(c)(2) to refer to ''extension or exemption'' instead of the former ''extension or waiver'').

We proposed to update these policies by: (1) Allowing the facility to submit a form signed by the facility's CEO or designated personnel; (2) clarifying that we will strive to provide our formal response notifying the facility of our decision within 90 days of receipt of the facility's request; and (3) allowing CMS to have the authority to grant ECEs due to CMS data system issues which affect data submission. These proposed policies generally align with policies in the Hospital IQR Program (76 FR 51651 through 51652), (78 FR 50836 through 50837), and (81 FR 57181 through 57182), the Hospital OQR Program (77 FR 68489 and 81 FR 79795), as well as other quality reporting programs. We proposed that these policies would apply beginning in FY 2018 as related to extraordinary circumstances that occur on or after October 1, 2017.

We note that there may be circumstances in which it is not feasible for a facility's CEO to sign the ECE request form. In these circumstances, we believe that facilities affected by such circumstances should be able to submit ECE forms regardless of the CEO's availability to sign. This proposed change would allow hospitals to designate an appropriate, non-CEO, contact at its discretion. This individual would be responsible for the submission, and would be the one signing the form. Therefore, we proposed to accept ECE forms which have been signed by designated personnel.

We also believe that it is important for facilities to receive timely feedback regarding the status of ECE requests. We strive to complete our review of each ECE request as quickly as possible. However, we recognize that the number of requests we receive, and the complexity of the information provided impacts the actual timeframe to make ECE determinations. To improve transparency of our process, we believe it is appropriate to clarify that we will strive to complete our review of each request within 90 days of receipt.

Although we do not anticipate this situation will happen on a regular basis, there may be times where CMS experiences issues with its data systems that directly affects facilities' abilities to submit data. In these cases, we believe

it would be inequitable to require facilities to report. Therefore, we proposed to allow CMS to grant ECEs to facilities if we determine that a systemic problem with one of our data collection systems directly affected the ability of the facilities to submit data. If we make the determination to grant ECEs, we proposed to communicate this decision through routine communication channels.

We invited public comment on these proposed modifications to the Extraordinary Circumstance Exception policy.

Comment: Commenters supported the proposals to modify the extraordinary circumstances exceptions (ECE) policies to align across CMS quality reporting and value-based purchasing programs.

Response: We thank commenters for their support.

Comment: A few commenters noted that there currently is no ECE policy for the Indian Health Service or Tribally-operated programs, although tribal programs have requested an exception from CMS in previous fiscal years. Commenters requested an ECE specifically for IHS and tribal healthcare programs.

Response: We appreciate the commenters' concern. However, we note that section 1886(q)(5)(C) of the Act defines applicable hospitals and requires all subsection (d) hospitals to be included in the Hospital Readmissions Reduction Program. The ECE policy was not designed to allow a hospital to seek exclusion from the Hospital Readmissions Reduction on Program in its entirety, but to provide relief for a hospital whose ability to accurately collect quality measure data and/or to report those data in a timely manner has been negatively impacted as a direct result of experiencing a significant disaster or other extraordinary circumstance beyond the control of the hospital.

After consideration of the public comments we received, we are finalizing, without modification, our proposal to update our extraordinary circumstances exception policies to align with other quality reporting programs.

13. Timeline for Public Reporting of Excess Readmission Ratios on *Hospital Compare* for the FY 2018 Payment Determination

Section 1886(q)(6) of the Act requires the Secretary to make information available to the public regarding readmission rates of each subsection (d) hospital under the program, and states that such information shall be posted on the *Hospital Compare* Internet Web site in an easily understandable format. Accordingly, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53401), we indicated that public reporting for excess readmission ratios could be available on the *Hospital Compare* Web site as early as mid-October. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56978 through 56979), we clarified that public reporting of excess readmission ratios will be posted on an annual basis to the *Hospital Compare* Web site as soon as is feasible following the review period. This may occur as early as October, but it could occur later for a particular year in order to streamline reporting and align with other hospital quality reporting and performance programs.

J. Hospital Value-Based Purchasing (VBP) Program: Policy Changes

1. Background

a. Statutory Background and Overview of Past Program Years

Section 1886(o) of the Act, as added by section 3001(a)(1) of the Affordable Care Act, requires the Secretary to establish a hospital value-based purchasing program (the Hospital VBP Program) under which value-based incentive payments are made in a fiscal year (FY) to hospitals that meet performance standards established for a performance period for such fiscal year. Both the performance standards and the performance period for a fiscal year are to be established by the Secretary.

For more of the statutory background and descriptions of our current policies for the Hospital VBP Program, we refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26490 through 26547); the FY 2012 IPPS/LTCH PPS final rule (76 FR 51653 through 51660); the CY 2012 OPPS/ASC final rule with comment period (76 FR 74527 through 74547); the FY 2013 IPPS/LTCH PPS final rule (77 FR 53567 through 53614); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50676 through 50707); the CY 2014 OPPS/ASC final rule (78 FR 75120 through 75121); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50048 through 50087); the FY 2016 IPPS/LTCH PPS final rule with comment period (80 FR 49544 through 49570); the FY 2017 IPPS/LTCH PPS final rule (81 FR 56979 through 57011); and the CY 2017 OPPS/ASC final rule with comment period (81 FR 79855 through 79862).

We also have codified certain requirements for the Hospital VBP Program at 42 CFR 412.160 through 412.167.

b. FY 2018 Program Year Payment Details

Section 1886(o)(7)(B) of the Act instructs the Secretary to reduce the base operating DRG payment amount for a hospital for each discharge in a fiscal year by an applicable percent. Under section 1886(o)(7)(A) of the Act, the sum total of these reductions in a fiscal year must equal the total amount available for value-based incentive payments for all eligible hospitals for the fiscal year, as estimated by the Secretary. We finalized details on how we would implement these provisions in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53571 through 53573) and refer readers to that rule for further details. Under section 1886(o)(7)(C)(iv) of the Act, the applicable percent for the FY 2018 program year is 2.00 percent. Using the methodology we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53571 through 53573), we estimate that the total amount available for value-based incentive payments for FY 2018 is approximately $1.9 billion, based on the March 2017 update of the FY 2016 MedPAR file.

As finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53573 through 53576), we will utilize a linear exchange function to translate this estimated amount available into a value-based incentive payment percentage for each hospital, based on its Total Performance Score (TPS). We will then calculate a value-based incentive payment adjustment factor that will be applied to the base operating DRG payment amount for each discharge occurring in FY 2018, on a per-claim basis. We published proxy value-based incentive payment adjustment factors in Table 16 associated with the FY 2018 IPPS/LTCH PPS proposed rule (which is available via the Internet on the CMS Web site). The proxy factors are based on the TPS from the FY 2017 program year.

These FY 2017 performance scores are the most recently available performance scores hospitals have been given the opportunity to review and correct. The updated slope of the linear exchange function used to calculate those proxy value-based incentive payment adjustment factors is 3.0693696034. This slope, along with the estimated amount available for value-based incentive payments has been updated based on the March 2017 update of the FY 2016 MedPAR file, and is published with this final rule in Table 16A (which is available via the Internet on the CMS Web site).

After hospitals have been given an opportunity to review and correct their

actual TPSs for FY 2018, we will add Table 16B (which will be available via the Internet on the CMS Web site) to display the actual value-based incentive payment adjustment factors, exchange function slope, and estimated amount available for the FY 2018 program year. We expect Table 16B will be posted on the CMS Web site in the fall of 2017.

We strive to put patients first, ensuring they are empowered to make decisions about their own healthcare along with their clinicians using information from data-driven insights that are increasingly aligned with meaningful quality measures. We support technology that reduces burden and allows clinicians to focus on providing high-quality healthcare for their patients. We also support innovative approaches to improve quality, accessibility, and affordability of care while paying particular attention to improving clinicians' and beneficiaries' experience when interacting with our programs. In combination with other efforts across the Department of Health and Human Services, we believe the Hospital VBP Program helps to incentivize hospitals to improve healthcare quality and value, while giving patients and providers the tools and information needed to make the best decisions for them. We recognize that the Hospital VBP Program represents a key component of the way that we bring quality measurement and improvement together with payment, we have taken efforts to review existing policies to identify how to move the program forward in the least burdensome manner possible while continuing to incentivize improvement in the quality of care provided to patients.

2. Accounting for Social Risk Factors in the Hospital VBP Program

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19968 through 19969), we discussed accounting for social risk factors in the Hospital VBP Program. We understand that social risk factors such as income, education, race and ethnicity, employment, disability, community resources, and social support (certain factors of which are also sometimes referred to as socioeconomic status (SES) factors or socio-demographic status (SDS) factors) play a major role in health. One of our core objectives is to improve beneficiary outcomes, including reducing health disparities, and we want to ensure that all beneficiaries, including those with social risk factors, receive high quality care. In addition, we seek to ensure that the quality of care furnished by providers and suppliers is assessed as fairly as possible under our programs while ensuring that beneficiaries have adequate access to excellent care.

We have been reviewing reports prepared by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) [30] and the National Academies of Sciences, Engineering, and Medicine on the issue of accounting for social risk factors in CMS' value-based purchasing and quality reporting programs, and considering options on how to address the issue in these programs. On December 21, 2016, ASPE submitted a Report to Congress on a study it was required to conduct under section 2(d) of the Improving Medicare Post Acute Care Transformation (IMPACT) Act of 2014. The study analyzed the effects of certain social risk factors in Medicare beneficiaries on quality measures and measures of resource use used in one or more of nine Medicare value-based purchasing programs, including the Hospital VBP Program.[31] The report also included considerations for strategies to account for social risk factors in these programs. In a January 10, 2017 report released by the National Academies of Sciences, Engineering, and Medicine, that body provided various potential methods for measuring and accounting for social risk factors, including stratified public reporting.[32]

In the ASPE report noted above, there is an analysis of and focus on the Medicare Spending Per Beneficiary (MSPB) measure, which was adopted by the Hospital VBP Program beginning with the FY 2015 program year.[33] We note that the MSPB measure is currently undergoing endorsement review for NQF, as part of the 2-year socioeconomic trial period described below.[34] ASPE's December 2016 Report to Congress did not include an analysis of the effect of social risk factors on hospital performance on any condition-specific payment measures that are currently adopted for the Hospital VBP Program beginning with the FY 2021 program year (Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI Payment) measure and Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Heart Failure (HF Payment) measure) (81 FR 56986 through 56990 and 81 FR 56990 through 56992, respectively). We look forward to ASPE's continued analyses in this area, such as the role of frailty and disability in explaining variation in hospital episode spending among Medicare beneficiaries.

As noted in the FY 2017 IPPS/LTCH PPS final rule, the NQF undertook a 2-year trial period in which certain new measures, measures undergoing maintenance review, and measures endorsed with the condition that they enter the trial period were assessed to determine whether risk adjustment for selected social risk factors is appropriate for these measures. This trial entailed temporarily allowing inclusion of social risk factors in the risk-adjustment approach for these measures. We await the recommendations of the NQF trial on risk adjustment for quality measures.

We note that the AMI Payment and HF Payment measures adopted in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56987 through 56990 and 81 FR 56990 through 56992, respectively), as well as the Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Pneumonia (PN Payment) measure (prior to the expansion of the measure cohort), recently underwent successful NQF re-endorsement following enrollment in the NQF's trial. Based on its review of these measures during the trial, the NQF re-endorsed these measures without modifications to their risk adjustment methodologies for social risk factors. We are finalizing our proposal to adopt the PN Payment measure beginning with the FY 2022 program year for the Hospital VBP Program (we refer readers to section V.J.4.a. of the preamble of this final rule), and we intend to submit the measure with the proposed expanded measure cohort for NQF review during the measure's next re-endorsement review.

As we continue to consider the analyses and recommendations from these reports and await the results of the NQF trial on risk adjustment for quality measures, we are continuing to work with stakeholders in this process. As we have previously communicated, we are

[30] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[31] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[32] National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

[33] Office of the Assistant Secretary for Planning and Evaluation. 2016. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs; Chapter 7: The Hospital Value-Based Purchasing Program (p. 141–176). Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[34] Medicare Spending Per Beneficiary (MSPB)—Hospital. See Section 2b.4.5 in National Quality Forum—Measure Testing. Accessed 2/21/17 from: *http://www.qualityforum.org/ProjectMeasures.aspx?projectID=83458.*

concerned about holding providers to different standards for the outcomes of their patients with social risk factors because we do not want to mask potential disparities or minimize incentives to improve the outcomes for disadvantaged populations. Keeping this concern in mind, while we sought input on this topic previously, we continue to seek public comment on whether we should account for social risk factors in the Hospital VBP Program, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors. Examples of methods include: Adjustment of the payment adjustment methodology under the Hospital VBP Program; adjustment of provider performance scores (for instance, stratifying providers based on the proportion of their patients who are dual eligible); confidential reporting of stratified measure rates to providers; public reporting of stratified measure rates; risk adjustment of a particular measure as appropriate based on data and evidence; and redesigning payment incentives (for instance, rewarding improvement for providers caring for patients with social risk factors or incentivizing providers to achieve health equity).

We note that in section V.I.9. of the preamble of this final rule, we discuss considerations for stratifying hospitals into peer groups for purposes of assessing payment adjustments under the Hospital Readmissions Reduction Program, as required under the 21st Century Cures Act. We refer readers to that section for a detailed discussion of these alternatives; while this discussion and corresponding proposal are specific to the Hospital Readmissions Reduction Program, they reflect the level of analysis we would undertake when evaluating methods and combinations of methods for accounting for social risk factors in CMS' other value-based purchasing programs, such as the Hospital VBP Program. While we consider whether and to what extent we currently have statutory authority to implement one or more of the above-described methods, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19969), we sought comments on whether any of these methods should be considered, and if so, which of these methods or combination of methods would best account for social risk factors in the Hospital VBP Program.

In addition, in the proposed rule, we sought public comment on which social risk factors might be most appropriate for stratifying measure scores and/or potential risk adjustment of a particular measure. Examples of social risk factors include, but are not limited to, dual eligibility/low-income subsidy, race and ethnicity, and geographic area of residence. We also sought comments on which of these factors, including current data sources where this information would be available, could be used alone or in combination, and whether other data should be collected to better capture the effects of social risk. We also welcomed comment on operational considerations. Of note, implementing any of the above methods would be taken into consideration in the context of how this and other CMS programs operate (for example, data submission methods, availability of data, statistical considerations relating to reliability of data calculations, among others).

We received extensive comments in response to our request for public comment on whether we should account for social risk factors in the Hospital VBP Program, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors.

Comment: Commenters were generally supportive of accounting for social risk factors at the domain and measure level for the Hospital VBP Program in order to avoid penalizing hospitals for factors beyond their control or issues with the measures themselves. These commenters further stated that because social risk factors influence health outcomes, failure to appropriately risk-adjust for these factors in outcome measures could result in inadvertent penalties for hospitals who treat large populations of socially at-risk patients, and unintended consequences, such as reduced access to care for complex patients, due to provider concern that treating high-risk patients could negatively affect their performance rating. Commenters specifically recommended that CMS look to risk-adjust for socio-demographic and socioeconomic factors—such as income, education, race, payer type, patient travel distance, homelessness, and language proficiency—as well as functional status and frailty. However, commenters also stated concerns that changing Medicare payment policies to risk adjust or stratify measure rates for social risk factors would not address the underlying disparities that are often associated with poor health outcomes, would mask potential disparities or minimize incentives to improve the outcomes for disadvantaged populations, and may create perverse incentives for poor performers to continue with the status quo and for high performers to retreat from their efforts to address disparities in high social risk factor populations.

Response: We appreciate all the comments and interest in this topic. As we have previously stated, we are concerned about holding providers to different standards for the outcomes of their patients with social risk factors, because we do not want to mask potential disparities or minimize incentives to improve outcomes for disadvantaged populations. We believe that the path forward should incentivize improvements in health outcomes for disadvantaged populations while ensuring that beneficiaries have access to excellent care. We intend to consider all suggestions as we continue to assess each measure and the overall program. We appreciate that some commenters recommended risk adjustment as a strategy to account for social risk factors, while others stated a concern that risk adjustment could minimize incentives and reduce efforts to address disparities for patients with social risk factors. We intend to conduct further analyses on the impact of strategies such as measure-level risk adjustment and stratifying performance scoring to account for social risk factors including the options suggested by commenters. In addition, we appreciate the recommendations from the commenters about consideration of specific social risk factor variables and will work to determine the feasibility of collecting these patient-level variables. As we consider the feasibility of collecting patient-level data and the impact of strategies to account for social risk factors through further analysis, we will continue to evaluate the reporting burden on providers. Future proposals would be made after further research and continued stakeholder engagement.

3. Retention and Removal of Quality Measures for the FY 2019 Program Year

a. Retention of Previously Adopted Hospital VBP Program Measures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53592), we finalized a policy to retain measures from prior program years for each successive program year, unless otherwise proposed and finalized. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19970), we did not propose any changes to this policy.

b. Removal of the PSI 90 Measure

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56979 through 56981), we finalized our proposal to shorten the performance period for the current [35]

[35] The ''current'' PSI 90 measure refers to the version of the PSI 90 measure previously finalized

PSI 90 measure for the FY 2018 program year due to concerns associated with combining measure performance data that use both ICD–9 and ICD–10 data in calculating performance scores under the measure. In that final rule, we explained our system requires an ICD–10 risk-adjusted version of the AHRQ PSI software [36] in order to calculate scores using ICD–10 codes, and AHRQ needs a full year of nationally representative ICD–10 coded data before it can complete development of risk-adjusted models based on a national reference population for this software. This means the AHRQ PSI software will not be available for us to calculate scores until late CY 2017. More importantly, we noted an ICD–10 version of the current PSI 90 measure is not being developed (81 FR 56980), nor will ICD–10 AHRQ PSI software be available to calculate performance scores for the FY 2019 program year (81 FR 56981). As a result, we will not be able to calculate performance scores for the current PSI 90 measure for the FY 2019 program year because these scores would include ICD–10 data. Based on these concerns, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56981), we signaled our intent to propose to remove the current PSI 90 measure from the Hospital VBP Program beginning with the FY 2019 program year. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19970), we proposed to remove the current PSI 90 measure from the Hospital VBP Program beginning with the FY 2019 program year.

We invited public comment on this proposal. We also refer readers to section V.J.4.b. of the preamble of this final rule where we discuss our proposal to adopt the modified version of the PSI 90 measure for the Hospital VBP Program beginning with the FY 2023 program year.

Comment: The vast majority of commenters supported CMS' proposal to remove the PSI 90 measure from the Hospital VBP Program beginning with the FY 2019 program year.

Response: We thank the commenters for their support.

Comment: Two commenters supported the removal of PSI 90 from the Hospital VBP Program measure set, but recommended CMS remove the measure immediately and permanently, including the FY 2018 program year. A few commenters noted the measure is unreliable and lacks appropriate exclusions based on patient social risk factors. One commenter stated that only 15 months of data will be available for the FY 2018 performance period, questioned the measure's reliability, and stated that the measure is flawed. Another commenter expressed concern that continued use of the current PSI 90 measure during the FY 2018 program year while the HAC Reduction Program implements the modified PSI 90 measure would create confusion and misalignment across the programs.

Response: While we understand commenters' concerns, we previously decided to retain the currently adopted version of the PSI 90 measure for the FY 2018 program year because we had the option to shorten the performance period so that performance standards can be calculated using the ICD–9 AHRQ PSI software (81 FR 56981). We also continue to believe that this measure meets the program goal of providing important information on hospital performance on patient safety and adverse events. In addition, the PSI 90 measure was developed using a scientifically rigorous process that involved the input of technical experts and stakeholders. Further, AHRQ has supported a series of validation studies, based on detailed abstraction of medical records, that have informed AHRQ's PSI development process, including making further refinements to indicators and working with others to improve coding practices. We refer commenters to the AHRQ PSI Development zip file and AHRQ Composite Measures Workgroup document available at: *http://www.qualityindicators.ahrq.gov/modules/psi_resources.aspx*. We therefore believe that the PSI 90 measure in its current form is reliable, valid, and appropriate to retain in the Hospital VBP Program for the FY 2018 program year because it encourages robust hospital attention to patient safety. We further believe that a 15-month performance period is sufficiently reliable, particularly in light of the case minimum of three cases for any of the underlying PSI 90 indicators as finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53609). Because we believe the measure is sufficiently reliable with 15 months of data, we do not believe we need to suspend or remove the measure or extend the measure's performance period for the FY 2018 program year.

Comment: A few commenters did not support the removal of PSI 90, stating that retaining consistency in measures over time enables hospitals to focus on improvement and CMS should not allow a 3-year lapse in public reporting of a critical safety measure. One commenter expressed particular concern that removing the current PSI 90 measure will result in a redistribution of the Safety domain score across the NHSN measures, which the commenter believed are of limited value because they allow hospitals to use different surveillance methods and have inadequate risk adjustment. Commenters therefore urged CMS to look more broadly for opportunities to accelerate the inclusion of the proposed Patient Safety and Adverse Events (Composite) measure into the Hospital VBP Program, such as suspending the current PSI 90 measure for one year and phasing in a 24-month performance period beginning in FY 2020, or continuing to include the current PSI 90 measure rather than waiting for the new measures to become available to ensure that surgical complications remain a key component of the Hospital VBP Program.

Response: We thank the commenters for their recommendations, but note that, as discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19970), we will be unable to calculate measure scores for the current PSI 90 measure in the FY 2019 program year because ICD–10 AHRQ PSI software for the currently adopted measure will not be available. This lack of measure calculation software also precludes us from suspending the measure for one year and re-instituting the measure in FY 2020 using only ICD–10 data, because we will not be able to calculate measure scores.

Furthermore, due to certain statutory requirements in the Hospital VBP Program, we are unable to adopt the proposed Patient Safety and Adverse Events (Composite) measure earlier than proposed. Section 1886(o)(2)(A) of the Act requires the Hospital VBP Program to select measures that have been specified for the Hospital IQR Program. In addition, section 1886(o)(2)(C)(i) of the Act requires the Hospital VBP Program to refrain from beginning the performance period for a new measure until data on the measure have been posted on *Hospital Compare* for at least one year. The Hospital IQR Program finalized adoption of the modified PSI 90 measure (also known as the Patient Safety and Adverse Events (Composite) measure) in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57133), and we are required to wait one full year after data has been posted before that measure's performance period may begin in the Hospital VBP Program. Because measure data for the Patient Safety and Adverse Events (Composite) measure has not

for use in the Hospital VBP Program in the FY 2013 IPPS/LTCH PPS final rule (78 FR 50694).

[36] The AHRQ PSI Software is the software used to calculate PSIs and the composite measure. More information is available at: *http://www.qualityindicators.ahrq.gov/Downloads/Resources/Publications/2015/Empirical_Methods_2015.pdf*.

been posted on *Hospital Compare,* we are unable to adopt the measure for the FY 2019 program year. However, as discussed the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19973 through 19974), we proposed to adopt the Patient Safety and Adverse Events (Composite) measure beginning with the FY 2023 program year, which was the soonest program year possible under the Hospital VBP Program's statutory authority.

After consideration of the public comments we received, we are finalizing our proposal to remove the current PSI 90 measure from the Hospital VBP Program beginning with the FY 2019 program year.

c. Summary of Previously Adopted Measures and Finalized Measure for Removal for the FY 2019 and FY 2020 Program Years

In summary, for the FY 2019 and FY 2020 program years, we have finalized the following measure set, which no longer includes the current PSI 90 measure, as we are finalizing our proposal to remove the measure from the Hospital VBP Program beginning with the FY 2019 program year:

PREVIOUSLY ADOPTED MEASURES AND FINALIZED MEASURE FOR REMOVAL FOR THE FY 2019 AND FY 2020 PROGRAM YEARS

Measure short name	Domain/measure name	NQF #
	Person and Community Engagement Domain *	
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS)** (including Care Transition Measure)	0166 (0228)
	Clinical Care Domain	
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0230
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization.	0229
MORT–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization.	0468
THA/TKA	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550
	Safety Domain	
CAUTI	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138
CLABSI	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI.	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	1716
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.	1717
PC–01	Elective Delivery	0469
	Efficiency and Cost Reduction Domain	
MSPB	Payment-Standardized Medicare Spending Per Beneficiary (MSPB)	2158

* In section IV.H.3.b. of the preamble of the FY 2017 IPPS/LTCH PPS final rule (81 FR 56984), we renamed this domain from Patient- and Caregiver-Centered Experience of Care/Care Coordination domain to Person and Community Engagement domain beginning with the FY 2019 program year.

** In section XIX.B.3. of the preamble of the CY 2017 OPPS/ASC final rule with comment period (81 FR 79855 through 79862), we finalized the removal of the Pain Management dimension from the Hospital VBP Program beginning with the FY 2018 program year.

4. New Measures for the FY 2022 Program Year, FY 2023 Program Year, and Subsequent Years

We consider measures for adoption based on the statutory requirements, including specification under the Hospital IQR Program, posting dates on the *Hospital Compare* Web site, and our priorities for quality improvement as outlined in the current CMS Quality Strategy, available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html.* Due to the time necessary to adopt measures, we often adopt policies for the Hospital VBP Program well in advance of the program year for which they will be applicable.

a. New Measure for the FY 2022 Program Year and Subsequent Years: Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Pneumonia (PN Payment)

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19971 through 19973), we proposed a new measure for the FY 2022 program year and subsequent years:

Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Pneumonia (PN Payment).

(1) Measure Proposal

Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Pneumonia (PN Payment) is a measure assessing hospital risk-standardized payment associated with a 30-day episode-of-care for pneumonia. We adopted this measure in the Hospital IQR Program in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50227 through 50231), and we adopted an updated version of the measure, with an expanded cohort and modified risk-adjustment model, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57125 through 57128). For purposes of describing this measure, the ''cohort'' is the set of hospitalizations, or ''index admissions,'' that meet all of the measure's inclusion and exclusion criteria and, thus, are used to calculate the total payments Medicare makes on behalf of these Medicare beneficiaries for a 30-day episode-of-care. The cohort for the expanded version of the PN Payment measure includes Medicare FFS patients aged 65 or older with: (1) A principal hospital discharge diagnosis of pneumonia, including not only viral or bacterial pneumonia but also aspiration pneumonia; or (2) a principal discharge diagnosis of sepsis (but not severe sepsis) with a secondary diagnosis of pneumonia (including viral or bacterial pneumonia and aspiration pneumonia) coded as present on admission. The measure calculates payments for these patients over a 30-day episode-of-care, beginning with the index admission, using administrative claims data. In general, the measure uses the same approach to risk-adjustment as 30-day outcome measures previously adopted for the Hospital VBP Program, including the 30-day PN mortality measure, MORT–30–PN. Initial measure data collected under the Hospital IQR Program for the expanded PN Payment cohort and modified risk-adjustment model will be posted on *Hospital Compare* in July 2017, and the full measure specifications are available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

Promoting high-value care is an essential part of our mission to provide better health care for individuals, better health for populations, and lower costs for health care. Our aim is to encourage higher value care where there is the most opportunity for improvement, the greatest number of patients to benefit from improvements, and the largest sample size to ensure reliability. Pneumonia is one of the leading causes of hospitalization for Americans aged 65 and over,[37] and pneumonia patients incur roughly $10.2 billion in aggregate health care costs.[38] There is evidence of variation in payments at hospitals for pneumonia patients in the proposed PN Payment measure; median 30-day risk-standardized payment among Medicare FFS patients aged 65 or older hospitalized for pneumonia was $15,988 and ranged from $9,193 to $26,546 for the July 2011 through June 2014 reporting period in the Hospital IQR Program.[39] This variation in payment suggests there is opportunity for improvement. We believe it is important to adopt the PN Payment measure for the Hospital VBP Program because variation in payment may reflect differences in care decision-making and resource utilization (for example, treatment, supplies, or services) for patients with pneumonia both during hospitalization and immediately post-discharge. The PN Payment measure specifically addresses the NQS priority and CMS Quality Strategy goal to make quality care more affordable.

We recognize high or low payments to hospitals are difficult to interpret in isolation. Some high payment hospitals may produce better clinical outcomes when compared with low payment hospitals, while other high payment hospitals may not produce better outcomes. For this reason, payment measure results viewed in isolation are not necessarily an indication of quality. However, by viewing such information along with quality measure results, consumers, payers, and providers would be able to better assess the value of care. In order to incentivize innovation that promotes high-quality care at high value, it is important to examine measures of payment and patient outcomes concurrently. The proposed PN Payment measure is intended to be paired with the MORT–30–PN measure in the Hospital VBP Program,[40] thereby directly linking payment to quality by the alignment of comparable populations and risk-adjustment methodologies to facilitate the assessment of efficiency and value of care. We believe adopting the PN Payment measure will create stronger incentives for appropriately reducing practice pattern variation to achieve the aim of lowering the cost of care and creating better coordinated care for Medicare beneficiaries.

We proposed to adopt the PN Payment measure beginning with the FY 2022 program year. The PN Payment measure would be added to the Efficiency and Cost Reduction domain. The proposed measure fulfills all of the statutory requirements for the Hospital VBP Program based on our adoption of the measure in the Hospital IQR Program, and our anticipated posting of measure data for the refined PN Payment measure, with the expanded cohort and modified risk-adjustment model, on *Hospital Compare* beginning July 2017, which would be at least one year before the beginning of the proposed performance period of August 1, 2018. We refer readers to sections V.J.5.c.(3) through V.J.5.c.(5) of the preamble of this final rule where we discussed our proposed baseline periods and performance periods for this measure if adopted for the Hospital VBP Program.

The proposed PN Payment measure (MUC15–378) was reviewed by the MAP in December 2015 and did not receive support for adoption into the Hospital VBP Program.[41] The result of the MAP vote was 31 percent support, 15 percent conditional support, and 54 percent do not support. The MAP's decision of ''do not support'' for the proposed PN Payment measure was based on concerns that the measure may overlap with and thereby double count services that are already captured in the MSPB measure. In addition, some MAP members expressed a desire to have more experience with the measure in the Hospital IQR Program to understand

[37] Lindenauer PK, Lagu T, Shieh M, Pekow PS, Rothberg MB. Association of diagnostic coding with trends in hospitalizations and mortality of patients with pneumonia, 2003–2009. JAMA. 2012;307(13):1405–1413.

[38] Pfuntner, A (Truven Health Analytics), Wier, LM (Truven Health Analytics), Steiner, C (AHRQ). Costs for Hospital Stays in the United States, 2010. HCUP Statistical Brief #146. January 2013. Agency for Healthcare Research and Quality, Rockville, MD. Available at: *http://www.hcup-us.ahrq.gov/reports/statbriefs/sb146.pdf*.

[39] 2016 Reevaluation and Re-Specifications Report of the Hospital-Level 30-Day Risk-Standardized Pneumonia Payment Measure. AMI, HF, PN Payment Updates (zip file). Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

[40] The Hospital VBP Program first adopted the MORT–30–PN measure for the FY 2014 program year in the Hospital Inpatient Value-Based Purchasing Program final rule (76 FR 26497 through 26511). We subsequently expanded the measure cohort beginning with the FY 2021 program year in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56994 through 56996).

[41] ''2016 Spreadsheet of Final Recommendations to HHS and CMS'' available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367* and ''Process and Approach for MAP Pre-Rulemaking Deliberations'' found at: *http://www.qualityforum.org/Publications/2016/02/Process_and_Approach_for_MAP_Pre-Rulemaking_Deliberations.aspx*.

whether there may be unintended consequences or a need to adjust for social risk factors. We note some MAP members expressed support for the proposed PN Payment measure and other condition-specific payment measures, expressing that the increased granularity provided by condition-specific payment measures will provide valuable feedback to hospitals for targeted improvement.

With respect to MAP stakeholder concerns that treatment- or condition-specific payment measures may overlap and double count services, we note that the proposed PN Payment measure addresses a topic of critical importance to quality improvement in the inpatient hospital setting. As discussed above, we selected the PN Payment measure because we believe it is appropriate to provide stronger incentives for hospitals to provide high-value and efficient care, especially for a high-volume condition such as pneumonia. We acknowledge that hospitals that do not perform well on the PN Payment measure may also perform poorly on the MSPB measure and potentially receive a lower incentive payment, depending upon their performance on other measures. However, because admissions for pneumonia make up only a part of all admissions included in the MSPB measure, a hospital's results on the MSPB measure may not be the same as their result on the PN Payment measure. In other words, a hospital's results for one measure are not deterministic of its results of the other, so we cannot state conclusively that if a hospital performs well (or poorly) on one measure, that they will also perform well (or poorly) on the second measure. Hospitals would perform differently on the MSPB and PN Payment measures because these measures evaluate performance on different metrics. For example, some hospitals with poorer results on the MSPB measure may have better results on the PN Payment measure allowing them to improve their overall score. In addition, the overlap between the MSPB and PN Payment measures may result in some hospitals receiving an increased benefit by performing well on both measures. Furthermore, if a hospital does not perform as well on the MSPB measure relative to other hospitals but performs very well with respect to its pneumonia patients on the proposed PN Payment measure, that hospital would have the opportunity to earn a higher score in the Efficiency and Cost Reduction domain.

Regarding MAP stakeholder concerns for the need to adjust for social risk factors, we note the proposed PN Payment measure already incorporates a risk-adjustment methodology that accounts for age and comorbidities. We understand the important role social risk factors play in the care of patients, routinely monitor the impact of social risk factors on hospitals' results on our measures, and will continue to do so. In addition, as discussed in section V.J.3. of the preamble of this final rule, the original PN Payment measure using the previous measure cohort (Hospital-level, risk-standardized payment associated with a 30-day episode-of-care for pneumonia (NQF #2579)), as well as the AMI Payment and HF Payment measures adopted in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56987 through 56990 and 81 FR 56990 through 56992, respectively), which use the same measurement methodology as the proposed PN Payment measure, recently underwent successful NQF re-endorsement following enrollment in the NQF's trial. The NQF re-endorsed these measures without requesting modifications to their risk adjustment methodologies for adjustment by social risk factors. The proposed PN Payment measure includes an updated risk-adjustment model that accounts for patient comorbidities, and we intend to submit to NQF that risk adjustment model as part of the overall proposed PN Payment measure specifications during the next Cost and Resource Use project.

As noted above, some MAP members expressed support for the proposed PN Payment measure and other condition-specific payment measures, agreeing the increased granularity provided by condition-specific payment measures will provide valuable feedback to hospitals for targeted improvement. In addition, a NQF-commissioned white paper also supports the position that cost or payment measures should be interpreted in the context of quality measures and that measures which link cost and quality are the preferred method of assessing hospital efficiency.[42] The PN Payment measure, which directly pairs with the MORT–30–PN measure in the Hospital VBP Program, follows this recommended approach. Based on our analysis of the issues surrounding condition-specific payment measures, we believe the benefits of adopting the PN Payment measure outweigh any potential risks; however, we also remain committed to monitoring for unintended consequences.

We invited public comment on this proposal.

[42] Ryan AM, Tompkins CP. Efficiency and Value in Healthcare: Linking Cost and Quality Measures. Washington, DC: NQF; 2014.

Comment: A number of commenters supported the addition of the PN Payment measure. A few commenters supported adoption of the PN Payment measure because pneumonia is one of the leading causes of hospitalization for Americans aged 65 and over, and these hospitalizations result in high aggregate costs for patients. Two commenters expressed particular support for the measure's inclusion of patients with a principal diagnosis of aspiration pneumonia, or a principal diagnosis of sepsis with a secondary diagnosis of pneumonia, because including these patients addresses stakeholder concerns regarding variation in coding of pneumonia as a principal diagnosis in order to avoid patients being captured by the pneumonia episode of care measure. Two other commenters noted the measure's alignment with the National Quality Strategy, and that tracking of this measure will enable identification of outlier performers in managing pneumonia and thereby spur incorporation of evidence-based practices for monitoring and managing pneumonia patients. One commenter expressed support for CMS' intention to focus more strongly on cost as an element of value in the Hospital VBP Program.

Response: We thank the commenters for their support.

Comment: One commenter expressed support for CMS' goals in proposing to adopt the PN Payment measure, but urged CMS to carefully consider the risk adjustments used in this measure because not all pneumonia diagnoses are comparable and factors outside the control of hospitals, such as geographic location, can impact the disease. Another commenter strongly recommended that CMS not include the PN Payment measure in the Hospital VBP Program because the expansion of the PN Payment measure cohort to include patients with a principal discharge diagnosis of aspiration pneumonia or sepsis with a secondary diagnosis of pneumonia coded as present on admission could make hospitals that care for complex patients look worse unless there is appropriate risk adjustment for social risk factors.

Response: We appreciate the commenters' concerns that different types of pneumonia, such as community acquired pneumonia and aspiration pneumonia, have different causes and associated risks (for example, recurrent aspiration due to other comorbidities). While the pathological causes of aspiration pneumonia are slightly different from the causes of community acquired pneumonia, in routine clinical practice, evidence shows it can be very

challenging for physicians to differentiate aspiration syndromes, including pneumonitis and pneumonia, from other types of pneumonia included in the measure.[43] [44] This is reflected in the tremendous variation across hospitals in the use of aspiration pneumonia diagnosis codes. This variation suggests that hospitals are not consistently distinguishing between these conditions as distinct subtypes regardless of patients' comorbid conditions. Furthermore, we note that the treatment of patients hospitalized for pneumonia, aspiration pneumonia, or sepsis due to pneumonia is very similar and involves treatment with antibiotics, IV fluids, and symptom management.[45] In addition, although some patients with aspiration pneumonia, such as medically frail patients, have a higher predicted mortality risk (that is, are more complex), many of the associated comorbidities are captured in the PN Payment measure's risk-adjustment methodology.

With respect to geographic variation, the incidence of fungal and mycobacterial infections are strongly associated with a patient's area of residence, and these infections would be expected to have different outcomes than typical bacterial and viral pneumonias, including higher levels of spending. They also involve different treatments than those provided to patients with typical bacterial and viral pneumonia. These considerations justify their continued exclusion from the pneumonia outcome measures. Although similar arguments might be applied to the different bacterial pathogens included in the pneumonia measure, most treatment of pneumonia remains empiric, and it is unusual to identify a specific etiologic agent. For this reason, we do not believe that is appropriate to include the specific bacterial pathogen in risk-adjustment models.

The risk adjustment model adequately accounts for the varying severity and comorbidities of patients across the modified cohort; therefore, we believe that hospitals will not be unfairly penalized for treating sicker patients. Expanding the measure cohort ensures that the measure is clinically comprehensive. Moreover, the treatment of patients hospitalized for pneumonia, aspiration pneumonia, or sepsis due to pneumonia is very similar and involves treatment with antibiotics, IV fluids, and symptom management. In addition, although some patients with aspiration pneumonia, such as medically frail patients, have a higher predicted mortality risk, many of the associated comorbidities are captured in the MORT–30–PN (updated cohort) measure's risk-adjustment methodology. Of note, due to the increased number of patients that are included in the expanded cohort, we reselected risk-adjustment variables to ensure that the measure does not bias hospital performance as well as accounts for the differences in risk among the subgroup of patients. For example, the risk model includes clinical history of stroke, as well as conditions associated with frailty, such as neuromuscular disease, and dementia. The full PN Payment measure specifications are available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

Comment: Many commenters did not support adoption of the PN Payment measure because it will overlap with the MSPB measure in the Efficiency and Cost Reduction domain. A large subset of these commenters did not support adoption of the PN Payment measure because the MAP did not support this measure for inclusion in the Hospital VBP Program, and stated their belief that CMS has not addressed the MAP's concerns of double-counting and overlap with services already captured by the MSPB measure, which could potentially penalize hospitals twice for the same episode. A number of commenters urged CMS to reconcile this overlap before adopting the PN Payment measure by removing episodes of pneumonia payment from the MSPB measure calculation. One commenter expressed concern that the overlap between the MSPB and proposed PN Payment measures may send mixed signals to hospitals about their resource use performance. One commenter also noted that it will be possible for hospitals to score well on the MSPB measure, but poorly on the condition-specific payment measures, even though the measures will capture many of the same services.

Response: While we acknowledge that there may be some overlap between the MSPB and condition-specific payment measures, including the PN Payment measure, we believe that the condition-specific measures are of critical importance to improving efficiency of care. We selected the PN Payment measure for the Hospital VBP Program because pneumonia is one of the leading causes of hospitalization for Americans aged 65 and over,[46] and pneumonia patients incur roughly $10 billion in aggregate health care costs.[47] Including condition-specific measures alongside the MSPB measure provides hospitals with actionable feedback that will better equip them to implement targeted improvements, in comparison to an overall payment measure alone. Moreover, these condition-specific measures will allow consumers, providers, and payers to make a more fully informed assessment of value of care.

As we noted in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19972), because admissions for pneumonia make up only a part of all admissions included in the MSPB measure, a hospital's results on the MSPB measure may not be the same as their result on the PN Payment measure, and hospitals would perform differently on the MSPB and PN Payment measures because these measures evaluate performance on different metrics. In other words, a hospital's results for one measure are not deterministic of its results of the other, so we cannot state conclusively that if a hospital performs well (or poorly) on one measure, that they will also perform well (or poorly) on the second measure. We believe that even if some services were double counted, hospitals that offer quality service and maintain better results on the MSPB and condition-specific payment measures relative to other hospitals in the Hospital VBP Program could receive an increased benefit by performing well on both quality measures and payment measures. Furthermore, because hospitals would have bigger financial incentives, they would strive to perform better, which would lead to better quality.

In addition, we note that the PN Payment measure already incorporates a risk-adjustment methodology that accounts for age and comorbidities, discussed in more detail below. We understand the important role social risk factors play in the care of patients, routinely monitor the impact of social

[43] Lanspa MJ, Jones BE, Brown SM, Dean NC. Mortality, morbidity, and disease severity of patients with aspiration pneumonia. J Hosp Med. 2013 Feb;8(2):83–90. doi: 10.1002/jhm.1996. Epub 2012 Nov 26.

[44] Marik PE. Aspiration pneumonitis and aspiration pneumonia. N Engl J Med. 2001 Mar 1;344(9):665–71.

[45] *Ibid.*

[46] Lindenauer PK, Lagu T, Shieh M, Pekow PS, Rothberg MB. Association of diagnostic coding with trends in hospitalizations and mortality of patients with pneumonia, 2003–2009. JAMA. 2012;307(13):1405–1413.

[47] Pfuntner, A (Truven Health Analytics), Wier, LM (Truven Health Analytics), Steiner, C (AHRQ). Costs for Hospital Stays in the United States, 2010. HCUP Statistical Brief #146. January 2013. Agency for Healthcare Research and Quality, Rockville, MD. Available at: *http://www.hcup-us.ahrq.gov/reports/statbriefs/sb146.pdf*.

risk factors on hospitals' results on our measures, and will continue to do so.

Comment: A number of commenters did not support adoption of the PN Payment measure because the measure is not risk-adjusted to account for socio-demographic status factors. Some of these commenters expressed further concern that the measure is not risk-adjusted to account for socioeconomic status factors. One commenter stated that previous testing of the measure should have included additional social risk factors, such as community characteristics. One commenter stated that it is premature to adopt the PN Payment measure without the NQF SDS trial results. Another commenter acknowledged the PN Payment measure was reviewed as part of the NQF's SDS trial and NQF's evaluation indicated that SDS adjustment was not necessary, but recommended that CMS continue to examine the impact of socioeconomic factors on measure performance under the PN Payment measure and incorporate adjustments as needed. A third commenter encouraged CMS to continue to engage with stakeholders regarding the inclusion of social risk factors for the PN Payment measure, noting that specific risk factors often lead to worse outcomes, so providing care may cost more and make it more difficult for hospitals to achieve high performance on quality measures.

Response: We acknowledge commenters' concerns that the proposed PN Payment measure is not properly risk-adjusted and we understand the important role that socio-demographic status plays in the care of patients; however, we continue to believe the PN Payment measure's risk-adjustment methodology is appropriate and reliable. As we noted in the FY 2018 IPPS/LTCH PPS proposed rule, the proposed measure already incorporates a risk-adjustment methodology that accounts for age and comorbidities and we intend to submit to NQF that risk adjustment model as part of the overall proposed PN Payment measure specifications during the next Cost and Resource Use project. We also continue to have concerns about holding hospitals to different standards for the outcomes of their patients of diverse socio-demographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations.

In addition, as discussed in section V.J.3. of the preamble of this final rule, the original PN Payment measure using the previous measure cohort (Hospital-level, risk-standardized payment associated with a 30-day episode-of-care for pneumonia (NQF #2579)), as well as the AMI Payment and HF Payment measures adopted in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56987 through 56990 and 81 FR 56990 through 56992, respectively), which use the same measurement methodology as the proposed PN Payment measure, recently underwent successful NQF re-endorsement following enrollment in the NQF's trial. The NQF 2-year trial period allowed for the temporary inclusion of socio-demographic factors in the risk-adjustment approach for some performance measures. This trial period considered the analyses and interpretations as well as performance scores with and without socio-demographic factors in the risk-adjustment model. NQF's evaluation indicated that SDS adjustment was not necessary for this measure. We routinely monitor the impact of socio-demographic status on hospitals' results on our measures and, as noted in section V.J.2. of the preamble of this final rule where we discuss accounting for social risk factors in the Hospital VBP Program, we will conduct further research and continue engaging stakeholders as we assess the appropriateness of any specific strategies such as measure-level risk adjustment or stratified performance scoring.

We also thank commenters for their recommendation that we engage with stakeholders regarding risk adjustments for the PN Payment measure, and note we routinely solicit public comment on our payment measures and other measures under development. For current and future opportunities, we encourage the commenter to visit the CMS Quality Measures Public Comment page at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html*. In addition, there are opportunities for stakeholders to serve on Technical Expert Panels and provide technical input to CMS and the measure contractors on the development, selection, and maintenance of measures. We refer the commenter to the following Web site for more information: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TechnicalExpertPanels.html*.

Comment: Some commenters did not support the addition of condition-specific payment measures because the commenters believed the measures inappropriately assign costs to the hospitals. A few commenters noted that variations in Medicare payments are due primarily to readmission rates and post-acute care. One commenter further noted that post-acute care use varies due to wide-ranging differences in local market availability of these services and patterns of care, which are not within the hospital's control. Two commenters recommended that CMS work with the hospital community to develop and implement efficiency metrics of spending that hospitals directly influence because the current and proposed condition-specific payment measures include physician spending and preferences, which are beyond the control of the hospital. One commenter recommended limiting inclusion of payments used in the calculation of the measures to only payment directly related to the condition-specific index admission, because the commenter believed this would be a more accurate proxy for factors within a hospital's control than all spending over a 30-day period.

Response: We continue to believe that hospitals that provide quality inpatient care and conduct appropriate discharge planning can work with providers and suppliers in coordinating efficient follow-up care. When examining variation in payments, consideration of the episode-of-care triggered by admissions is meaningful for several reasons. First, hospitalizations represent a brief period of a patient's illness that require ongoing management post discharge, and decisions made at the admitting hospital affect payments for care in the immediate post discharge period. Second, attributing payments for a continuous episode-of-care to admitting hospitals may reveal practice variations in the full care of the patient's illness that can result in increased payments. Third, a 30-day preset window provides a standard observation period by which to compare all hospitals. Lastly, we note the PN Payment measure is intended to be paired with the MORT–30–PN measure to capture payments for Medicare fee-for-service patients age 65 and older across all care settings, services, and supplies (that is, inpatient, outpatient, skilled nursing facility, home health, hospice, physician/clinical laboratory/ambulance services, durable medical equipment, prosthetics/orthotics, and supplies).

We thank commenters for the recommendations and note that we have developed, and will continue to develop, efficiency measures in consultation with clinical and measurement experts, key stakeholders (including the hospital and patient communities), and the public. We disagree with commenters that all payment measures should be limited to only payments directly related to the index admission because, as noted

above, we continue to believe that inclusion of payments on a broad range of services incentivizes quality care and care coordination. The intensity of services needed for patients after an inpatient stay may be the result of quality failures during the stay that led to poor clinical outcomes.

Comment: A few commenters did not support adoption of the proposed PN Payment measure due to concerns about the measure's validity and reliability. One commenter asserted that because not all hospitals will have sufficient volume to be scored on each condition-specific payment measure, the statistical reliability of those measures' scores will likely be lower than the MSPB measure and, as a result, provide a less useful picture of hospital performance. Another commenter recommended that CMS not adopt the PN Payment measure because the measure's population is too small to be stable, reliable, or meaningful for many smaller facilities. A third commenter cautioned against implementation of the PN Payment measure without conclusive evidence that the measure is clinically and statistically fair and meaningful. One commenter recommended that if CMS chooses to finalize the PN Payment measure, it use the years leading up to FY 2022 to ensure the validity of the measure and resolve MAP stakeholder concerns about incorporating social risk factors into the measure to improve quality of care while not unduly penalizing essential hospitals.

Response: We disagree with the commenter that hospitals will not be able to report statistically reliable information on the condition-specific payment measures because, as discussed in section V.J.7.c.(5) below, hospitals must report a minimum number of 25 cases to receive a payment measure score. We believe the case minimum will ensure that each hospital's payment measure rate is sufficiently reliable to generate a score that meaningfully distinguishes hospital performance on the measures. We also disagree with the commenter's assertion that the statistical reliability of the condition-specific payment measures is likely to be weaker than the MSPB measure. The statistical model that we use to calculate the payment measures allows for the inclusion of hospitals with relatively few cases by taking into account the uncertainty associated with sample size. In addition, we note the PN Payment measure uses longer baseline and performance periods than the MSPB measure (three years instead of a single year) in order to increase the measure's sample size and ensure sufficiently reliable measure results.

Comment: A number of commenters expressed concern that the PN Payment measure, without a linkage to a quality measure, is purely focused on payment for pneumonia episodes of care and therefore does not reflect appropriateness of care. A few commenters expressed concern that the PN Payment measure is not an indicator of value because it does not capture the quality of care provided and is not paired with measures that do so. Other commenters expressed concern about the inclusion of additional payment measures in the Hospital VBP Program and stated their belief that condition-specific payment measures themselves do not provide insight into where improvements need to be made in the delivery of care across the continuum of care. Three commenters further stated these measures do not give beneficiaries a sense of their financial obligation. A few commenters agreed with CMS' stated intent to interpret the condition-specific payment measures alongside corresponding quality measures, but asserted that adopting the payment and quality measures separately instead of directly linking the information from each measure will not provide an assessment of value. One commenter acknowledged CMS' intent to link the PN Payment and MORT–30–PN measures, but stated there are outcomes other than mortality relevant to understanding the quality and cost of care that pneumonia patients receive in the hospital.

Response: We disagree with the commenters who believed that the PN Payment measure, and condition-specific payment measures more generally, will not provide hospitals with actionable data for quality improvement efforts. By adopting condition-specific payment measures and viewing results alongside quality measure results, we believe that consumers, payers, and providers will be able to better assess the overall value of care provided at a hospital. We also believe that adopting condition-specific payment measures for the Hospital VBP Program that are directly paired with clinical outcome measures, aligned by comparable populations, performance periods, or risk-adjustment methodologies, helps move toward achievement of this goal. We also believe that adopting condition-specific payment measures (for example, the MORT–30–PN measure) will create stronger incentives for appropriately reducing practice pattern variation to achieve the aim of lowering the cost of care and creating better coordinated care for Medicare beneficiaries.

Comment: Two commenters expressed concern that the PN Payment measure's focus on reducing cost will not necessarily lead to or provide measurable proof of improved patient care and outcomes. One commenter expressed concern that focusing on cost-effectiveness will overshadow patients' needs during a care episode. One commenter expressed concern that measures focusing solely on the cost of care without consideration of overall quality create incentives for hospitals to cut costs without consideration of patients' unique needs. The commenter recommended that CMS work with hospitals and other stakeholders to ensure that existing and future episode-based measures align with the objectives of creating efficiency and economy in the Medicare program and to appropriately tailor measures in the Hospital VBP Program to support these objectives.

Response: We understand commenter's concern that condition-specific payment measures, viewed in isolation, may create an incentive for hospitals to focus on reducing costs without accounting for potential impacts on the quality of care provided. We also agree the PN Payment measure as a standalone measure is not designed to assess improvements in patient care or outcomes. However, we note that the Hospital VBP Program explicitly proposed to adopt the PN Payment measure for interpretation alongside the previously finalized MORT–30–PN measure, thereby linking the condition-specific payment measure with a measure of quality of care. We believe that adding the PN Payment measure, paired with the MORT–30–PN measure, will provide actionable feedback to hospitals on the overall value of their services to beneficiaries. In addition, we note that the Hospital VBP Program scoring methodology takes into account both quality and cost of care by weighting the quality domains at 75 percent of a hospital's TPS and the Efficiency and Cost Reduction domain at 25 percent of a hospital's TPS. We thank commenters for the recommendations and note that we have developed, and will continue to develop, efficiency measures in consultation with clinical and measurement experts, key stakeholders (including the hospital community), and the public.

Comment: A few commenters strongly recommended that CMS not include the PN Payment measure because hospital performance on the measure will not be publicly reported until after the public comment period for the FY 2018 IPPS/LTCH PPS proposed rule has ended.

Commenters noted that publicly reporting measures provides transparency on provider performance, allows hospitals to gain experience submitting data for the measure, and allows time to identify errors, unintended consequences, or other concerns with the measure methodology. One commenter asserted that stakeholders are unable to provide sufficient feedback on the PN Payment measure without access to publicly reported data on this measure. One commenter stated that all measures should be publicly reported under the Hospital IQR Program for one year before being considered for inclusion in the Hospital VBP Program.

Response: While we understand stakeholders' desire to see performance data from the PN Payment measure before deciding whether to adopt this measure for the Hospital VBP Program, we note that, as discussed in the FY 2018 IPPS/LTCH PPS proposed rule, the measure has undergone extensive testing and has been determined to be both reliable and valid. Furthermore, we note that the proposed adoption of this measure before its public reporting on *Hospital Compare* did not preclude hospitals from submitting questions and comments on the measure to CMS. Publicly reported PN Payment measure data became available on July 26, 2017, and we encourage hospitals, providers, patients, and other stakeholders to review these data. We further note the PN Payment measure is not proposed for implementation in the Hospital VBP Program until the FY 2022 program year with a performance period of August 1, 2018 through June 30, 2020; we believe the time period before implementation provides hospitals with sufficient time to become familiar with the measure's specifications and reporting requirements before performance on the PN Payment measure is reflected in hospitals' TPSs.

We further disagree that, absent publicly reported performance data, hospitals lack sufficient information to comment on the proposed adoption of the PN Payment measure. In proposing to adopt this measure, CMS provided a full description of the measure's specifications and its development history, explained how the proposal satisfied the requirements of the statute, and provided links to additional sources of in-depth information regarding the detailed specifications for this measure. In addition, performance data for the PN Payment measure using the original cohort has been publicly available for hospitals' review on *Hospital Compare* since July 2015. We therefore believe commenters had sufficient information to use in reviewing the PN Payment measure, allowing them to comment meaningfully on its proposed adoption.

Comment: One commenter did not support CMS' proposal to adopt the PN Payment measure because the commenter believed CMS lacks a mechanism to provide claims data to hospitals in a timely manner for use in performance improvement activities under the condition-specific payment measure. The commenter further stated that risk-standardized measures are difficult to track using hospitals' internal data due to a lack of insight into care and payments provided outside of the hospital. Another commenter requested that CMS make the claims data for the measure available to hospitals on a more timely basis to allow hospitals to review the current spending per episode and make the necessary changes in improving processes.

Response: We acknowledge the commenter's concern that hospitals' internal data only include care provided at their hospital and the payments made on behalf of the patient for that care, whereas the PN Payment measure is designed to capture the full spectrum of care provided during and for 30 days following the index hospitalization. We therefore provide confidential, hospital-specific reports to each hospital on this and other claims-based outcome measures, which for the payment measures provides hospitals with additional information about care their patients received following discharge. The type of follow-up care patients receive is often influenced by the discharging hospital (for example, discharge to a skilled nursing facility or provision of home health care) which will then impact the cost of care for the 30 days captured by the measure.

We recognize that there is a delay in reporting the claims data because this measure reports hospitals' results on a yearly basis, but we believe using the available annual data would enable hospitals to improve their performance year-over-year. We note that we previously addressed this concern in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53380) in the context of the Hospital Readmissions Reduction Program. In addition, we note that the Hospital VBP Program uses a 90 day ''run-out'' period following the last date of discharge used in the performance period for purposes of calculating claims-based measure rates (77 FR 53579 through 53580). This ''run-out'' period balances our desire to provide hospitals with timely quality data for the purpose of quality improvement and the need to have as complete a data set as possible for measure calculations. After we run the data and create the data extract for purposes of calculating the measure rate for a claims-based measure, it takes several months to incorporate other data needed to complete the rate calculation; generate and check the rate calculations; and program, populate, and deliver the confidential reports and accompanying data to hospitals. As a result, we cannot provide the PN Payment hospital-specific reports earlier than the spring following the end of the performance period.

Comment: One commenter recommended that instead of adding the PN Payment measure to the Hospital VBP Program now, CMS should first examine methods of pairing cost and payment measures so that they signal value to beneficiaries.

Response: We believe that adding the PN Payment measure now will provide actionable feedback to hospitals on the overall value of their services to pneumonia patients as both payment data and mortality data would be made available through the Hospital VBP Program. We note that we solicited comments on methods of accounting for value of care in the Hospital VBP Program scoring methodology in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25105 through 25106), and discussed comments received in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56993 through 56994). We are continuing to evaluate the feasibility of incorporating condition- or procedure-specific assessments of value in the Hospital VBP Program scoring methodology. We also note currently for public reporting purposes our *Hospital Compare* Web site shows individual hospital's results for the payment (AMI, HF, and PN Payment) measures and corresponding mortality measures together to assess the value of care.[48]

Comment: One commenter recommended that CMS develop a plan for incorporating additional measures of efficiency and either focus on condition-specific payment measures or global efficiency measures, without overlapping.

Response: We thank the commenter for this recommendation, and will take this into consideration in future years of the program.

(2) Scoring Methodology for the PN Payment Measure

We proposed to calculate the PN Payment measure using the same methodology we use to score the MSPB measure and, as finalized in the FY

[48] *https://www.medicare.gov/hospitalcompare/Data/Value-of-care.html.*

2017 IPPS/LTCH PPS final rule (81 FR 56992 through 56993), the AMI Payment and HF Payment measures so that all measures in the Efficiency and Cost Reduction domain are scored in the same manner. We note for these measures that lower values represent better performance.

For achievement points, we proposed to calculate a spending ratio of PN spending for each hospital to the median PN spending across all hospitals during the performance period. We would then use each hospital's PN spending ratio to calculate between 0 and 10 achievement points. We proposed to set the achievement threshold at the median PN spending ratio across all hospitals during the performance period. Because lower values represent better performance under the proposed PN Payment measure, we proposed to set the benchmark at the mean of the lowest decile of the PN spending ratios during the performance period. Therefore, if a hospital's individual PN spending ratio falls above the achievement threshold, the hospital would score 0 achievement points on the measure. If a hospital's individual PN spending ratio falls at or below the benchmark, the hospital would score the maximum 10 achievement points on the measure. If a hospital's individual PN spending ratio falls at or below the achievement threshold but above the benchmark, the hospital would score between 1 and 9 points according to the following formula:

[9 * ((achievement threshold − Hospital's performance period ratio)/(achievement threshold − benchmark))] + 0.5

For improvement points, we proposed to calculate a spending ratio of PN spending for each hospital to the median PN spending across all hospitals during the performance period. We would then use each hospital's PN spending ratio to calculate between 0 and 9 improvement points by comparing each hospital's ratio to its own performance during the baseline period. Again, because lower values represent better performance under the proposed PN Payment measure, we proposed to set the benchmark as the mean of the lowest decile of PN spending ratios across all hospitals. Therefore, if a hospital's PN spending ratio is equal to or higher than its baseline period ratio, the hospital would score 0 improvement points on the measure. If a hospital's score on the measure during the performance period is less than its baseline period score but above the benchmark, the hospital would receive a score of 0 to 9 according to the following formula:

[10 * ((Hospital baseline period ratio − Hospital performance period ratio)/(Hospital baseline period ratio − benchmark))] − 0.5

We note that if a hospital scores at or below the benchmark on the achievement scoring methodology, that hospital will receive the maximum 10 points for this measure. As a result, the hospital would not receive an improvement score for this measure.

For more information about the proposed scoring methodology for the proposed PN Payment measure, we refer readers to section IV.B.3.b. of the preamble of the FY 2012 IPPS/LTCH PPS final rule (76 FR 51654 through 51656) where we discuss the MSPB measure's identical scoring methodology in detail.

We invited public comment on the proposed scoring methodology for the proposed PN Payment measure.

We did not receive any public comments specific to the proposed scoring methodology for the proposed PN Payment measure. After considering all of the comments received regarding the proposed adoption of the PN Payment measure in the Hospital VBP Program as discussed above, we are finalizing our proposal to adopt the PN Payment measure beginning with the FY 2022 program year as proposed.

b. New Measure for the FY 2023 Program Year and Subsequent Years: Patient Safety and Adverse Events (Composite) (NQF #0531)

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19973 through 19974), we proposed a new measure for the FY 2023 program year and subsequent years: Patient Safety and Adverse Events (Composite) (NQF #0531).

The current PSI 90 measure previously adopted for the Hospital VBP Program underwent NQF maintenance review and re-endorsement in 2015, leading to several substantive measure changes.[49] Due to statutory requirements in the Hospital VBP Program,[50] we were unable to adopt the newly re-endorsed version of the PSI 90 measure in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56981), but stated our intent to propose to adopt the modified version of the PSI 90 measure in future rulemaking. In section V.J.3.b. of the preamble of this final rule, we discuss our proposal to remove the current PSI 90 measure from the Hospital VBP Program beginning with the FY 2019 program year due to the operational constraints associated with calculating measure scores for the current measure for FY 2019 and subsequent years. Because of the priority of improving patient safety and reducing adverse events during inpatient stays, and with substantive refinements made to the measure in response to feedback as further described below, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19973 through 19974), we proposed to adopt a modified version of the current PSI 90 measure, entitled Patient Safety and Adverse Events (Composite) (NQF #0531), for the Hospital VBP Program for the FY 2023 program year and subsequent years.

The Hospital IQR Program adopted this measure in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57128 through 57133),[51] beginning with the FY 2018 payment determination, and we intend to publicly report initial measure data on the measure on *Hospital Compare* in the fall of 2017. The full measure specifications are available at: *https://www.qualityindicators.ahrq.gov/Modules/PSI_TechSpec_ICD09_v60.aspx*.

The Patient Safety and Adverse Events (Composite) measure is a weighted average of the reliability-adjusted, indirectly standardized, observed-to-expected ratios for the following 10 individual PSI component indicators:

- PSI 03 Pressure Ulcer Rate;
- PSI 06 Iatrogenic Pneumothorax Rate;
- PSI 08 In-Hospital Fall with Hip Fracture Rate;[52]
- PSI 09 Perioperative Hemorrhage or Hematoma Rate; *

[49] National Quality Forum QPS Measure Description for ''Patient Safety for Selected Indicators (modified version of PSI 90) (Composite Measure)'' found at: *https://www.qualityforum.org/QPS/MeasureDetails.aspx?standardID=321&print=0&entityTypeID=3*; and PSI 90 Fact Sheet found at: *http://www.qualityindicators.ahrq.gov/News/PSI90_Factsheet_FAQ_v2.pdf* (*we note that this fact sheet is written from an all-payer perspective, and is therefore not limited to the measure as used in the Medicare FFS population*).

[50] First, section 1886(o)(2)(A) of the Act requires the Hospital VBP Program to select measures that have been specified for the Hospital IQR Program. Second, section 1886(o)(2)(C)(i) of the Act requires the Hospital VBP Program to refrain from beginning the performance period for a new measure until data on the measure have been posted on *Hospital Compare* for at least one year. Finally, section 1886(o)(3)(C) of the Act requires that the Hospital VBP Program establish performance standards for each measure not later than 60 days prior to the beginning of the performance period.

[51] We note that the HAC Reduction Program also adopted this measure in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57013 through 57030).

[52] Previously titled ''Postoperative Hip Fracture'' prior to v6.0.

- PSI 10 Postoperative Acute Kidney Injury Requiring Dialysis Rate;* [53]
- PSI 11 Postoperative Respiratory Failure Rate; *
- PSI 12 Perioperative Pulmonary Embolism (PE) or Deep Vein Thrombosis (DVT) Rate;
- PSI 13 Postoperative Sepsis Rate;
- PSI 14 Postoperative Wound Dehiscence Rate; and
- PSI 15 Unrecognized Abdominopelvic Accidental Puncture/Laceration Rate.[54] [55]

(* Denotes new component for the Patient Safety and Adverse Events (Composite) measure)

The Patient Safety and Adverse Events (Composite) measure no longer includes PSI 07 Central Venous Catheter-Related Blood Stream Infection Rate, because of potential overlap with the CLABSI measure (NQF #0139), which has been included in the Hospital VBP Program since the FY 2013 IPPS/LTCH PPS final rule (77 FR 53597 through 53598).

The measure is calculated using administrative claims data. Like the previously adopted PSI 90 measure, under the Patient Safety and Adverse Events (Composite) measure, the predicted value for each case is computed using a Generalized Estimating Equation hierarchical modeling approach that adjusts for demographic and clinical characteristics. The expected rate for each of the indicators is computed as the sum of the predicted value for each case divided by the number of cases for the unit of analysis of interest (that is, the hospital). The risk-adjusted rate for each of the indicators is computed using indirect standardization as the observed rate divided by the expected rate, multiplied by the reference population rate.[56]

As stated above, the previously adopted eight-indicator version of the PSI 90 measure underwent an extended NQF maintenance re-endorsement in the 2014 NQF Patient Safety Committee. In its final report, the NQF Patient Safety Committee deferred their final decision for the PSI 90 measure until the following measure evaluation cycle.[57] Following this report, AHRQ worked to address many of the NQF stakeholders' concerns about the PSI 90 measure, and subsequently completed NQF maintenance re-review and received re-endorsement on December 10, 2015. As a result of this process, the current PSI 90 measure's NQF maintenance re-endorsement led to several changes to the measure, specifically: A change to the measure name; the addition of three indicators; the removal of one indicator; the re-specification of two indicators; and a revision to the weighting of component indicators.[58] For more information on the proposed Patient Safety and Adverse Events (Composite) measure and component indicators, we refer readers to the AHRQ Quality Indicators Web site available at: *www.qualityindicators.ahrq.gov*.

We continue to believe the PSI 90 measure is an important measure of patient safety, addressing the NQS priority and CMS Quality Strategy goal to make care safer, and that these modifications help broaden and strengthen the measure. We expect inclusion of the Patient Safety and Adverse Events (Composite) measure in the Hospital VBP Program will encourage improvement in patient safety over the long-term for all hospitals. Conditions such as perioperative hemorrhage, postoperative respiratory failure, pressure ulcers, and other complications or conditions that arise after a patient was admitted to the hospital for the treatment of another condition are often preventable, and cost Medicare and the private sector billions of dollars each year and take a significant toll on patients and families. In most cases, hospitals can prevent these conditions when they follow protocols, procedures, and evidence-based guidelines. We anticipate the Patient Safety and Adverse Events (Composite) measure will provide actionable information and specific direction for prevention of patient safety events, because hospitals can track and monitor individual PSI rates and develop targeted improvements to patient safety using this measure data.[59]

We proposed to adopt the Patient Safety and Adverse Events (Composite) measure for the Hospital VBP Program beginning with the FY 2023 program year because we believe the measure would continue to create strong incentives for hospitals to ensure that patients are not harmed by the medical care they receive, which is a critical consideration in quality improvement. We also proposed that the measure would be added to the Safety domain, like the previously adopted PSI 90 measure that we proposed to remove in section V.J.3.b. of the preamble of the proposed rule. The Patient Safety and Adverse Events (Composite) measure fulfills all statutory requirements for the Hospital VBP Program based on our adoption of that measure in the Hospital IQR Program and the anticipated posting of measure data on *Hospital Compare* at least 1 year prior to the start of the proposed measure performance period. The Patient Safety and Adverse Events (Composite) measure (MUC15–604) was included on the ''List of Measures Under Consideration for December 1, 2015'' [60] and received support from the MAP, which noted the importance of safety measures for the Hospital VBP Program.[61] Therefore, we proposed to add the Patient Safety and Adverse Events (Composite) measure to the Safety domain for the FY 2023 program year and subsequent years.

We invited public comment on this proposal.

Comment: A number of commenters supported CMS' proposal to adopt the Patient Safety and Adverse Events (Composite) measure because it was updated using the NQF maintenance re-endorsement process; the measure aligns with CMS' priority to improve patient safety and reduce adverse events during patient stays; and the measure is used in other programs and adopting it for the Hospital VBP Program would align quality measures across programs. Some commenters strongly supported adoption of the Patient Safety and Adverse Events (Composite) measure, but expressed concern that the Hospital VBP Program will lack a patient safety composite measure between the FY

[53] Previously titled ''Postoperative Physiologic and Metabolic Derangement'' prior to v6.0.

[54] Previously titled ''Accidental Puncture or Laceration Rate'' prior to v6.0.

[55] Available at: *http://www.qualityforum.org/QPS/0531*.

[56] For more information regarding the Patient Safety and Adverse Events (Composite) measure's risk adjustment methodology, we refer readers to: *http://www.qualityindicators.ahrq.gov/Downloads/Resources/Publications/2015/Empirical_Methods_2015.pdf*.

[57] National Quality Forum. NQF-Endorsed Measures for Patient Safety, Final Report. Available at: *http://www.qualityforum.org/Publications/2015/01/NQF-Endorsed_Measures_for_Patient_Safety,_Final_Report.aspx*.

[58] National Quality Forum QPS Measure Description for ''Patient Safety for Selected Indicators (modified version of PSI 90) (Composite Measure)'' found at: *https://www.qualityforum.org/QPS/MeasureDetails.aspx?standardID=321&print=0&entityTypeID=3*.

[59] For further guidance on PSI monitoring and strategies for applying quality improvements to PSI data, we refer readers to the Toolkit for Using the AHRQ quality indicators available at: *http://www.ahrq.gov/professionals/systems/hospital/qitoolkit/index.html*.

[60] ''List of Measures Under Consideration for December 1, 2015.'' Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*.

[61] National Quality Forum, Measure Applications Partnership, ''MAP 2016 Considerations for Implementing Measures in Federal Programs: Hospitals'' Final Report, (February 2016). Available at: *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_Hospitals.aspx*.

2019 and FY 2023 program years. Commenter urged CMS to look for opportunities to advance use of this measure in the Hospital VBP Program prior to the FY 2023 program year, or look to include other available measures to ensure that surgical complications remain a key component of the Hospital VBP Program.

Response: We thank the commenters for their support. As discussed in section V.J.3.b. of the preamble of this final rule, above, we will be unable to calculate measure scores for the current PSI 90 measure in the FY 2019 program year or a subsequent year because ICD–10 AHRQ PSI software for the currently adopted measure will not be available. Furthermore, due to certain statutory requirements in the Hospital VBP Program, we are unable to adopt the proposed Patient Safety and Adverse Events (Composite) measure earlier than the FY 2023 program year. Section 1886(o)(2)(A) of the Act requires the Hospital VBP Program to select measures that have been specified for the Hospital IQR Program. In addition, section 1886(o)(2)(C)(i) of the Act requires the Hospital VBP Program to refrain from beginning the performance period for a new measure until data on the measure have been posted on *Hospital Compare* for at least one year. The Hospital IQR Program finalized adoption of the modified PSI 90 measure (also known as the Patient Safety and Adverse Events (Composite) measure) in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57133), and we are required to wait one full year after data has been posted before that measure's performance period may begin in the Hospital VBP Program. Because measure data for the Patient Safety and Adverse Events (Composite) measure has not been posted on *Hospital Compare,* and because AHRQ requires sufficient time to develop the ICD–10 AHRQ PSI software for a given year, we are unable to adopt the measure before the FY 2023 program year.

We agree with commenters that surgical complications remain a key concern to address within our quality programs, including the Hospital VBP Program, and note that the NHSN measures will continue in the Safety domain of the Hospital VBP Program. We note that information on hospital performance on the Patient Safety and Adverse Events (Composite) measure will be publicly available through the Hospital IQR Program beginning in the fall of 2017. In addition, the HAC Reduction Program, which is not subject to the same statutory requirements as the Hospital VBP Program, will use this measure beginning with the FY 2018 program year. We believe earlier inclusion of this measure in the HAC Reduction Program will help incentivize hospitals to reduce patient safety events until the measure can be implemented in the Hospital VBP Program.

Comment: Many commenters strongly recommended that CMS not include the Patient Safety and Adverse Events (Composite) measure because hospital performance on the measure will not be publicly reported until after the comment period has ended. A number of these commenters noted that publicly reporting measures: Provides transparency on provider performance; allows hospitals to gain experience submitting data and become familiar with the measure's refinements and use of ICD–10 codes; allows time to identify errors and unintended consequences; and informs CMS and the measure developer of any implementation concerns. Some commenters further asserted that all measures should be publicly reported under the Hospital IQR Program for one year before being considered for inclusion in the Hospital VBP Program. One commenter asserted that stakeholders are unable to provide sufficient feedback on the proposed Patient Safety and Adverse Events measure without access to publicly reported measure data from the Hospital IQR Program. For these reasons, commenters urged CMS to postpone finalizing this measure for the Hospital VBP Program until stakeholders have sufficient data to review this measure to determine the appropriateness of the Patient Safety and Adverse Events (Composite) measure in the Hospital VBP Program.

Response: While we understand stakeholders' desire to see performance data from the Patient Safety and Adverse Events (Composite) measure before commenting on whether this measure should be adopted for the Hospital VBP Program, we note that, as discussed in the FY 2018 IPPS/LTCH PPS proposed rule, the measure has undergone extensive testing and found to be both reliable and valid. Furthermore, we note that adoption of this measure before its public reporting on *Hospital Compare* does not preclude hospitals from submitting questions and comments on the measure to CMS. Publicly reported Patient Safety and Adverse Events (Composite) measure data will be available in the fall of 2017, and we encourage hospitals, providers, patients, and other stakeholders to review these data and contact CMS with any questions regarding their measure scores. We further note the Patient Safety and Adverse Events (Composite) measure is being finalized for implementation in the Hospital VBP Program for the FY 2023 program year with a performance period of July 1, 2019 through June 30, 2021; we believe the time period before implementation provides hospitals with sufficient time to become familiar with the measure's specifications and reporting requirements before performance on the Patient Safety and Adverse Events (Composite) measure is reflected in hospitals' TPSs.

We further disagree that, absent publicly reported performance data, hospitals lack sufficient information to sufficiently comment on the proposed adoption of the Patient Safety and Adverse Events (Composite) measure. In proposing to adopt this measure, CMS provided a full description of the measure's specifications and its development history, explained the satisfaction of all statutorily-required actions, and provided links to additional sources of in-depth information regarding the detailed specifications for this measure. In addition, seven of the ten Patient Safety and Adverse Event (Composite) component indicators were also included in the previously adopted PSI 90 measure. We therefore believe commenters had ample information to use in reviewing the Patient Safety and Adverse Events (Composite) measure, allowing them to comment meaningfully on its proposed adoption.

Comment: A number of commenters did not support CMS' proposal to adopt the Patient Safety and Adverse Events (Composite) measure because the measure is subject to reliability and accuracy concerns; commenters believe the measure will not provide accurate, meaningful, actionable data on hospital safety performance; and commenters believe the measure is not sufficiently risk-adjusted for patient characteristics. Two commenters asserted that the proposed Patient Safety and Adverse Events (Composite) measure is flawed, stating that, according to the developer, the measure was not meant to be used in pay-for-performance programs. One commenter expressed concern regarding CMS' proposal to use a composite measure of patient safety, because the commenter believes composite measures limit the ability of a hospital to identify the specific component of the composite measure causing them to fall out of compliance. Another commenter believed it was likely that the PSI 90 measure will undergo additional updates before the FY 2023 program year, which would render this measure proposal outdated before the measure's implementation.

Response: We disagree with commenters that the Patient Safety and Adverse Events (Composite) measure has not demonstrated that it is an accurate, reliable, and valid indicator of quality and safety of care that is adequately risk-adjusted. Over the past decade, AHRQ has supported a series of validation studies based on detailed abstraction of medical records.[62] These studies informed AHRQ's PSI development process, including further refinements to the indicators, working with others to improve coding practices, and retirement of a few indicators. Furthermore, many of these claims-based indicators have been endorsed by the NQF, which includes a review process that assesses reliability and validity.[63] We note that NQF endorsed the Patient Safety and Adverse Events (Composite) measure (NQF #0531), including the risk-adjustment methodology of the component indicators, as reliable and valid. Further, we believe this measure does provide actionable information and specific direction for prevention of patient safety events, because hospitals can track and monitor individual PSI rates and develop targeted improvements to improve patient safety. For further guidance on PSI monitoring and strategies for applying quality improvements to PSI data, we refer readers to the Toolkit for Using the AHRQ quality indicators available at: *http://www.ahrq.gov/professionals/systems/hospital/qitoolkit/index.html*.

While we do not anticipate any further updates to the Patient Safety and Adverse Events (Composite) measure at this time, we acknowledge that the measure may undergo additional updates in the future as part of measure maintenance. Depending on the nature of these updates and their applicability to the Hospital VBP Program's aims, we will determine how best to address them in future years of the program.

Comment: Several commenters did not support adoption of the Patient Safety and Adverse Events (Composite) measure because it is susceptible to surveillance bias; measures components that occur infrequently or may not be preventable through evidence-based practices; lacks appropriate and necessary exclusions associated primarily with large academic centers; and is based on administrative claims data that does not fully reflect a patient's history, course of care, and clinical risk factors and therefore impacts the measure's ability to draw meaningful conclusions about hospital performance on safety issues. Some commenters also believe that it may disproportionately impact teaching hospitals because they tend to have robust infection control programs and are therefore more likely to identify patient safety events.

Response: While we acknowledge commenters' concerns, administrative claims data are valid for quality measurement and significantly less burdensome on hospitals for quality reporting. We note that there are previously conducted studies that validate the relationship between administrative claims data and medical records.[64] These studies demonstrate that administrative claims data can provide sufficient clinical information to assess patient safety. We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50091) for a further discussion of this issue in the context of the HAC Reduction Program.

We also acknowledge commenters' concern regarding the impact of surveillance bias, but note that there is little evidence that hospitals that may have a less robust surveillance program or underreport diagnoses for the PSI 90 indicators. Further, the measure exhibits a high degree of sensitivity (true positives, or the proportion of positives that are correctively identified as such) with respect to indicator diagnoses among hospitals. In addition, we note that many teaching hospitals do as well or better on the measure than non-teaching hospitals, and many of the patient safety indicator components are preventable through evidence-based practices. We have previously addressed commenters' concerns regarding the use of administrative claims, coding issues, and the impact on academic hospitals. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50684) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50064) for this discussion.

Comment: One commenter expressed particular concern about the vulnerability of PSI 12 (Perioperative PE or DVT Rate) to surveillance bias, because hospitals with more sophisticated tools to identify and track venous thromboembolism (VTE) show higher rates of VTE and may therefore be penalized for doing a better job at detection. Commenter stated that performance on PSI 12 may reflect differences in VTE imaging use rather than differences in the quality of care, and the inclusion of PSI 12 in the Patient Safety and Adverse Events (Composite) measure could unfairly penalize hospitals with increased vigilance in VTE detection.

Response: CMS and AHRQ recognize the commenter's concerns about surveillance bias for PSI 12, and note this issue was addressed in the NQF Patient Safety Steering Committee in 2015. Several research teams have examined DVT and PE rates and surveillance bias.[65] However, studies have not specifically examined whether the observed rates reflect underdiagnosis of DVT or PE at low-testing hospitals, or the underlying true incidence of symptomatic DVT or PE, and there is no evidence currently available to support the hypothesis that increased vigilance in DVT or PE detection is desirable from the perspective of patients and their families. Thus, while we acknowledge commenter's concerns regarding surveillance bias, we believe the PSI 12 is an important component indicator of the Patient Safety and Adverse Events (Composite) measure because it encourages hospitals not only to prevent DVT or PE, but also to appropriately assess a patient's risk for DVT and PE to prevent over-diagnosis and underdiagnosis.

Comment: Several commenters expressed concern that the timing and operational difficulties associated with procuring the AHRQ software hospitals need in order to calculate their own scores makes it impossible for hospitals to use this measure for internal quality improvement activities. Two commenters recommended that CMS delay adoption of the Patient Safety and Adverse Events (Composite) measure until the measure and associated software have been developed and validated in order to provide hospitals time to acquire the AHRQ software required to assess hospital performance on an ongoing basis and inform intervention strategies.

[62] AHRQ, ''AHRQ PSI Development,'' available at: *https://www.qualityindicators.ahrq.gov/Modules/psi_resources.aspx*. AHRQ, ''Quality Indicator Measure Development, Implementation, Maintenance, and Retirement,'' available at: *https://www.qualityindicators.ahrq.gov/Downloads/Resources/Publications/2011/QI_Measure_Development_Implementation_Maintenance_Retirement_Full_5-3-11.pdf*.

[63] *http://www.qualityforum.org/Publications/2013/10/Review_and_Update_of_Guidance_for_Evaluating_Evidence_and_Measure_Testing_-_Technical_Report.aspx*.

[64] Zrelak PA, Romano PS, Tancredi DJ, Geppert JJ, Utter GH. Validity of the AHRQ Patient Safety Indicator for Postoperative Physiologic and Metabolic Derangement based on a national sample of medical records. Medical Care 2013; 51(9):806–11.

[65] Bilimoria Y, Chun J. Ju MH, et al. Evaluation of surveillance bias and the validity of venous thromboembolism quality measure. JAMA. 2013;310(14):1482–1489; Holcomb CN, DeRussy A, Richman JS, Hawn MT. Association between inpatient surveillance and venous thromboembolism rates after hospital discharge. JAMA Surg. 2015;150(6):520–527.

Response: We appreciate commenters' commitment to continuous monitoring of performance. We understand that it is imperative for hospitals to monitor performance in an ongoing manner, and we are working with AHRQ to have the risk-adjusted software available as soon as possible. For more information on the release plan for ICD–10 risk adjusted software, we refer commenters to the AHRQ Quality Indicators Software page available at: *http://www.qualityindicators.ahrq.gov/Software/Default.aspx*.

Comment: Two commenters did not support CMS' proposal to adopt the Patient Safety and Adverse Events (Composite) measure beginning with the FY 2023 program year because this measure has already been adopted for the HAC Reduction Program, and adopting this measure for Hospital VBP would result in double counting of measure scores across programs.

Response: While we acknowledge that there is some overlap in quality measures between the Hospital VBP Program and the HAC Reduction Program, we note that these measures cover topics of critical importance to quality improvement and patient safety in the inpatient hospital setting. We selected these quality measures because we believe that hospital acquired condition measures comprise some of the most critical patient safety areas. These measures track infections and adverse events that could cause significant health risks to Medicare beneficiaries, and we believe it is appropriate to provide incentives for hospitals to avoid them under more than one program.

We further stress that the HAC Reduction Program and the Hospital VBP Program are separate programs with different purposes and policy goals. The HAC Reduction Program reduces payments to hospitals for excess hospital acquired conditions to increase patient safety in hospitals. On the other hand, the Hospital VBP Program is an incentive program that redistributes a portion of the Medicare payments made to hospitals based on their performance on a variety of measures, including safety measures, in order to provide a more holistic assessment of hospitals' quality of care. Accordingly, we believe that the critical importance of these measures to patient safety warrants their inclusion in both programs. We will, in the future, continue to monitor the HAC Reduction Program and Hospital VBP Program and analyze the impact of our measures selection, including any unintended consequences with having a measure in more than one program, and will revise the measure set in one or both programs if needed.

Comment: A few commenters did not support adoption of the Patient Safety and Adverse Events (Composite) measure because the first performance periods for the Patient Safety and Adverse Event (Composite) measure data that involve the use of ICD–10–CM data in the Hospital IQR Program did not end until June 30, 2017, and hospitals will see initial performance scores once CMS performs those calculations for FY 2019. Commenters noted the transition from ICD–9–CM to ICD–10–CM resulted in a number of issues with the previous PSI 90 measure, and therefore recommended CMS delay finalizing adoption of the measure in order to allow hospitals time to review their performance data and identify any issues with the Patient Safety and Adverse Events (Composite) measure's specifications.

Response: We thank the commenter for their recommendation, but note that one of the factors in our decision to delay the use of ICD–10 claims data for this measure in the Hospital IQR Program until the FY 2019 payment determination was to allow for the necessary time for AHRQ to create a risk-adjusted software version. While we are not aware that the transition to ICD–10–CM/PCS codes has currently caused inaccuracies in PSI reporting and evaluation, we are actively monitoring for any potential issues related to ICD–10 conversion. We note that all measure specifications for the Patient Safety and Adverse Events (Composite) measure have been translated to and updated for corresponding ICD–10 code specifications; these changes for ICD–10–CM/PCS conversion of AHRQ's patient safety indicators are available at: *http://www.qualityindicators.ahrq.gov/FAQs_Support/FAQ_QI.aspx#*.

We further note that AHRQ welcomes input from the user community on the AHRQ PSI ICD–10–CM/PCS software. Please provide suggestions and comments directly to: *QISupport@ahrq.hhs.gov*.

Comment: One commenter requested additional information about how performance for selected indicators under the Patient Safety and Adverse Events (Composite) measure will be assessed for conditions where a hospital's expected rate of a given safety event is less than 1.0. A second commenter strongly recommended CMS revisit the scoring methodology for the Patient Safety and Adverse Events (Composite) measure because hospitals that have been effective in driving down infection rates to below 1.0 are, in effect, penalized by the measure not being scored, rather than being rewarded for their work.

Response: The Patient Safety and Adverse Events (Composite) measure does not use minimum criteria as described in commenters' comments; we therefore interpret commenters' reference to expected rates of safety events less than 1.0 to refer to the minimum precision criteria for the NHSN HAI measures, that is, at least one predicted infection for a reporting period for the measure result to be reported. We would note the Patient Safety and Adverse Events (Composite) measure requires that hospitals have a minimum of three eligible cases on any one underlying indicator during the baseline period in order to receive an improvement score and three eligible cases on any one underlying indicator during performance period in order to receive an improvement or achievement score. For the purposes of the Patient Safety and Adverse Events (Composite) measure, a case is ''eligible'' for a given indicator if it meets the criterion for inclusion in the indicator measure population. This minimum number of cases is based on AHRQ's methodology for scoring performance on the Patient Safety and Adverse Events (Composite) measure. Under this methodology, all hospitals that meet the case minimum will be scored based on their performance on this measure, and those that do not meet the case minimum will not receive a score for that component indicator. In addition, a hospital will be eligible to receive a score on the Patient Safety and Adverse Events (Composite) measure if they meet the case minimum criteria for at least one component indicator. We note that this case minimum applies to all hospitals, including those that experience zero numerator events during the performance period. Therefore, a hospital that meets the case minimum for a given component indicator but experiences zero numerator events will still receive a score on that component indicator.

Comment: Two commenters recommended that CMS consider replacing the current PSI 90 measure with objective, clinical outcome measures from the CDC's National Healthcare Safety Network.

Response: We thank the commenters for their recommendation, and we will take this into consideration in the future. We note that the Hospital VBP Program has adopted a number of NHSN-based measures in previous years, including the CLABSI, CAUTI, CDI, Colon and the Abdominal

Hysterectomy SSI, and MRSA Bacteremia measures.

Comment: A few commenters urged CMS to remove PSI 03 (Pressure Ulcer Rate) from the Patient Safety and Adverse Events (Composite) measure because pressure ulcers are complex and may not be appropriately captured under the composite measure. In the alternative, commenters recommended that CMS adopt the Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (NQF #0678) measure for the Hospital VBP Program.

Response: We thank the commenters for their recommendation; however, we believe it is appropriate to use the PSI 03 indicator in the Patient Safety and Adverse Events (Composite) measure for the Hospital VBP Program because none of the measures previously adopted for the program capture pressure ulcer or injury data. The recommended measure, Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (NQF #0678), is not currently specified for use in the acute, inpatient hospital setting of care.[66] In addition, this measure is also collected via chart abstraction, and we believe the additional reporting burden on hospitals for this measure currently outweighs the benefit of collecting this data in the inpatient hospital setting when the PSI 03 indicator in the Patient Safety and Adverse Events (Composite) measure is available for use and hospitals are familiar with this indicator. Furthermore, due to the statutory requirements of the Hospital VBP Program, we are unable to adopt the recommended measure at this time. However, if the same or similar measure that is specified for the acute, inpatient hospital setting becomes available, we will consider the measure for future program years.

After consideration of the public comments we received, we are finalizing our proposal to adopt the Patient Safety and Adverse Events (Composite) measure beginning with the FY 2023 program year.

5. Previously Adopted and Newly Finalized Baseline and Performance Periods

a. Background

Section 1886(o)(4) of the Act requires the Secretary to establish a performance period for the Hospital VBP Program that begins and ends prior to the beginning of such fiscal year. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49561 through 49562) for the baseline and performance periods for the Clinical Care, Person and Community Engagement, Safety, and Efficiency and Cost Reduction domains that we have adopted for the FY 2018 program year. We refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56998 through 57003) for additional baseline and performance periods that we have adopted for the FY 2018, FY 2019, FY 2020, FY 2021 and FY 2022 program years. Although in past rulemaking we have proposed and adopted a new baseline and performance period for each program year for each measure in each final rule, in the FY 2017 IPPS/LTCH PPS final rule, we finalized a schedule for all future baseline and performance periods.

b. Person and Community Engagement Domain

Since the FY 2015 program year, we have adopted a 12-month baseline period and 12-month performance period for measures in the Person and Community Engagement domain (previously referred to as the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain) (77 FR 53598; 78 FR 50692; 79 FR 50072; 80 FR 49561). In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56998), we finalized our proposal to adopt a 12-month performance period for the Person and Community Engagement domain that runs on the calendar year two years prior to the applicable program year and a 12-month baseline period that runs on the calendar year four years prior to the applicable program year, for the FY 2019 program year and subsequent years.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19974 through 19775), we did not propose any changes to these policies.

c. Efficiency and Cost Reduction Domain

(1) MSPB Measure

Since the FY 2016 program year, we have adopted a 12-month baseline period and 12-month performance period for the MSPB measure in the Efficiency and Cost Reduction domain (78 FR 50692; 79 FR 50072; 80 FR 49562). In the FY 2017 IPPS/LTCH PPS final rule, we finalized our proposal to adopt a 12-month performance period for the MSPB measure that runs on the calendar year two years prior to the applicable program year and a 12-month baseline period that runs on the calendar year four years prior to the applicable program year for the FY 2019 program year and subsequent years (81 FR 56998).

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19775), we did not propose any changes to these policies.

(2) AMI Payment and HF Payment Measures

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56999), we adopted a 24-month performance period and a 36-month baseline period for the AMI Payment and HF Payment measures for the FY 2021 program year. We did so in order to adopt the measures as early as feasible into the Hospital VBP Program, and stated our belief that using a 24-month performance period rather than a 36-month performance period for the first program year of these measures would still enable us to accurately assess the quality of care provided by hospitals and would not substantially change a hospital's performance on the measure (81 FR 56998 through 56999). In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19975), we did not propose any changes to the length of these performance or baseline periods for the FY 2021 program year.

In the FY 2017 IPPS/LTCH PPS final rule, we also adopted a 36-month performance period and 36-month baseline period for the AMI Payment and HF Payment measures for the FY 2022 program year (81 FR 57000). In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19975), we did not propose any changes to the length of these performance or baseline periods for the FY 2022 program year.

For the FY 2023 program year and subsequent years, we proposed it would be appropriate to use a 36-month performance period and 36-month baseline period for the AMI Payment and HF Payment measures as we have adopted for the FY 2022 program year. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19975), for the FY 2023 program year and subsequent years, we proposed to adopt a 36-month performance period that runs from July 1st five years prior to the applicable fiscal program year to June 30th two years prior to the applicable fiscal program year. We also proposed to adopt a 36-month baseline period that runs from July 1, 10 years prior to the applicable fiscal program year, to June 30, 7 years prior to the applicable fiscal program year.

We invited public comment on these proposals.

Comment: One commenter supported CMS' proposal to adopt 36-month performance and baseline periods for the AMI and HF Payment measures.

[66] National Quality Forum. ''0678: Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay).'' Available at: *https://www.qualityforum.org/QPS/QPSTool.aspx* after searching ''0678.''

Response: We thank the commenter for their support.

Comment: Two commenters urged CMS to reevaluate the length of time between the baseline period, performance period, and payment implications of the AMI and HF Payment measures because commenters believed using a baseline period that begins 10 years prior to the program year would fail to provide relevant data to CMS on hospital performance.

Response: We use a three-year period of index admissions for the PN Payment measure in order to increase the number of cases per hospital used for measure calculation, which improves the precision of each hospital's measure rate. As a result, the baseline and performance periods cover a much longer period of time than used in other measures, and are further in time from the payment impacts for a given program year. Although this approach utilizes older data, it also identifies more variation in hospital performance and still allows for improvement from one year of reporting to the next. We decided to use the proposed timeframe because it balances the need for the most recent claims and sufficient time to process the claims data and calculate the measures to meet the program's timelines.

After consideration of the public comments we received, we are finalizing the baseline and performance periods for the AMI and HF Payment measures as proposed.

(3) PN Payment Measure in the FY 2022 Program Year

As discussed in section V.J.4.a. of the preamble of this final rule, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19971 through 19973), we proposed a new PN Payment measure for the FY 2022 program year and subsequent years. In order to adopt this measure as early as feasible into the Hospital VBP Program, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19975 through 19976), we proposed to adopt a 36-month baseline period and a 23-month performance period. We proposed to adopt a 23-month performance period because we anticipate that the refined measure will not be posted on *Hospital Compare* for one year until July 2017. Therefore, for the FY 2022 program year, we proposed to adopt a 23-month performance period that runs from August 1, 2018 to June 30, 2020 and a baseline period that runs from July 1, 2013 to June 30, 2016.

We believe that using a 23-month performance period for the proposed PN Payment measure, rather than a 36-month performance period, in the FY 2022 program year would accurately assess the quality of care provided by hospitals and would not substantially change hospitals' performance on the measure. To determine the viability of using a 23-month performance period to calculate the proposed PN Payment measure's scores, we compared the measure score reliability for a 24-month and 36-month performance period. We calculated the Intraclass Correlation Coefficient (ICC) to determine the extent to which assessment of a hospital using different but randomly selected subsets of patients produces similar measures of hospital performance.[67] We calculated the risk-standardized payment (RSP) using a random split-sample of a 36-month performance period (we used July 1, 2013 through June 30, 2016) and a random split-sample of a 24-month performance period (we used July 1, 2013 through June 30, 2015).

For both the 36-month and 24-month performance period, we obtained two RSPs for each hospital, using an entirely distinct set of patients from the same time period. If the RSPs for both the 36-month and 24-month performance periods agree, we can demonstrate that the measure assesses the quality of the hospital rather than the types of patients treated. To calculate agreement between these measure subsets, we calculated the ICC (2,1)[68] for both the 36-month and 24-month performance periods.

For the proposed PN Payment measure, there were 1,170,762 index admissions and 3,242 hospitals that met the minimum case threshold for reporting a measure result (at least 25 cases) in the 36-month performance period. There were 787,817 index admissions and 3,218 hospitals that met the minimum case threshold for reporting a measure result in the 24-month performance period.

For the 36-month performance period, the ICC for the two independent assessments of each hospital was 0.868. For the 24-month performance period, the ICC for the two independent assessments of each hospital was 0.834. Therefore, the data subsets showcase ''substantial'' agreement of hospital performance, and we can demonstrate that, even with a shortened performance period, the proposed PN Payment measure assesses the quality of care provided at a hospital rather than the types of patients that these hospitals treat.[69]

To assess whether using fewer than 36 months of data change the performance in the same hospital, we compared the percent change in a hospital's predicted/expected (P/E) ratio using 24 months of data. For hospitals that met the minimum case threshold in the 24-month performance period, the median percent change was 0.11 percent (with an interquartile range of −1.5 percent to 0.07 percent). These results suggest minimal difference in same-hospital performance when using a 24-month measurement period. Based on these analyses, we are confident that using a 23-month performance period will result in reliable measure scores because our analysis demonstrates strong reliability at 24 months and we believe the change in available data due to a one month difference in the performance period is insufficient to substantially impact the measure's reliability.

In summary, based on the analysis described above, we are confident that using a 23-month performance period, rather than 36-month performance period, for the initial performance period for this measure would accurately assess the quality of care provided by that hospital and would not substantially change the hospital's performance on that measure.

We invited public comment on these proposals.

Comment: One commenter requested that CMS consider reducing the performance period for the PN Payment measure from three years to one year.

Response: As noted above, our goal is to use a three-year period of index admissions for the PN Payment measure in order to increase the number of cases per hospital used for measure calculation, which improves the precision of each hospital's measure rate. Although this approach utilizes older data, it also identifies more variation in hospital performance and still allows for improvement from one year of reporting to the next.

Comment: One commenter recommended that, if CMS finalizes adoption of the PN Payment measure, CMS delay implementation of the measure until a 36-month performance period can be adopted for this measure because the commenter believes that having a performance period that is different from the performance period used for other condition-specific measures is confusing for providers and patients.

[67] Shrout P, Fleiss J. Intraclass Correlations: Uses in Assessing Rater Reliability. *Psychol. Bull.* Mar 1979;86(2):420–428.

[68] Shrout P, Fleiss J. Intraclass Correlations: Uses in Assessing Rater Reliability. *Psychol. Bull.* Mar 1979;86(2):420–428.

[69] Landis J, Joch G. The Measurement of Observer Agreement for Categorical Data. *Biometrics.* Mar 1997;33(1):159–174.

Response: We continue to believe that the 23-month performance period for the FY 2022 program year and 35-month performance period for the FY 2023 program year are sufficiently reliable to accurately assess the resource use by hospitals and would not substantially change hospitals' performance on the measure. We note that the PN Payment measure will only have an abbreviated performance period in the FY 2022 and FY 2023 program years, the first two years this measure is in the program, but we are adopting a 36-month performance period for the FY 2024 program year and subsequent years, as detailed in the next section below.

After consideration of the public comments we received, we are finalizing the baseline and performance periods for the PN Payment measure for the FY 2022 program year as proposed.

(4) PN Payment Measure in the FY 2023 Program Year

We have stated in past rules that we would strive to adopt 36-month performance periods and baseline periods when possible to accommodate the time needed to process measure data and to ensure that we collect enough measure data for reliable performance scoring for all mortality measures (78 FR 50074; 79 FR 50057; and 80 FR 49588). While we cannot adopt a 36-month performance period for the FY 2023 program year because we anticipate that the refined measure will not be posted on *Hospital Compare* for 1 year until July 2017, we could lengthen the PN Payment measure performance period from 23 months to 35 months. As demonstrated above, our analysis of the proposed PN Payment measure indicates that the measure would produce reliable measure scores using 24 months of data as well as 36 months of data. As such, we are confident they will also be reliable when calculated using 35 months of data for the performance period for the FY 2023 program year. Therefore, for the FY 2023 program year, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19776), we proposed to adopt a 35-month performance period that runs from August 1, 2018 to June 30, 2021 and a 36-month baseline period that runs from July 1, 2013 to June 30, 2016.

We invited public comment on these proposals. We did not receive public comments on the proposed baseline and performance periods for the PN Payment measure for the FY 2023 program year and subsequent years. We are finalizing the baseline and performance periods for the PN Payment measure for the FY 2023 program year as proposed.

(5) PN Payment Measure in the FY 2024 Program Year and Subsequent Years

For the FY 2024 program year and subsequent years, we believe it would be appropriate to use a 36-month performance period and 36-month baseline period for the PN Payment measure. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19976), for the FY 2024 program year and subsequent years, we proposed to adopt a 36-month baseline period and a 36-month performance period for the proposed PN Payment measure. Specifically, we proposed to adopt a 36-month performance period that runs from July 1, 5 years prior to the applicable fiscal program year, to June 30, 2 years prior to the applicable fiscal program year and a 36-month baseline period that runs from July 1, 10 years prior to the applicable fiscal program year, to June 30, 7 years prior to the applicable fiscal program year.

We invited public comment on these proposals. We did not receive public comments on the proposed baseline and performance periods for the PN Payment measure for the FY 2024 program year and subsequent years. We are finalizing the baseline and performance periods for FY 2024 and subsequent years as proposed.

d. Safety Domain

(1) Previously Adopted Measures in the Safety Domain

Since the FY 2016 program year, we have adopted a 12-month baseline period and 12-month performance period for all measures in the Safety domain, with the exception of the PSI 90 measure (78 FR 50692; 79 FR 50071; 80 FR 49562). In the FY 2017 IPPS/LTCH PPS final rule, we finalized our proposal to adopt a performance period for all measures in the Safety domain—with the exception of the PSI 90 measure, as discussed in more detail below—that runs on the calendar year 2 years prior to the applicable program year and a baseline period that runs on the calendar year 4 years prior to the applicable program year for the FY 2019 program year and subsequent program years (81 FR 57000).

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19976), we did not propose any changes to these policies.

(2) Patient Safety and Adverse Events (Composite) Measure in the FY 2023 Program Year

As discussed above in section V.J.3.b. of the preamble of this final rule, In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19970), we proposed to remove the currently adopted PSI 90 measure beginning with the FY 2019 program year, and in section V.J.4.b. of the preamble of this final rule, we discuss our proposal to adopt the Patient Safety and Adverse Events (Composite) measure beginning with the FY 2023 program year. In order to adopt the Patient Safety and Adverse Events (Composite) measure as early as feasible into the Hospital VBP Program, we proposed to adopt a 21-month baseline period and 24-month performance period for the measure for the FY 2023 program year. Specifically, we proposed to adopt a performance period that runs from July 1, 2019 to June 30, 2021, and a baseline period that runs from October 1, 2015 to June 30, 2017. The 21-month baseline period would only apply to the FY 2023 program year and would only use ICD–10 data.

Prior to deciding to propose an abbreviated baseline period for the FY 2023 program year, we took several factors into consideration, including the recommendations of the measure steward, the feasibility of using a combination of ICD–9 and ICD–10 data without the availability of the appropriate measure software, minimizing provider burden, program implementation timelines, and the reliability of using a shortened baseline period. We believe using a 21-month baseline period for the Patient Safety and Adverse Events (Composite) measure for the FY 2023 program year best serves the need to provide important information on hospital patient safety and adverse events by allowing sufficient time to process the claims data and calculate measure scores, while minimizing the reporting burden and program disruption. We also believe that measure scores would continue to be reliable for the above proposed baseline period because the NQF, which re-endorsed the modified version of the measure that we proposed, found it to be reliable using 12 months of data.[70]

We invited public comment on these proposals. We did not receive public comments on the proposed baseline and performance periods for the Patient Safety and Adverse Events (Composite) measure for the FY 2023 program year. We are finalizing the baseline and performance period as proposed.

(3) Patient Safety and Adverse Events (Composite) Measure in the FY 2024 Program Year and Subsequent Years

For the FY 2024 program year and subsequent years, in the FY 2018 IPPS/

[70] ''Patient Safety 2015 Final Report'' is available at: *http://www.qualityforum.org/Publications/2016/02/Patient_Safety_2015_Final_Report.aspx.*

LTCH PPS proposed rule (82 FR 19976), we proposed to lengthen the Patient Safety and Adverse Events (Composite) measure baseline period to 24 months and continue to adopt a 24-month performance period because we believe the measure is most reliable with a 24-month baseline period. For the FY 2024 program year, the baseline period would run from July 1, 2016 to June 30, 2018. Therefore, we proposed to adopt a performance period that runs from July 1, 4 years prior to the applicable fiscal program year, to June 0, 2 years prior to the applicable fiscal program year, and a baseline period that runs from July 1, 8 years prior to the applicable program year, to June 30, 6 years prior to the applicable program year.

We invited public comment on these proposals. We did not receive public comments on the proposed baseline and performance periods for the Patient Safety and Adverse Events (Composite) measure for the FY 2024 program year and subsequent years. We are finalizing the baseline and performance periods for the FY 2024 program year and subsequent years as proposed.

e. Clinical Care Domain

(1) Previously Adopted Measures in the Clinical Care Domain

For the FY 2019, FY 2020, and FY 2021 program years, we adopted a 36-month baseline period and 36-month performance period for measures in the Clinical Care domain (78 FR 50692 through 50694; 79 FR 50073; 80 FR 49563).[71] In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57000), we finalized our proposal to adopt a 36-month performance period and 36-month baseline period for the FY 2022 program year for each of the previously finalized measures in the Clinical Care domain—that is, the MORT–30–AMI, MORT–30–HF, MORT–30–COPD, THA/TKA, and MORT–30–CABG measures. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19977), we proposed to adopt a 36-month performance period and 36-month baseline period for these measures for the FY 2023 program year and subsequent years.

Specifically, for the mortality measures (MORT–30–AMI, MORT–30–HF, MORT–30–COPD, and MORT–30–CABG), the performance period would run for 36 months from July 1, 5 years prior to the applicable fiscal program year, to June 30, 2 years prior to the applicable fiscal program year, and the baseline period would run for 36 months from July 1, 10 years prior to the applicable fiscal program year, to June 30, 7 years prior to the applicable fiscal program year. For the THA/TKA measure, the performance period would run for 36 months from April 1, 5 years prior to the applicable fiscal program year, to March 31, 2 years prior to the applicable fiscal program year, and the baseline period would run for 36 months from April 1, 10 years prior to the applicable fiscal program year, to March 31, 7 years prior to the applicable fiscal program year.

We invited public comment on these proposals. We did not receive any public comments on these proposals; we are finalizing our proposals to set the baseline and performance periods for the MORT–30–AMI, MORT–30–HF, MORT–30–COPD, THA/TKA, and MORT–30–CABG measures for FY 2023 program year and subsequent years as proposed.

(2) MORT–30–PN (Updated Cohort) Measure

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57001), we adopted a 22-month performance period for the MORT–30–PN (updated cohort) measure and a 36-month baseline period for the FY 2021 program year. In the same final rule, we adopted a 34-month performance period and 36-month baseline period for the MORT–30–PN (updated cohort) measure for the FY 2022 program year. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19977), we did not propose any changes to the length of these performance or baseline periods for the FY 2021 and FY 2022 program years.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57001), we also stated our intent to lengthen the MORT–30–PN (updated cohort) measure performance period to a full 36-month performance period beginning in July, instead of September. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19977), we proposed to adopt a 36-month performance period that would run from July 1, 5 years prior to the applicable fiscal program year, to June 30, 2 years prior to the applicable fiscal program year, and a 36-month baseline period that would run from July 1, 10 years prior to the applicable fiscal program year, to June 30, 7 years prior to the applicable fiscal program year for the MORT–30–PN (updated cohort) measure for the FY 2023 program year and subsequent years.

We invited public comment on these proposals. We did not receive any public comments on this proposal; we are finalizing our proposal to set the baseline and performance periods for the MORT–30–PN (updated cohort) measure for the FY 2023 program year and subsequent years as proposed.

f. Summary of Previously Adopted and Newly Finalized Baseline and Performance Periods for the FY 2019 Through FY 2023 Program Years

The tables below summarize the baseline and performance periods that we have previously adopted and are finalizing in this final rule.

PREVIOUSLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2019 PROGRAM YEAR

Domain	Baseline period	Performance period
Person and Community Engagement:		
• HCAHPS Survey	• January 1, 2015–December 31, 2015	• January 1, 2017–December 31, 2017.
Clinical Care:		
• Mortality (MORT–30–AMI, MORT–30–HF, MORT–30–PN).	• July 1, 2009–June 30, 2012	• July 1, 2014–June 30, 2017.
• THA/TKA	• July 1, 2010–June 30, 2013	• January 1, 2015–June 30, 2017.
Safety:*		
• PC–01 and NHSN measures (CAUTI, CLABSI, SSI, CDI, MRSA).	• January 1, 2015–December 31, 2015	• January 1, 2017–December 31, 2017.
Efficiency and Cost Reduction:		

[71] The THA/TKA measure was added for the FY 2019 program year with a 36-month baseline period and a 24-month performance period (79 FR 50072), but we have since adopted 36-month baseline and performance periods for the FY 2021 program year (80 FR 49563). We intend to continue having 36-month baseline periods and 36-month performance periods in the future for all measures in the Clinical Care domain.

PREVIOUSLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2019 PROGRAM YEAR—Continued

Domain	Baseline period	Performance period
• MSPB	• January 1, 2015–December 31, 2015	• January 1, 2017–December 31, 2017.

* In section V.J.3.b. of the preamble of this final rule, we discuss our decision to finalize the removal of the current PSI 90 measure beginning with the FY 2019 program year. As a result, the previously finalized performance and baseline periods for this measure were not included in this table.

PREVIOUSLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2020 PROGRAM YEAR

Domain	Baseline period	Performance period
Person and Community Engagement:		
• HCAHPS Survey	• January 1, 2016–December 31, 2016.	• January 1, 2018–December 31, 2018.
Clinical Care:		
• Mortality (MORT–30–AMI, MORT–30–HF, MORT–30–PN).	• July 1, 2010–June 30, 2013	• July 1, 2015–June 30, 2018.
• THA/TKA	• July 1, 2010–June 30, 2013	• July 1, 2015–June 30, 2018.
Safety: *		
• PC–01 and NHSN measures (CAUTI, CLABSI, SSI, CDI, MRSA).	• January 1, 2016–December 31, 2016.	• January 1, 2018–December 31, 2018.
Efficiency and Cost Reduction:		
• MSPB	• January 1, 2016–December 31, 2016.	• January 1, 2018–December 31, 2018.

* In section V.J.3.b. of the preamble of this final rule, we discuss our decision to finalize the removal of the current PSI 90 measure beginning with the FY 2019 program year. As a result, the previously finalized performance and baseline periods for this measure were not included in this table.

PREVIOUSLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2021 PROGRAM YEAR

Domain	Baseline period	Performance period
Person and Community Engagement:	• January 1, 2017–December 31, 2017	• January 1, 2019–December 31, 2019.
• HCAHPS Survey.		
Clinical Care:		
• Mortality (MORT–30–AMI, MORT–30–HF, MORT–30–COPD).	• July 1, 2011–June 30, 2014	• July 1, 2016–June 30, 2019.
• MORT–30–PN (updated cohort)	• July 1, 2012–June 30, 2015	• September 1, 2017–June 30, 2019.
• THA/TKA	• April 1, 2011–March 31, 2014	• April 1, 2016–March 31, 2019.
Safety: *		
• PC–01 and NHSN measures (CAUTI, CLABSI, SSI, CDI, MRSA).	• January 1, 2017–December 31, 2017	• January 1, 2019–December 31, 2019.
Efficiency and Cost Reduction:		
• MSPB	• January 1, 2017–December 31, 2017	• January 1, 2019–December 31, 2019.
• Payment (AMI Payment and HF Payment)	• July 1, 2012–June 30, 2015	• July 1, 2017–June 30, 2019.

* In section V.J.3.b. of the preamble of this final rule, we discuss our decision to finalize the removal of the current PSI 90 measure beginning with the FY 2019 program year. As a result, the previously finalized performance and baseline periods for this measure were not included in this table.

PREVIOUSLY ADOPTED AND NEWLY FINALIZED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2022 PROGRAM YEAR

Domain	Baseline period	Performance period
Person and Community Engagement:		
• HCAHPS Survey	• January 1, 2018–December 31, 2018	• January 1, 2020–December 31, 2020.
Clinical Care:		
• Mortality (MORT–30–AMI, MORT–30–HF, MORT–30–COPD, MORT–30–CABG).	• July 1, 2012–June 30, 2015	• July 1, 2017–June 30, 2020.
• MORT–30–PN (updated cohort)	• July 1, 2012–June 30, 2015	• September 1, 2017–June 30, 2020.
• THA/TKA	• April 1, 2012–March 31, 2015	• April 1, 2017–March 31, 2020.
Safety: *		
• PC–01 and NHSN measures (CAUTI, CLABSI, SSI, CDI, MRSA).	• January 1, 2018–December 31, 2018	• January 1, 2020–December 31, 2020.
Efficiency and Cost Reduction:		
• MSPB	• January 1, 2018–December 31, 2018	• January 1, 2020–December 31, 2020.
• Payment (AMI Payment, HF Payment)	• July 1, 2012–June 30, 2015	• July 1, 2017–June 30, 2020.

PREVIOUSLY ADOPTED AND NEWLY FINALIZED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2022 PROGRAM YEAR—Continued

Domain	Baseline period	Performance period
• PN Payment**	• July 1, 2013–June 30, 2016	• August 1, 2018–June 30, 2020.

*In section V.J.3.b. of the preamble of this final rule, we discuss our decision to finalize the removal of the current PSI 90 measure beginning with the FY 2019 program year. As a result, the previously finalized performance and baseline periods for this measure are not included in this table.

**In section V.J.4.a. of the preamble of this final rule, we discuss our decision to adopt the PN Payment measure beginning with the FY 2022 program year.

PREVIOUSLY ADOPTED AND NEWLY FINALIZED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2023 PROGRAM YEAR

Domain	Baseline period	Performance period
Person and Community Engagement:		
• HCAHPS Survey	• January 1, 2019–December 31, 2019.	• January 1, 2021–December 31, 2021.
Clinical Care:		
• Mortality (MORT-30–AMI, MORT–30–HF, MORT–30–COPD, MORT–30–CABG, MORT-30–PN (updated cohort).	• July 1, 2013–June 30, 2016	• July 1, 2018–June 30, 2021.
• THA/TKA	• April 1, 2013–March 31, 2016.	• April 1, 2018–March 31, 2021.
Safety:		
• PC–01 and NHSN measures (CAUTI, CLABSI, SSI, CDI, MRSA).	• January 1, 2019–December 31, 2019.	• January 1, 2021–December 31, 2021.
• Patient Safety and Adverse Events (Composite)*.	• October 1, 2015–June 30, 2017.	• July 1, 2019–June 30, 2021.
Efficiency and Cost Reduction:		
• MSPB	• January 1, 2019–December 31, 2019.	• January 1, 2021–December 31, 2021.
• Payment (AMI Payment, HF Payment)	• July 1, 2013–June 30, 2016	• July 1, 2018–June 30, 2021.
• PN Payment**	• July 1, 2013–June 30, 2016	• August 1, 2018–June 30, 2021.

*In section V.J.4.b. of the preamble of this final rule, we discuss our decision to adopt the Patient Safety and Adverse Events (Composite) measure beginning with the FY 2023 program year.

**In section V.J.4.a. of the preamble of this final rule, we discuss our decision to adopt the PN Payment measure beginning with the FY 2022 program year.

6. Performance Standards for the Hospital VBP Program

a. Background

Section 1886(o)(3)(A) of the Act requires the Secretary to establish performance standards for the measures selected under the Hospital VBP Program for a performance period for the applicable fiscal year. The performance standards must include levels of achievement and improvement, as required by section 1886(o)(3)(B) of the Act, and must be established no later than 60 days before the beginning of the performance period for the fiscal year involved, as required by section 1886(o)(3)(C) of the Act. We refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513) for further discussion of achievement and improvement standards under the Hospital VBP Program.

In addition, when establishing the performance standards, section 1886(o)(3)(D) of the Act requires the Secretary to consider appropriate factors, such as: (1) Practical experience with the measures, including whether a significant proportion of hospitals failed to meet the performance standard during previous performance periods; (2) historical performance standards; (3) improvement rates; and (4) the opportunity for continued improvement.

We refer readers to the FY 2013, FY 2014, and FY 2015 IPPS/LTCH PPS final rules (77 FR 53604 through 53605; 78 FR 50694 through 50698; and 79 FR 50077 through 50079, respectively) for a more detailed discussion of the general scoring methodology used in the Hospital VBP Program.

We note that the performance standards for the following measures are calculated with lower values representing better performance:

- The NHSN measures (the CLABSI, CAUTI, CDI, Colon and the Abdominal Hysterectomy SSI, and MRSA Bacteremia measures);
- The THA/TKA measure;
- The PC–01 measure;
- The MSPB measure;
- The HF, AMI, and PN Payment measures; and
- The Patient Safety and Adverse Events (Composite) measure.

This distinction is made in contrast to other measures for which higher values indicate better performance.[72] As discussed further in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50684), the performance standards for the Colon and Abdominal Hysterectomy SSI measure are computed separately for each procedure stratum, and we first award achievement and improvement points to each stratum separately, then compute a weighted average of the points awarded to each stratum by predicted infections.

b. Previously Adopted and Newly Finalized Performance Standards for the FY 2020 Program Year

In accordance with our finalized methodology for calculating performance standards (discussed more fully in the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513)), in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19979 through 19980), we proposed to adopt additional

[72] We note that the mortality measures in the Hospital VBP Program use survival rates rather than mortality rates; as a result, higher values indicate better performance on these measures.

performance standards for the FY 2020 program year. We noted that the numerical values for the performance standards displayed in the proposed rule represented estimates based on the most recently available data, and we stated our intention to update the numerical values in this FY 2018 IPPS/LTCH PPS final rule. We noted further that the MSPB measure's performance standards are based on performance period data; therefore, we are unable to provide numerical equivalents for the standards at this time.

We invited public comment on the proposed performance standards. We did not receive any public comments on the proposed performance standards for the FY 2020 program year. We are adopting the performance standards listed in the table below. These performance standards have been updated from the FY 2018 IPPS/LTCH PPS proposed rule and represent the most recently available data.

PREVIOUSLY ADOPTED AND NEWLY FINALIZED PERFORMANCE STANDARDS FOR THE FY 2020 PROGRAM YEAR: SAFETY, CLINICAL CARE, AND EFFICIENCY AND COST REDUCTION DOMAINS [#]

Measure short name	Achievement threshold	Benchmark
Safety Domain ♦		
CAUTI *†	0.828	0.000.
CLABSI *†	0.784	0.000.
CDI *†	0.852	0.091.
MRSA Bacteremia *†	0.815	0.000.
Colon and Abdominal Hysterectomy SSI *†	• 0.781 • 0.722	• 0.000. • 0.000.
PC–01 *	0.000000	0.000000.
Clinical Care Domain		
MORT–30–AMI ±	0.853715	0.875869.
MORT–30–HF ±	0.881090	0.906068.
MORT–30–PN ±	0.882266	0.909532.
THA/TKA *±	0.032229	0.023178.
Efficiency and Cost Reduction Domain		
MSPB *±	Median Medicare Spending Per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending Per Beneficiary ratios across all hospitals during the performance period.

[#] In section V.J.3.b. of the preamble of this final rule, we are removing the current PSI 90 measure beginning with the FY 2019 program year. As a result, the previously finalized performance standards for this measure are not included in this table.

♦ The performance standards displayed in this table for the Safety domain measures are updated using four quarters of CY 2016 data in this final rule.

† In section III.F.2.e. of preamble of the FY 2016 IPPS/LTCH PPS final rule (80 FR 49554 thorough 49555), we finalized our proposal to use the CDC's new standard population data to calculate performance standards for the NHSN measures beginning with the FY 2019 program year. We refer readers to that final rule for additional information regarding the NHSN measures' standard population data. In addition, we note that a technical update was released for these measures for the FY 2019 program year in order to ensure that hospitals have the correct performance standards for the applicable performance period.

* Lower values represent better performance.

± Previously adopted performance standards.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79857), we discussed how the removal of the Pain Management dimension of the HCAHPS Survey, beginning with the FY 2018 program year, affects the scoring of the Person and Community Engagement domain. The eight dimensions of the HCAHPS measure are calculated to generate the HCAHPS Base Score. For each of the eight dimensions, Achievement Points (0–10 points) and Improvement Points (0–9 points) are calculated, the larger of which is then summed across the eight dimensions to create the HCAHPS Base Score (0–80 points). Each of the eight dimensions is of equal weight, thus the HCAHPS Base Score ranges from 0 to 80 points. HCAHPS Consistency Points are then calculated, which range from 0 to 20 points. The Consistency Points take into consideration the scores of all eight Person and Community Engagement dimensions; as noted above, the Pain Management dimension is not included in the scoring of this Domain. The final element of the scoring formula is the summation of the HCAHPS Base Score and the HCAHPS Consistency Points, which results in the Person and Community Engagement Domain score that ranges from 0 to 100 points.

We invited public comment on the proposed performance standards for the eight HCAHPS survey dimensions. We did not receive any public comments on these proposed performance standards, and are adopting the performance standards listed in the table below. These HCAHPS survey dimension performance standards have been updated from the FY 2018 IPPS/LTCH PPS proposed rule and represent the most recently available data.

NEWLY FINALIZED PERFORMANCE STANDARDS FOR THE FY 2020 PROGRAM YEAR: PERSON AND COMMUNITY ENGAGEMENT DOMAIN *±

HCAHPS survey dimension	Floor (percent)	Achievement threshold (percent)	Benchmark (percent)
Communication with Nurses	51.80	79.08	87.12
Communication with Doctors	50.67	80.41	88.44
Responsiveness of Hospital Staff	35.74	65.07	80.14
Communication about Medicines	26.16	63.30	73.86
Hospital Cleanliness & Quietness	41.92	65.72	79.42
Discharge Information	66.72	87.44	92.11
Care Transition	20.33	51.14	62.50
Overall Rating of Hospital	32.47	71.59	85.12

* We renamed this domain from Patient- and Caregiver-Centered Experience of Care/Care Coordination domain to Person and Community Engagement domain beginning with the FY 2019 program year, as discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56984).
± The performance standards displayed in this table were calculated using four quarters of CY 2016 data in this final rule.

c. Previously Adopted Performance Standards for Certain Measures for the FY 2021 Program Year

As discussed above, we have adopted certain measures for the Clinical Care and Efficiency and Cost Reduction domains for future program years in order to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49567), we adopted performance standards for the FY 2021 program year for the Clinical Care domain measures (THA/TKA, MORT–30–HF, MORT–30–AMI, and MORT–30–COPD). In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57008), we adopted performance standards for the MORT–30–PN (updated cohort) measure (81 FR 57008) and the AMI Payment and HF Payment measures for the FY 2021 program year. We note that the performance standards for the MSPB, AMI Payment, and HF Payment measures are based on performance period data; therefore, we are unable to provide numerical equivalents for the standards at this time. The previously adopted performance standards for these measures are set out in the table below.

PREVIOUSLY ADOPTED PERFORMANCE STANDARDS FOR THE FY 2021 PROGRAM YEAR

Measure short name	Achievement threshold	Benchmark
Clinical Care Domain		
MORT–30–AMI ±	0.860355	0.879714.
MORT–30–HF±	0.883803	0.906144.
MORT–30–PN (updated cohort)†	0.836122	0.870506.
MORT–30–COPD±	0.923253	0.938664.
THA/TKA*±	0.031157	0.022418.
Efficiency and Cost Reduction Domain		
MSPB *±	Median Medicare Spending Per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending Per Beneficiary ratios across all hospitals during the performance period.
AMI Payment *±	Median Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.	Mean of the lowest decile Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.
HF Payment *±	Median Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.	Mean of the lowest decile Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.

± Previously adopted performance standards.
* Lower values represent better performance.
† After publication of the FY 2017 IPPS/LTCH PPS final rule, we determined there was a display error in the performance standards for this measure. We have since undertaken a technical update for these performance standards in order to ensure that hospitals have the correct performance standards for the applicable performance period. The corrected performance standards are displayed here.

d. Previously Adopted and Newly Finalized Performance Standards for Certain Measures for the FY 2022 Program Year

As discussed above, we have adopted certain measures for the Clinical Care and Efficiency and Cost Reduction domains for future program years in order to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57009), we adopted performance standards for the FY 2022 program year for the Clinical Care domain measures (THA/TKA, MORT–30–HF, MORT–30–AMI, MORT–30–PN (updated cohort), MORT–30–COPD, and MORT–30–CABG) and the Efficiency and Cost Reduction domain measures (AMI Payment and HF Payment). In section V.J.4.a. of the preamble of the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19971 through 19973), we proposed to add one measure, the PN Payment

measure, beginning with the FY 2022 program year. We note that the performance standards for the MSPB, AMI Payment, HF Payment, and PN Payment measures are based on performance period data; therefore, we are unable to provide numerical equivalents for the standards at this time.

We invited public comment on the proposed performance standards for certain measures for the FY 2022 program year. We did not receive any public comments on the proposed PN Payment measure performance standards for the FY 2022 program year and are are adopting the performance standards listed in the table below. The previously adopted and newly finalized performance standards for these measures are set out in the table below.

The table below is up-to-date and represents the most recently available data.

PREVIOUSLY ADOPTED AND NEWLY FINALIZED PERFORMANCE STANDARDS FOR THE FY 2022 PROGRAM YEAR

Measure short name	Achievement threshold	Benchmark
Clinical Care Domain		
MORT–30–AMI ±	0.861793	0.881305.
MORT–30–HF ±	0.879869	0.903608.
MORT–30–PN (updated cohort) ±	0.836122	0.870506.
MORT–30–COPD ±	0.920058	0.936962.
MORT–30–CABG ±	0.968210	0.979000.
THA/TKA * ±	0.029833	0.021493.
Efficiency and Cost Reduction Domain		
MSPB * ±	Median Medicare Spending Per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending Per Beneficiary ratios across all hospitals during the performance period.
AMI Payment * ±	Median Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.	Mean of the lowest decile Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.
HF Payment * ±	Median Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.	Mean of the lowest decile Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.
PN Payment * #	Median Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.	Mean of the lowest decile Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.

± Previously adopted performance standards.

† After publication of the FY 2017 IPPS/LTCH PPS final rule, we determined there was a display error in the performance standards for this measure. Specifically, the Achievement Threshold and Benchmark values, while accurate, were presented in the wrong categories. We have corrected this issue in the table above, and the correct performance standards are displayed here.

* Lower values represent better performance.

Scored the same as the MSPB, AMI Payment, and HF Payment measures, as discussed in section V.J.4.a.(2) of the preamble of this final rule.

e. Performance Standards for Certain Measures for the FY 2023 Program Year

As discussed above, we have adopted certain measures for the Clinical Care and Efficiency and Cost Reduction domains for future program years in order to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19982 through 19983), we proposed the following performance standards for the FY 2023 program year for the Clinical Care domain measures (THA/TKA, MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, and MORT–30–CABG) and for the Efficiency and Cost Reduction domain measures (MSPB, AMI Payment, HF Payment, and the proposed PN Payment measure). Although we are finalizing our proposal to adopt the Patient Safety and Adverse Events (Composite) measure beginning with the FY 2023 program year, we do not currently have data available to calculate the performance standards; we therefore intend to propose the FY 2023 performance standards for this measure in next year's rulemaking. We note that the performance standards for the MSPB, AMI Payment, HF Payment, and PN Payment measures are based on performance period data; therefore, we are unable to provide numerical equivalents for the standards at this time. These newly proposed performance standards for these measures are set out in the table below.

We invited public comment on the proposed performance standards for certain measures for the FY 2023 program year. We did not receive any public comments on the proposed performance standards for the FY 2023 program year, and are adopting the performance standards listed below. The table below is up-to-date and represents the most recently available data.

NEWLY FINALIZED PERFORMANCE STANDARDS FOR THE FY 2023 PROGRAM YEAR

Measure short name	Achievement threshold	Benchmark
Clinical Care Domain		
MORT–30–AMI	0.866548	0.885499.
MORT–30–HF	0.881939	0.906798.
MORT–30–PN (updated cohort)	0.840138	0.871741.
MORT–30–COPD	0.919769	0.936349.
MORT–30–CABG	0.968747	0.979620.
THA/TKA *	0.027428	0.019779.
Efficiency and Cost Reduction Domain		
MSPB *	Median Medicare Spending Per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending Per Beneficiary ratios across all hospitals during the performance period.
AMI Payment *#	Median Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.	Mean of the lowest decile Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.
HF Payment *#	Median Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.	Mean of the lowest decile Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.
PN Payment *#	Median Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.	Mean of the lowest decile Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.

* Lower values represent better performance.
# Scored the same as the MSPB, AMI Payment, and HF Payment measures, as discussed in section V.J.4.a.(2) of the preamble of this final rule.

7. Scoring Methodology and Data Requirements for the FY 2019 Program Year and Subsequent Years

a. Domain Weighting for the FY 2020 Program Year and Subsequent Years for Hospitals That Receive a Score on All Domains

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49568 through 49570), we adopted equal weight of 25 percent for each of the four domains in the FY 2018 program year for hospitals that receive a score in all domains. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57009 through 57010), for the FY 2019 program year, we retained this domain weighting. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19983), we did not propose any changes to the domain weights for the FY 2018 and FY 2019 program years.

For the FY 2020 program year and subsequent years, we proposed to retain this same domain weighting for hospitals receiving a score on all four domains. The previously adopted domain weighting is summarized in the table below.

DOMAIN WEIGHTS FOR THE FY 2019 PROGRAM YEAR AND SUBSEQUENT YEARS FOR HOSPITALS RECEIVING A SCORE ON ALL DOMAINS

Domain	Weight (percent)
Safety	25
Clinical Care	25
Efficiency and Cost Reduction	25
Person and Community Engagement *	25

* We renamed this domain from Patient- and Caregiver-Centered Experience of Care/Care Coordination domain to Person and Community Engagement domain beginning with the FY 2019 program year, as discussed in section IV.H.3.b. of the FY 2017 IPPS/LTCH PPS final rule (81 FR 56984).

We invited public comment on this proposal.

Comment: A few commenters recommended that CMS remove the Efficiency and Cost Reduction domain from the Hospital VBP Program because commenters believe the domain is poorly defined and its only current measure, the MSPB measure, cannot be meaningfully interpreted. In the alternative, commenters recommended that CMS reduce the weighting of the Efficiency and Cost Reduction domain until the measures finalized for that domain are further defined and tested.

One commenter stated that the MSPB measure contains a substantial proportion of expense which is outside the influence or control of the hospital, and is not risk adjusted for clinical or social factors, for market resources, or for patient preference and decision-making and is, therefore, not appropriate for inpatient care. In addition, the commenter stated that because Medicare has very few 30-day episode payments benchmarked, this domain may not reflect performance on Medicare populations. The commenter therefore recommended CMS reduce the weight of the Efficiency and Cost Reduction domain as a whole and should focus on the episode payments which are most reliably manageable and suitable for influence and improvement by actions taken in the inpatient setting.

Response: As we stated in the FY 2014 IPPS/LTCH PPS final rule (79 FR 50048 through 50087), we believe we have appropriately balanced our desire to provide strong incentives for hospitals to consider both the cost and the quality of the care that they provide to Medicare beneficiaries by weighting the Efficiency and Cost Reduction domain at 25 percent of the TPS while the quality-focused domains encompass 75 percent of the TPS. We note that section 1886(o)(2)(B)(ii) of the Act requires that the Hospital VBP Program include efficiency measures, including measures of Medicare spending per beneficiary. We continue to believe the

Efficiency and Cost Reduction domain merits a significant portion of the TPS in order to ensure that hospitals monitor the costs of the care they provide to Medicare beneficiaries during the inpatient hospitalization and are involved in the coordination of beneficiaries' care immediately prior to a hospitalization and post-discharge. We believe based on the current Hospital VBP Program measure set that the Efficiency and Cost Reduction domain is appropriately weighted, and despite not directly addressing patient outcomes, this domain encourages hospitals to assess cost in conjunction with quality of care. We also believe that hospitals can effect change through the measures in each of the four domains in the Hospital VBP Program.

After consideration of the public comments we received, we are finalizing our proposal to retain the equal weight of 25 percent for each of the four domains in the FY 2020 program year and subsequent years for hospitals that receive a score in all domains.

b. Domain Weighting for the FY 2019 Program Year and Subsequent Years for Hospitals Receiving Scores on Fewer Than Four Domains

For the FY 2017 program year and subsequent years, we adopted a policy that hospitals must receive domain scores on at least three of four quality domains in order to receive a TPS, and hospitals with sufficient data on only three domains will have their TPSs proportionately reweighted (79 FR 50084 through 50085). In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19983), we did not propose any changes to these domain weights for the FY 2019 program year or subsequent years.

For a hospital to receive a TPS for the FY 2019 program year and subsequent years:

- Hospitals must report a minimum number of 100 completed HCAHPS surveys for a hospital to receive a Person and Community Engagement domain score.
- Hospitals must receive a minimum of one measure score within the Efficiency and Cost Reduction domain.
- Hospitals must receive a minimum of two measure scores within the Clinical Care domain.
- Hospitals must receive a minimum of two measure scores within the Safety domain.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19983 through 19984), we proposed two changes to our domain scoring policies for the FY 2019 program year and subsequent years. We proposed to change the minimum number of measures scores a hospital must receive to receive a score on the Safety domain from three measures to two measures. Second, we proposed that hospitals must receive a minimum of one measure score within the Efficiency and Cost Reduction domain to receive a domain score rather than requiring that hospitals meet the requirements to receive a MSPB measure score.

The proposed change to the Safety domain minimum number of measure scores was based on our proposal to remove the current PSI 90 measure from the Hospital VBP Program beginning with the FY 2019 program year. Based on our analyses, removing this measure but maintaining the requirement that a hospital receive three measure scores in order to receive a Safety domain score would have a significant impact on the number of hospitals eligible to receive a Safety domain score. Therefore, in order to include the greatest number of hospitals in the Hospital VBP Program possible while ensuring the need for TPSs to be sufficiently reliable, we proposed to reduce the minimum number of required measure scores within the Safety domain from three measures to two.

In addition, we note that we did not propose to reduce the number of measures a hospital must receive a score on in order to receive an Efficiency and Cost Reduction domain score. Under the current program requirements (79 FR 50086), a hospital must be eligible to receive a score on the MSPB measure in order to receive a score for this domain. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56987 through 56990 and 81 FR 56990 through 56992), we adopted two condition-specific payment measures, the AMI Payment and HF Payment measures, beginning with the FY 2021 program year, and as discussed in section V.J.4.a. of the preamble of this final rule in the FY 2018 IPPS/LTCH PPS proposed rule, we proposed to adopt one additional condition-specific payment measure, the PN Payment measure. We therefore proposed to require that hospitals must be eligible to receive a score on at least one measure within the Efficiency and Cost Reduction domain, rather than on the MSPB measure specifically, to reflect this expansion of the domain's measure set.

We believe these proposed changes reflect the evolution of the Hospital VBP Program measure set, and we continue to believe that these requirements appropriately balance our desire to enable as many hospitals as possible to participate in the Hospital VBP Program and the need for TPSs to be sufficiently reliable to provide meaningful distinctions between hospitals' performance on quality measures.

We invited public comment on these proposals.

Comment: A few commenters supported CMS' proposal to reduce the number of measures for which a hospital must have a score to receive a Safety domain score from three measures to two.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing our proposals to: Reduce the number of measures for which a hospital must have a score to receive a Safety domain score from three measures to two; and that hospitals must be eligible to receive a score on at least one measure within the Efficiency and Cost Reduction domain as proposed.

c. Minimum Numbers of Cases for Hospital VBP Program Measures for the FY 2019 Program Year and Subsequent Years

(1) Background

Section 1886(o)(1)(C)(ii)(IV) of the Act requires the Secretary to exclude for the fiscal year hospitals that do not report a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for the fiscal year. Under section 1886(o)(1)(C)(iii) of the Act, in determining the minimum number of reported cases for a given measure, the Secretary must conduct an independent analysis of what minimum numbers would be appropriate. For additional discussion of the previously finalized minimum numbers of cases for measures under the Hospital VBP Program, we refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26527 through 26531); the CY 2012 OPPS/ASC final rule (76 FR 74532 through 74534); the FY 2013 IPPS/LTCH PPS final rule (77 FR 53608 through 53609); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50085); the FY 2016 IPPS/LTCH PPS final rule (80 FR 49570); and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57011).

(2) Person and Community Engagement Domain

In the Hospital Inpatient VBP Program final rule (76 FR 26527 through 26531), we adopted a minimum number of 100 completed HCAHPS Surveys for a hospital to receive a score on the HCAHPS measure.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19984), we did not propose any changes to this policy.

(3) Clinical Care Domain

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74532 through 74534), we adopted a minimum number of 10 cases for the MORT–30–AMI, MORT–30–HF, and MORT–30–PN measures beginning with the FY 2014 program year. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53608 through 53609), we adopted a new minimum number of 25 cases for the MORT–30–AMI, MORT–30–HF, and MORT–30–PN measures for the FY 2015 program year. We adopted the same 25-case minimum for the MORT–30–COPD measure in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49570), and for the MORT–30–CABG, MORT–30–PN (updated cohort), and THA/TKA measures in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57011).

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19984), we did not propose any changes to these policies.

(4) Safety Domain

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53608 through 53609), we adopted a minimum of one predicted infection for NHSN-based surveillance measures (that is, the CAUTI, CLABSI, CDI, MRSA, and SSI measures) based on CDC's minimum case criteria. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50085), we adopted this case minimum for the NHSN-based surveillance measures FY 2016 Hospital VBP Program and subsequent years. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 26530), we adopted a minimum of 10 cases for the PC–01 measure.[73]

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19984), beginning with the FY 2023 program year, we proposed that hospitals must report a minimum of three eligible cases on any one underlying indicator during the baseline period in order to receive an improvement score and three eligible cases on any one underlying indicator during performance period in order to receive an achievement score on the Patient Safety and Adverse Events (Composite) measure. For the purposes of the Patient Safety and Adverse Events (Composite) measure, a case is ''eligible'' for a given indicator if it meets the criterion for inclusion in the indicator measure population. This minimum number of cases is based on AHRQ's methodology for scoring performance on the Patient Safety and Adverse Events (Composite) measure. We note that these proposed minimum data requirements for the Patient Safety and Adverse Events (Composite) measure are the same as those previously finalized for the current PSI 90 measure.

We invited public comment on our proposal regarding the minimum number of cases for the Patient Safety and Adverse Events (Composite) measure.

We did not receive any public comments on our proposal regarding the minimum number of cases for the Patient Safety and Adverse Events (Composite) measure, and are finalizing our proposal that hospitals must report a minimum of three eligible cases on any one underlying indicator during the baseline period in order to receive an improvement score and three eligible cases on any one underlying indicator during performance period in order to receive an achievement score on the Patient Safety and Adverse Events (Composite) measure.

(5) Efficiency and Cost Reduction Domain

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53609 through 53610), we adopted a minimum of 25 cases in order to receive a score for the MSPB measure. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50085 through 50086), we retained the same MSPB measure case minimum for the FY 2016 program year and subsequent years.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56987 through 56990 and 81 FR 56990 through 56992, respectively), we adopted the AMI Payment and HF Payment measures in the Efficiency and Cost Reduction domain for the FY 2021 program year and subsequent years. In section V.J.4.a. of the preamble of this final rule, we discuss our decision to adopt the PN Payment measure in the Efficiency and Cost Reduction domain for the FY 2022 program year and subsequent years. For these condition-specific payment measures (namely, the AMI Payment, HF Payment, and PN Payment measures), in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19984 through 19985), we proposed that hospitals must report a minimum number of 25 cases per measure in order to receive a measure score for the FY 2021 program year, FY 2022 program year, and subsequent years. We believe this minimum number of cases is appropriate because it balances our interest in allowing the maximum possible number of hospitals the opportunity to receive a score on the measure and maintaining sufficiently reliable scores. As we noted in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56992), we expect this case minimum will ensure that each hospital's payment measure rate is sufficiently reliable to generate a score that meaningfully distinguishes hospital performance on the measures. In addition, the statistical model that CMS uses to calculate the payment measures allows for the inclusion of hospitals with relatively few cases by taking into account the uncertainty associated with sample size.

We invited public comment on our proposal regarding the minimum number of cases for the AMI, HF, and PN Payment measures.

Comment: One commenter stated that requiring only 25 cases to calculate condition-specific payment measure scores for the AMI, HF, and PN Payment measures is insufficient for stable, reliable, and meaningful performance metrics.

Response: We disagree with the commenter that hospitals will not be able to report statistically reliable information on the PN Payment measure because we believe the case minimum will ensure that each hospital's payment measure rate is sufficiently reliable to generate a score that meaningfully distinguishes hospital performance on the measures. The statistical model that we use to calculate the payment measures allows for the inclusion of hospitals with relatively few cases by taking into account the uncertainty associated with sample size.

After consideration of the public comments we received, we are finalizing our proposal that hospitals must report a minimum number of 25 cases per measure in order to receive a measure score on the condition-specific payment measures as proposed.

(6) Summary of Previously Adopted and Newly Finalized Minimum Numbers of Cases for the FY 2019 Program Year and Subsequent Years

The previously adopted and newly finalized minimum numbers of cases for these measures are set forth in the table below.

[73] We note that the PC–01 measure was previously included in the Clinical Care—Process domain. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49553 through 49554), we re-categorized this measure as a Safety domain measure beginning with the FY 2018 program year.

PREVIOUSLY ADOPTED AND NEWLY FINALIZED MINIMUM CASE NUMBER REQUIREMENTS FOR THE FY 2019 PROGRAM YEAR AND SUBSEQUENT YEARS

Measure short name	Minimum number of cases
Person and Community Engagement Domain	
HCAHPS	Hospitals must report a minimum number of 100 completed HCAHPS surveys.
Clinical Care Domain	
MORT–30–AMI	Hospitals must report a minimum number of 25 cases.
MORT–30–HF	Hospitals must report a minimum number of 25 cases.
MORT–30–PN (updated cohort)	Hospitals must report a minimum number of 25 cases.
MORT–30–COPD	Hospitals must report a minimum number of 25 cases.
MORT–30–CABG	Hospitals must report a minimum number of 25 cases.
THA/TKA	Hospitals must report a minimum number of 25 cases.
Safety Domain	
CAUTI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
CLABSI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
Colon and Abdominal Hysterectomy SSI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
MRSA Bacteremia	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
CDI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
Patient Safety and Adverse Events (Composite)#	Hospitals must report a minimum of three eligible cases on any one underlying indicator.
PC–01	Hospitals must report a minimum of 10 cases.
Efficiency and Cost Reduction Domain	
MSPB	Hospitals must report a minimum number of 25 cases.
AMI Payment	Hospitals must report a minimum number of 25 cases.
HF Payment	Hospitals must report a minimum number of 25 cases.
PN Payment*	Hospitals must report a minimum number of 25 cases.

In section V.J.3.b. of the preamble of this final rule, we are finalizing our proposal to remove the current PSI 90 measure beginning with the FY 2019 program year. In section V.J.4.b. of the preamble of this final rule, we are finalizing our proposal to adopt the Patient Safety and Adverse Events (Composite) measure beginning with the FY 2023 program year.

* In section V.J.4.a. of the preamble of this final rule, we are finalizing our proposal to adopt the PN Payment measure beginning with the FY 2022 program year.

d. Weighting Measures Within the Efficiency and Cost Reduction Domain

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51618 through 51627), we adopted the MSPB measure for the Hospital VBP Program beginning with the FY 2015 program year. MSPB is the only cost measure in the Hospital VBP Program through the FY 2020 program year; as a result, hospitals' Efficiency and Cost Reduction domain scores are currently based solely on their MSPB measure scores. In the FY 2017 IPPS/LTCH PPS final rule, we adopted two condition-specific cost measures, the AMI Payment and HF Payment measures, beginning with the FY 2021 program year (81 FR 56987 through 56990 and 81 FR 56990 through 56992, respectively). In addition, as discussed in section V.J.4.a. of the preamble of this final rule, we are finalizing our proposal to adopt an additional condition-specific cost measure, the PN Payment measure, beginning with the FY 2022 program year. Based on this evolution of the Hospital VBP Program measure set, we believe it is appropriate to address measure score weighting within the Efficiency and Cost Reduction domain.

In determining how to weight measures in the Efficiency and Cost Reduction domain, we took into consideration hospitals' experience with the measures and the measures' ability to incentivize greater coordination among hospitals, physicians, and providers of post-acute care services to optimize the value of care they provide to Medicare beneficiaries. Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19985 through 19986), we proposed to weight the measures within the Efficiency and Cost Reduction domain such that the MSPB measure comprises 50 percent of a hospital's domain score and the other condition-specific payment measures, weighed equally, comprise the remaining 50 percent of a hospital's domain score, beginning with the FY 2021 program year and for subsequent years. We further proposed that:

- If a hospital meets the case minimum to receive a score on the MSPB measure but does not meet the minimum number of cases for any other measures in the Efficiency and Cost Reduction domain, its domain score will be based solely on its MSPB score;
- If a hospital does not meet the case minimum to receive a score on the MSPB measure but meets the minimum number of cases for any other measure or measures within the Efficiency and Cost Reduction domain, its domain score will be based on its scores on the other payment measures, weighted equally (that is, the MSPB measure's weight will be redistributed equally among the Efficiency and Cost Reduction domain measures for which the hospital is eligible receive a score); and
- If a hospital meets the case minimum to receive a score on the MSPB measure and one or more other measures within the Efficiency and Cost Reduction domain, but not all measures within this domain, the hospital's MSPB measure score will comprise 50 percent of its domain score and the remaining 50 percent will be divided equally among the measures for which the hospital is eligible to receive a score.

Under our proposed weighting scheme, a hospital's MSPB measure score could constitute between 12.5 percent and 25 percent of the hospital's TPS. We believe the proposed weighting is appropriate because the MSPB

measure is an overall spending measure and is therefore more broadly applicable than the condition-specific payment measures. In addition, hospitals have the most familiarity with this measure because it has been in the program the longest. We also considered proposing to weight all measures within the Efficiency and Cost Reduction domain equally. However, we determined this weighting may not reflect the broader applicability of the MSPB measure and its importance in ensuring that hospitals monitor the overall costs of care they provide to a larger subset of Medicare beneficiaries during an inpatient hospitalization and are involved in the coordination of beneficiaries' care immediately prior to hospitalization and post-discharge.

We invited public comment on these proposals.

Comment: Some commenters supported CMS' proposal to reweight the Efficiency and Cost Reduction domain to reflect the adoption of additional condition-specific payment measures. One commenter specifically supported CMS' proposal to reweight the Efficiency and Cost Reduction domain because these measures encourage providers to consider the resource use implications of their hospital and specialist referral patterns.

Response: We thank the commenters for their support.

Comment: A few commenters recommended that CMS weight all measures within the Efficiency and Cost Reduction domain equally, because these commenters believe doing so would enable hospitals to more easily improve performance in this domain by targeting cost reduction for specific conditions. One commenter noted the other measure domains in the Hospital VBP Program weight all measures equally within a given domain, and therefore recommended that CMS weight all measures within the Efficiency and Cost Reduction domain equally.

Response: While we acknowledge the commenter's concerns regarding the disproportionate weighting of the MSPB measure, we believe the fundamental differences between this measure and condition-specific payment measures justify weighting the MSPB measure higher in the Efficiency and Cost Reduction domain. The MSPB measure is an overall spending measure that has been in the Hospital VBP Program for many years. In addition, we note this weighting allocation actually reduces the total weight of the MSPB measure in hospitals' TPSs from 25 percent to 12.5 percent, depending upon whether the hospital is eligible to receive a score on one of the condition-specific payment measures.

Comment: Many commenters recommended that CMS not finalize its proposal to weight the MSPB measure at 50 percent of the Efficiency and Cost Reduction domain, noting that the measure double-counts payments captured in the condition-specific measures in the domain, the measure's comprehensiveness makes it difficult for hospitals to improve, and the recent ASPE report that noted deficiencies in the measure's current risk adjustment which may penalize providers for medical risk beyond the provider's control. Two commenters recommended that the MSPB measure should be removed from the program starting FY 2021, stating that reliance on condition-specific measures will ensure that payments are not double-counted and will make it easier for providers to implement targeted strategies to improve performance. At a minimum, commenters requested that the measure be equally weighted with the other episode of care payment measures.

Response: We thank the commenters for their recommendations. However, we note that section 1886(o)(2)(B)(ii) of the Act requires that the Hospital VBP Program ''include efficiency measures, including measures of 'Medicare spending per beneficiary.' '' While we agree the condition-specific payment measures will provide hospitals with important data on payments associated with an episode of care, we continue to believe the MSPB measure also provides hospitals with valuable information because this measure captures resource use data for a wide range of services provided in the inpatient hospital setting. We will continue to consider other future measures for the Efficiency and Cost Reduction domain, and encourage commenters to submit any fully developed measures for consideration for the Measures Under Consideration List as part of the pre-rulemaking process (details available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rule-Making.html*).

Comment: One commenter stated that weighting the HF and PN Payment measures together at 50 percent of the Efficiency and Cost Reduction domain in the FY 2021 program year gives these measures a significantly disproportionate weight in the overall calculation compared to other measures.

Response: We interpret commenter's reference to PN Payment in the FY 2021 program year to mean the AMI Payment measure finalized for that year alongside the HF Payment measure. While we recognize this proposed weighting results in the condition-specific payment measures represent between 12.5 percent and 6.25 percent, we believe this weight is appropriate for the condition-specific payment measures. The condition-specific payment measures, paired with their corresponding quality measures, are intended to serve as a larger assessment of value of care provided at a hospital. We therefore believe it is important to weight the measures in a manner that incentivizes hospitals to strive for continued improvement in this area.

Comment: One commenter recommended weighting the condition-specific payment measures at 20 percent of the Efficiency and Cost Reduction domain in order to mitigate the overlap between these measures and the MSPB measure, and to reduce the possibility of this overlap leading to mixed signals for hospitals regarding their resource use.

Response: We interpret commenter's recommendation to mean weighting the three condition-specific payment measures, combined, at 20 percent of the Efficiency and Cost Reduction domain, which represents 25 percent of a hospital's TPS. Assuming this position, under this recommendation, if a hospital were eligible to receive a score on all three condition-specific payment measures, these three measures would only represent five percent of the hospital's TPS. We believe weighting the condition-specific payments measures at 20 percent of the Efficiency and Cost Reduction domain does not afford the measures sufficient weight to drive an increased focus on the value of care provided at hospitals. However, we will continue to monitor the impact of weighting the measures within the Efficiency and Cost Reduction domain for unintended consequences.

After consideration of the public comments we received, we are finalizing our proposal to weight the measures within the Efficiency and Cost Reduction domain such that the MSPB measure comprises 50 percent of a hospital's domain score and the other condition-specific payment measures, weighed equally, comprise the remaining 50 percent of a hospital's domain score, beginning with the FY 2021 program year.

K. Changes to the Hospital-Acquired Condition (HAC) Reduction Program

1. Background

We refer readers to section V.I.1.a. of the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50708) for a general overview of the HAC Reduction Program. For a detailed discussion of

the statutory basis of the HAC Reduction Program, we refer readers to section V.I.2. of the FY 2014 IPPS/LTCH PPS final rule (78 FR 50708 through 50709). For a further description of our previously finalized policies for the HAC Reduction Program, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50729), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50087 through 50104), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49570 through 49581), and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57011 through 57026). These policies describe the general framework for implementation of the HAC Reduction Program, including: (a) The relevant definitions applicable to the program; (b) the payment adjustment under the program; (c) the measure selection process and conditions for the program, including a risk-adjustment and scoring methodology; (d) performance scoring; (e) the process for making hospital-specific performance information available to the public, including the opportunity for a hospital to review the information and submit corrections; and (f) limitation of administrative and judicial review.

We also have codified certain requirements of the HAC Reduction Program at 42 CFR 412.170 through 412.172.

2. Implementation of the HAC Reduction Program for FY 2018

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), we finalized the following Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) measures for Domain 2 for use in the FY 2015 program and subsequent years: CLABSI, CAUTI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57020), we finalized the use of the Patient Safety and Adverse Events Composite (PSI 90) measure for use in the FY 2018 program and subsequent years for Domain 1.

CMS strives to put patients first, ensuring they are empowered to make decisions about their own healthcare along with their clinicians using information from data-driven insights that are increasingly aligned with meaningful quality measures. We support technology that reduces burden and allows clinicians to focus on providing high-quality healthcare for their patients. We also support innovative approaches to improve quality, accessibility, and affordability of care while paying particular attention to improving clinicians' and beneficiaries' experience when interacting with CMS programs. In combination with other efforts across the Department of Health and Human Services, we believe the HAC Reduction Program helps to encourage hospitals to improve healthcare quality and value, while giving patients and providers the tools and information needed to make the best decisions for themselves. We recognize that the HAC Reduction Program represents a key component of the way that we bring quality measurement and improvement together with payment, we have taken efforts to review existing policies to identify how to move the program forward in the least burdensome manner possible while continuing to promote improvement in the quality of care provided to patients. These previously finalized measures are shown in the table below.

HAC REDUCTION PROGRAM MEASURES FOR FY 2018

Short name	Measure name	NQF #
Domain 1		
PSI 90	Patient Safety and Adverse Events Composite	0531
Domain 2		
CAUTI	NHSN Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure	0138
CDI	NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.	1717
CLABSI	NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure	0139
Colon and Abdominal Hysterectomy SSI.	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
MRSA Bacteremia	NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	1716

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57022), we finalized a 15-month performance period from July 1, 2014 through September 30, 2015, for the Domain 1 measure (PSI 90 Patient Safety and Adverse Events Composite) and a 24-month performance period from January 1, 2015 through December 31, 2016 (CYs 2015 and 2016) for Domain 2 measures (CLABSI, CAUTI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI) for the FY 2018 HAC Reduction Program. We anticipate we will be able to provide hospitals with their confidential hospital-specific reports and discharge level information used in the calculation of their FY 2018 Total HAC Score in late summer 2017 via the QualityNet Secure Portal.[74] In order to access their hospital-specific reports, hospitals must register for a QualityNet Secure Portal account.

We did not make any changes to the review and correction policies for FY 2017. Hospitals have a period of 30 days after the information is posted to the QualityNet Secure Portal to review and submit corrections for the calculation of their HAC Reduction Program measure scores, domain scores, and Total HAC Score for the fiscal year. As we have noted on the QualityNet Web site,[75] the review and corrections process does not allow hospitals to submit additional corrections related to the underlying claims data for the PSI 90 Composite, or to add new claims to the data extract used to calculate the results. In addition, under the Hospital IQR Program, hospitals have an opportunity to submit, review, and correct the chart-abstracted information used to calculate the CLABSI, CAUTI, Surgical Site Infection (SSI), MRSA, and CDI healthcare-associated infection (HAI)

[74] Available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetBasic&cid=1228773343598.*

[75] Available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228774298609.*

measures. The HAC Reduction Program's review and corrections process does not allow hospitals to correct: (1) Reported number of HAIs, (2) Standardized Infection Ratios (SIRs), or (3) reported central-line days, urinary catheter days, surgical procedures performed, or patient days. For further information related to the review and correction process we refer readers to the 2014 IPPS/LTCH PPS final rule (78 FR 50725 through 50728).

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50726), we stated that the HAC Reduction Program would use the same process as the Hospital IQR Program for hospitals to review and correct data for chart-abstracted measures in Domain 2. Under this process, hospitals can review and correct data they submit on all Hospital IQR Program chart-abstracted measures, whether or not the measures were adopted as a measure for the HAC Reduction Program. In that rule, we stated that under the Hospital IQR Program, hospitals had an opportunity to submit, review, and correct any of the chart-abstracted information for the full 4½ months following the last discharge date in a calendar quarter. To align with the Hospital IQR Program, we are clarifying the language used for reporting requirements for chart-abstracted measures. We note that NHSN requires that data be submitted on a monthly basis and CDC strongly encourages healthcare facilities to enter each month's data within 30 days of the end of the month in which it is collected so it has the greatest impact on infection prevention activities.

However, for purposes of fulfilling CMS quality measurement reporting requirements, each facility's data must be entered into NHSN no later than 4½ months after the end of the reporting quarter. We further note that NHSN data are reported based on when the event occurred, as opposed to when the patient was discharged. For data submitted for SSIs, facilities should include SSIs that are associated with procedures that were performed during the reporting time period. We refer readers to CDC Web site for additional resources and data submission requirements, which can be found at: *https://www.cdc.gov/nhsn/cms/index.html*.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19986 through 19990), for the HAC Reduction Program, we: (1) Proposed to specify the dates of the time period used to calculate hospital performance for the FY 2020 HAC Reduction Program; (2) requested comment on additional measures for potential future adoption; (3) requested comment on social risk factors; (4) requested comment on accounting for disability and medical complexity in the CDC NHSN measures in Domain 2; and (5) proposed to update the Extraordinary Circumstance Exception policy beginning in FY 2018 as related to extraordinary circumstances that occur on or after October 1, 2017. These proposals are described in more detail below.

3. Data Collection Time Periods for the FY 2020 HAC Reduction Program

Section 1886(p)(4) of the Act gives the Secretary the statutory authority to determine the ''applicable period'' during which data are collected for the HAC Reduction Program. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), we finalized and codified at 42 CFR 412.170 that we would use a 24-month data collection period of performance data to calculate the Total HAC Score. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57020), we finalized a truncated data collection period for Domain 1, shorter than the previous 24-month data collection period for calculating the Total HAC Score for the FY 2018 and FY 2019 HAC Reduction Programs, to accommodate the transition to the ICD–10 classification system. We also changed the definition of ''applicable period,'' in 42 CFR 412.170, to reflect this change.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19987), for the FY 2020 program, we proposed to return to a 24-month data collection period for the calculation of HAC Reduction Program measure results. We believe that using 24 months of data for both domains balances the needs of the program against the data-collection processes utilized by hospitals, and allows for sufficient time to process the claims data and calculate the measure results. The 24-month data collection period allows time to complete the complex calculation process for the measures, to perform comprehensive quality assurance to enhance the accuracy of measure results, and to disseminate confidential reports on hospital-level results to individual hospitals. For the Domain 1 measure (Patient Safety and Adverse Events Composite), we proposed to use the 24-month period from July 1, 2016 through June 30, 2018. The claims for all Medicare Fee-for-Service beneficiaries discharged during this period would be included in the calculations of measure results for Domain 1 for the FY 2020 program. For the CDC NHSN measures in Domain 2 (CLABSI, CAUTI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI), we proposed to use data from CYs 2017 and 2018, that is January 1, 2017–December 31, 2018, for the FY 2020 program.

Comment: Some commenters supported returning to a 24-month data collection period for all measures. However, a few commenters recommended adoption of a 12-month data collection period. These commenters stated that a shorter performance would provide hospitals with more timely information to develop quality improvement initiatives.

Response: We thank commenters for their support and we understand that reliable data is a critical component of accurately assessing hospital performance. We believe the 24-month data collection period supports our continued goal to minimize provider burden and incentivize high-quality care. As we noted in the 2014 IPPS/LTCH PPS final rule (78 FR 50717), we adopted the 24-month data collection period based on recommendations from AHRQ, the measure developer. An analysis of the recalibrated PSIs show that most PSIs included in the PSI 90 composite have at least moderate reliability, on average, using a 24-month time period. We continue to believe that the 24-month data collection period provides hospitals and the public the most reliable data available.

After consideration of the public comments we received, we are finalizing the Fiscal Year 2020 data collection period as proposed.

4. Request for Comments on Additional Measures for Potential Future Adoption

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25123), we welcomed public comment and suggestions for additional HAC Reduction Program measures. We believe that our continued efforts to reduce HACs are vital to improving patients' quality of care and reducing complications and mortality, while simultaneously decreasing costs. The reduction of HACs is an important marker of quality of care and has a positive impact on both patient outcomes and cost of care. Our goal for the HAC Reduction Program is to heighten the awareness of HACs and reduce the number of incidences that occur.

As part of our ongoing efforts to evaluate and strengthen the HAC Reduction Program, we are conducting a review of patient safety measures to include in Domain 1. We seek to adopt outcomes-focused patient-safety measures with an emphasis on topic areas including, but not limited to: Falls with injury, adverse drug events (ADEs),

glycemic events and ventilator associated events (VAEs). NQF identified these as gap areas for the HAC Reduction Program.[76]

We note that falls are frequent in the inpatient setting. An estimated 700,000 to 1 million inpatients fall each year in U.S. hospitals.[77] These falls can result in further health care complications for patients and add costs by increasing the need for expensive imaging, like head computed-tomography scans.[78] Risk assessment is the primary tool for preventing falls [79] and research has indicated that inpatient fall prevention programs with patient education components are effective in reducing fall rates.[80]

ADEs are a frequent and preventable occurrence among hospital inpatients. They pose serious threats to patient safety and can result in prolonged hospitalization, increased morbidity and higher health care costs.[81]

Glycemic events, a common occurrence among inpatients, are associated with a greater risk of negative health outcomes.[82] Many guidelines exist to support glycemic control in hospitalized patients. The most common guideline recommendations include documenting diabetes diagnoses, obtaining a hemoglobin A1C on admission, use of the ''basal-bolus'' method for insulin delivery, discontinuation of noninsulin agents for non-ICU patients with type 2 diabetes, and use of standardized order sets.[83]

Mechanically ventilated patients are at greater risk for VAEs, which can result in morbidity and death.[84] VAEs include ventilator associated pneumonia (VAP) and preventable adverse events, such as pulmonary edema and acute respiratory distress syndrome. VAP continues to rank among the most common HACs. Effective prevention strategies for VAP include early removal of invasive devices and strict infection control and prevention efforts to target these high-risk groups.[85]

Our overarching purpose is to support the National Quality Strategy's goals of better health care for individuals, better health for populations, and lower costs for health care.[86] To the extent practicable, HAC Reduction Program measures should be nationally endorsed by a multi-stakeholder organization. Measures should be aligned with best practices among other payers and the needs of the end users of the measures. Measures should consider widely accepted criteria established in medical literature.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19987 through 19988), we welcomed public comment and suggestions on these measure areas, as well as additional outcome-based patient-safety measures that will help achieve the program goals.

Comment: Many commenters recommended that CMS emphasize measures of patient safety by adopting outcomes-focused measures which include falls and injury, adverse drug effects, glycemic events, and ventilator associated events (VAEs). Commenters noted that future inclusion of these measures supports the National Quality Strategy three-part aim of better health for individuals, better health for populations, and lower costs for health.

Commenters also recommended that CMS concentrate on patient-focused measures that increase quality, reduce harm, and provide opportunities for payers and consumers to be prudent purchasers of clinical services. Specifically, commenters recommended that measures reflect clinical reality by accurately measuring the intended target, be usable by providers who can use the data to implement evidence-based practices to improve care, align with one another using standardized definitions, and represent only the most important health priorities.

Some commenters stated that measures should be integrated in interoperable EHRs, allowing for more comprehensive measurement and requiring no extra reporting effort. In addition, commenters recommended that CMS utilize measures that were fully tested and received NQF endorsement. Commenters believed that NQF endorsement was the most prominent standard which confirmed that measures reflected evidence-based care, were feasible to collect and report in a specific care setting, were clearly defined and usable, and met the highest standard of reliability and validity.

Commenters further requested that CMS avoid measure overlap with the Hospital VBP Program. Commenters requested that any new measure should also be included in the Hospital IQR Program and reported on *Hospital Compare* for one year and approved by the MAP before the measure is proposed.

Some commenters expressed concern that hospitals and other providers were required to report on hundreds of measures and recommended against the addition of any new measures. These commenters did not support the addition of VAE measures, noting a lack of data on VAEs' responsiveness to quality improvement initiatives. These commenters also expressed concern with measures that focused on ADE and glycemic events unless appropriate clinical data could be efficiently collected and reliance on administrative data could be avoided.

One commenter believed it would be prudent to delay the adoption of such measures until more interventional studies were published to bolster the evidence base and better inform healthcare providers how best to reduce VAEs. This commenter noted that the number of published papers that delineate risk factors (for example, sedation, fluids, high tidal volumes, acid suppression) and effective ways to reduce VAEs (for example, spontaneous awakening trials, spontaneous breathing trials, conservative fluid management) were growing, but the subject is not mature at this point.

Some commenters believed that adding more HAI measures could serve to dilute the focus on improvement efforts. Commenters noted that when additional measures were added, facilities were not able to prioritize the

[76] The National Quality Forum. NQF: MAP hospital Workgroup—materials. October 18, 2016 *http://www.qualityforum.org/Project Materials.aspx?projectID=75369.*

[77] Sonnad, S.S., S. Mascioli, J. Cunningham, and J. Goldsack. ''Do Patients Accurately Perceive their Fall Risk?'' Nursing, vol. 44, no. 11, 2014, pp. 58–62.

[78] Fields, J., T. Alturkistani, N. Kumar, A. Kanuri, D.N. Salem, S. Munn, and D. Blazey-Martin. ''Prevalence and cost of imaging in inpatient falls: the rising cost of falling.'' ClinicoEconomics and Outcomes Research, vol. 7, 2015, pp. 281–286.

[79] Callis, N. ''Falls Prevention: Identification of Predictive Fall Risk Factors.'' Applied Nursing Research, vol. 29, 2016, pp. 53–58.

[80] Lee, D.A., E. Pritchard, F. McDermott, and T. P. Haines. ''Falls Prevention Education for Older Adults during and After Hospitalization: A Systematic Review and Meta-Analysis.'' Health Education Journal, vol. 73, no. 5, 2014, pp. 530–544.

[81] Martins, A.C., F. Giordani, and S. Rozenfeld. ''Adverse Drug Events among Adult Inpatients: A Meta-Analysis of Observational Studies.'' Journal of Clinical Pharmacy and Therapeutics, vol. 39, no. 6, 2014, pp. 609–620.

[82] Kilpatrick, C.R., M.B. Elliott, E. Pratt, S.J. Schafers, M.C. Blackburn, K. Heard, J.B. Mcgill, M. Thoelke, and G.S. Tobin. ''Prevention of Inpatient Hypoglycemia with a Real-Time Informatics Alert.'' Journal of Hospital Medicine, vol. 9, no. 10, 2014, pp. 621–626.

[83] Maynard, G., K. Kulasa, P. Ramos, D. Childers, B. Clay, M. Sebasky, E. Fink, A. Field, M. Renvall, P.S. Juang, C. Choe, D. Pearson, B. Serences, and S. Lohnes. ''Impact of a hypoglycemia reduction bundle and a systems approach to inpatient glycemic management.'' Endocrine Practice, vol. 21, no. 4, 2015, pp. 355–367.

[84] Resetar, E., K.M. McMullen, A.J. Russo, J.A. Doherty, K.A. Gase, and K.F. Woeltje. Development, ''Implementation and Use of Electronic Surveillance for Ventilator Associated Events (VAE) in Adults.'' AMIA Annual Symposium Proceedings, 2014, pp. 1010–1017.

[85] Mendoza, C., and S. Patel. ''Antimicrobial Therapy for Hospital-Acquired Pneumonia.'' U.S. Pharmacist, vol. 41, no. 7, 2016, pp. HS11–15.

[86] About the National Quality Strategy, *https://www.ahrq.gov/workingforquality/about.htm#aims.*

infection-related events that were most relevant to the population served and services provided in their facilities. Commenters requested that CMS: Commit to the minimum number of measures needed to evaluate healthcare quality, outcomes, and value; use measures that are naturally derived from the delivery of patient care; align with nationally endorsed, evidence-based measures; focus on measures that target the most vital aspects of care, are usable, tailored to the patient population, and that offer opportunities to directly and positively impact patient outcomes; and collaborate with key healthcare stakeholders, including patients, payers, regulators, and providers, to coordinate efforts.

One commenter recommended two NQF-endorsed measures of glycemic control, Glycemic Control—Hypoglycemia (NQF #2363) and Glycemic Control—Hyperglycemia (NQF #2362). This commenter noted that hypoglycemia and hyperglycemia occur frequently in the inpatient setting, have a negative impact on patient outcomes, and increase costs. This commenter encouraged CMS to consider adding these measures because: Studies have identified that the bundling of specific therapies is effective at preventing glycemic events; protocols to reduce the risk of glycemic events have been identified, documented, and are available for implementation by hospitals; and credible data are available to assess the rate of hypoglycemia and hyperglycemia among hospitalized patients.

Some commenters recommended that CMS consider the addition of a Medication Safety Domain (Domain 3). To construct this domain, commenters suggested two measures which address sources of medication errors and related adverse events: Medication Reconciliation: Unintentional Medication Discrepancies (NQF #2456) and the Computerized Provider Order Entry (CPOE) Evaluation Tool. Medication Reconciliation: Unintentional Medication Discrepancies (NQF #2456) measures the rate of unintentional medication discrepancies per patient and is currently in use in the MARQUIS Multi-Center Medication Reconciliation Quality Improvement Study funded by AHRQ. The measure calls for a licensed pharmacist to create a gold standard preadmission medication list (PAML) for a sample of twenty-five adult inpatients per quarter; the PAML is compared to the medication list at admission and to the medication list upon discharge. Hospitals report the number of unintentional medication discrepancies identified between the PAML and the admission and discharge orders, resulting in a rate of unintentional medication discrepancies per patient. The Computerized Provider Order Entry (CPOE) Evaluation Tool, funded by AHRQ, is designed to test the ability of inpatient CPOE systems to alert prescribers to common, serious medication errors. In addition, the Tool is designed to help hospitals improve their use of clinical decision support to reduce adverse drug events and improve medication safety.

Noting a measures gap in maternity care, one commenter recommended the addition of two maternity safety measures: Cesarean Birth (PC–02) (NQF #0471), developed by The Joint Commission, and Unexpected Newborn Complications (NQF #0716), developed by the California Maternal Quality Care Collaborative. The commenter noted that cesarean births result in increased neonatal and maternal morbidities when compared to vaginal deliveries which, in turn, leads to increased cost of care. The Unexpected Newborn Complications measure was initially endorsed by NQF in 2011 and was recently revised to incorporate several improvements to the measure.

One commenter recommended that CMS adopt the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (NQF #0678) measure. This commenter noted that pressure ulcers/injuries exact a significant clinical and financial toll; pressure ulcers result in pain, delayed recovery, prolonged hospital stays, increased risk of sepsis, and even death. The commenter also noted published international guidelines for the prevention and treatment of pressure ulcers/injuries that specify emerging therapies as part of pressure ulcer/injury prevention. The commenter further noted that CMS has implemented this measure in the LTCH QRP, and it had been vetted by the NQF.

Finally, the commenter stated their belief that using this measure would add consistency across sites of care and would advance the CMS goal of harmonizing key measures across the continuum of care.

One commenter requested that CMS put a process or system in place to account for patient safety among children. Another commenter recommended CMS explore a measure for the use of antipsychotics for patients with dementia.

Response: We appreciate the commenters' input. Improving patient safety is the primary objective of the HAC Reduction Program. When considering measures for inclusion in the program, we assess measures that are currently available, risk-adjusted, and reflective of hospital performance. Endorsement by the NQF and input from the Measures Application Partnership (MAP) are also considered. Section 1886(p)(3) of the Act defines ''hospital acquired conditions'' and does not require that each measure we adopt for the HAC Reduction Program be endorsed by a national consensus building entity, or the NQF specifically. Under this provision, the Secretary has further authority to adopt non-NQF-endorsed measures. While we strive to adopt NQF-endorsed measures when possible, we believe consensus among affected parties can be achieved in other ways, including through the measure development process, stakeholder input via the TEP, broad acceptance and use of the measure, and public comments. We will take commenters' feedback into consideration for future measure selection and rulemaking.

5. Accounting for Social Risk Factors in the HAC Reduction Program

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19988 through 19989), we discussed the issue of accounting for social risk factors in the HAC Reduction Program. We understand that social risk factors such as income, education, race and ethnicity, employment, disability, community resources, and social support (certain factors of which are also sometimes referred to as socioeconomic status (SES) factors or socio-demographic status (SDS) factors) play a major role in health. One of our core objectives is to improve beneficiary outcomes, including reducing health disparities, and we want to ensure that all beneficiaries, including those with social risk factors, receive high quality care. In addition, we seek to ensure that the quality of care furnished by providers and suppliers is assessed as fairly as possible under our programs while ensuring that beneficiaries have adequate access to excellent care.

We have been reviewing reports prepared by the Office of the Assistant Secretary for Planning and Evaluation (ASPE)[87] and the National Academies of Sciences, Engineering, and Medicine on the issue of accounting for social risk factors in CMS' quality measurement and payment programs, and considering options on how to address the issue in these programs. On December 21, 2016, ASPE submitted a report to Congress on

[87] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

a study it was required to conduct under section 2(d) of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. The study analyzed the effects of certain social risk factors in Medicare beneficiaries on quality measures and measures of resource use used in one or more of nine Medicare value-based purchasing programs, including the HAC Reduction Program.[88] The report also included considerations for strategies to account for social risk factors in these programs. In a January 10, 2017 report released by the National Academies of Sciences, Engineering, and Medicine, that body provided various potential methods for measuring and accounting for social risk factors, including stratified public reporting.[89]

As noted in the FY 2017 IPPS/LTCH PPS final rule, the NQF undertook a 2-year trial period in which certain new measures, measures undergoing maintenance review, and measures endorsed with the condition that they enter the trial period were assessed to determine whether risk-adjustment for selected social risk factors was appropriate for these measures. This trial entailed temporarily allowing inclusion of social risk factors in the risk-adjustment approach for these measures. The trial has concluded, and NQF will issue recommendations regarding the future inclusion of social risk factors in risk-adjustment for these quality measures, and we will closely review its findings.

We note that measures in the HAC Reduction Program, generally, represent never events,[90] and are often preventable conditions like central line associated bloodstream infections, catheter associated urinary tract infections, and other complications or conditions that arise after a patient was admitted to the hospital for the treatment of another condition. We believe these events should not be influenced by social risk factors; instead, they are risk-adjusted for factors listed in specifications for the AHRQ and CDC developed measures. Currently, risk factors such as the patient's age, gender, comorbidities, and complications are considered in the calculation of the measure rates so that they account for the clinical differences in the patients served by hospitals. Our measures continually undergo maintenance to determine the need for updated specifications, and to monitor for trends and any relevant risk-adjustment changes needed for the measures. We remind readers that, beginning for payments made in FY 2018, we adopted the modified PSI 90: Patient Safety and Adverse Events Composite (NQF #0531); the composite was revised to reflect the relative importance and harm associated with each component indicator, and to provide a more reliable and valid signal of patient safety events (81 FR 57020). We also adopted a continuous scoring approach in the HAC Reduction Program that brings our scoring domains into alignment with each other, essentially eliminates ties in Total HAC scores, reduces effects on outliers, and enhances the ability to distinguish among hospitals of varying quality (81 FR 57025).

As we continue to consider the analyses and recommendations from these reports and await the results of the NQF trial on risk-adjustment for quality measures, we are continuing to work with stakeholders in this process. As we have previously communicated, we are concerned about holding providers to different standards for the outcomes of their patients with social risk factors because we do not want to mask potential disparities or minimize incentives to improve the outcomes for disadvantaged populations. Keeping this concern in mind, we continue to seek public comment on whether we should account for social risk factors in the HAC Reduction Program and, if so, what method or combination of methods would be most appropriate for accounting for social risk factors. Examples of methods include: Adjustment of the payment adjustment methodology under the HAC Reduction Program; adjustment of provider performance scores (for instance, stratifying providers based on the proportion of their patients who are dual eligible); confidential reporting of stratified measure rates to providers; public reporting of stratified measure rates; risk-adjustment of a particular measure as appropriate based on data and evidence; and redesigning payment incentives (for instance, rewarding improvement for providers caring for patients with social risk factors or incentivizing providers to achieve health equity).

We note that in section V.I.9. of the preamble of this final rule, we discuss considerations for stratifying hospitals into peer groups for purposes of assessing payment adjustments under the Hospital Readmissions Reduction Program, as required under the 21st Century Cures Act. We refer readers to that section for a detailed discussion of these alternatives; while this discussion and corresponding proposal are specific to the Hospital Readmissions Reduction Program, they reflect the level of analysis we would undertake when evaluating methods and combinations of methods for accounting for social risk factors in CMS' other value-based purchasing programs, such as the HAC Reduction Program. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19989), we sought comment on whether any of these methods should be considered, and if so, which of these methods or combination of methods would best account for social risk factors in the HAC Reduction Program.

In addition, in the proposed rule, we sought public comment on which social risk factors might be most appropriate for stratifying measure scores and/or potential risk-adjustment of a particular measure. Examples of social risk factors include, but are not limited to, dual eligibility/low-income subsidy, race and ethnicity, and geographic area of residence. We also sought comments on which of these factors, including current data sources where this information would be available, could be used alone or in combination, and whether other data should be collected to better capture the effects of social risk. We will take commenters' input into consideration as we continue to assess the appropriateness and feasibility of accounting for social risk factors in the HAC Reduction Program. We note that any such changes would be proposed through future notice-and-comment rulemaking.

We look forward to working with stakeholders as we consider the issue of accounting for social risk factors and reducing health disparities in CMS programs. Of note, implementing any of the above methods would be taken into consideration in the context of how this and other CMS programs operate (for example, data submission methods, availability of data, statistical considerations relating to reliability of

[88] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[89] National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

[90] The term ''Never Event'' was first introduced in 2001 by Ken Kizer, MD, former CEO of the National Quality Forum (NQF), in reference to particularly shocking medical errors (such as wrong-site surgery) that should never occur. Over time, the list has been expanded to signify adverse events that are unambiguous (clearly identifiable and measurable), serious (resulting in death or significant disability), and usually preventable. The NQF initially defined 27 such events in 2002. The list has been revised since then, most recently in 2011, and now consists of 29 events grouped into 6 categories: Surgical, product or device, patient protection, care management, environmental, radiologic, and criminal. Never Events, *https://psnet.ahrq.gov/primers/primer/3/never-events*, accessed on February 22, 2017.

data calculations, among others), so we also welcomed comment on operational considerations. CMS is committed to ensuring its beneficiaries have access to and receive excellent care, and the quality of care furnished by providers and suppliers is assessed fairly in CMS programs.

Comment: Many commenters expressed concern that hospitals caring for large numbers of disadvantaged patients are more likely to receive penalties in the value-based programs. Commenters suggested that the lack of adjustment for social factors can worsen health care disparities because the penalties divert resources away from hospitals and other providers treating large proportions of vulnerable patients. Commenters recommended socio-demographic factors should be included in the HAC Reduction Program's risk-adjustment methodology to ensure the measures accurately reflect quality outcomes within a hospital's control. Commenters suggested that social and economic conditions within the patient population influence the health of the patients when they arrive to the hospital and impact whether patients acquire HACs.

Other commenters supported the inclusion of factors such as: Socioeconomic position (for example dual eligible status, income, and education); race, ethnicity and cultural context; gender; social relationships (for example marital status); residential and community context (for example, housing, walkability, transportation options, and proximity to services); and health literacy. Commenters further recommended that CMS stratify hospitals into peer groups so that hospitals are compared to others with a similar patient mix or grouping such as bed size. Commenters further recommended that, in addition to adjusting payments based on social risk factors, CMS should adjust the measures for public reporting. Commenters noted that failure to adjust measures for public reporting provides an inadequate picture to consumers about provider quality.

Commenters also recommended that CMS examine the National Academies of Sciences, Engineering, and Medicine report for examples of currently available data that could be included in measure risk-adjustment. Some commenters recommended CMS closely examine the considerations provided by National Association of Medicine (NAM) for risk-adjustment. NAM recommended four domains of risk indicators: Income, education, and dual eligibility; race, ethnicity, language, and nativity; marital/partnership status and living alone; and neighborhood deprivation, urbanicity, and housing. NAM found community-level elements that providers are not able to change can indicate risk unrelated to quality of care; this finding is also being reported in the growing body of research on socioeconomic risk-adjustment. Commenters recommended that CMS work closely with the relevant medical societies with the goal of incorporating appropriate social risk factors into quality measures as soon as possible.

Some commenters recommended that CMS consider the use of confidential patient-reported data because these offer a reasonably valid estimate of differences in utilization of health care between socioeconomic groups. Commenters requested that CMS consider providing hospitals with confidential reports of performance on accountability measures stratified by dual eligible status or other nationally available data elements. Once hospitals have had sufficient opportunity to review and understand their performance on these stratified measures, the commenters suggested that CMS work with stakeholders to publicly report this data in an appropriate fashion. Commenters further recommended the implementation of demonstration projects to encourage hospitals to collect data on social risk factors through their electronic health records (EHR). Commenters noted that where meaningful and comprehensive neighborhood level socio-demographic data currently exists, CMS should encourage empirical tests of quality metrics adjusted for those factors to assess the impact of those adjustments on local provider performance metrics. Commenters further recommended including functional status (activities of daily living, instrumental activities of daily living, and mobility) as a risk-adjustment variable to accurately assess patients across settings.

In addition, commenters specifically suggested that CMS stratify hospitals into peer groups so that hospitals would be compared to others with a similar patient mix or grouping, such as number of patient beds.

Some commenters did not support changing payment policies to risk-adjust for social risk factors. Commenters noted that this approach would not address the underlying disparities often associated with poor health outcomes. Instead, these commenters maintained, it would mask potential disparities or minimize incentives to improve the outcomes for disadvantaged populations. Commenters suggested that adjusting for socioeconomic and socio-demographic risk factors would create perverse incentives for poor performers to continue with the status quo and for high performers to retreat from their efforts to address disparities in high socioeconomic status populations. There was also a concern that risk-adjusting for social risk factors would not address the underlying disparities often associated with poor health outcomes and could mask potential disparities.

Commenters suggested that it was unacceptable for patients with social risk factors to experience never events, or a higher incidence of other serious events assessed by patient safety measures. Commenters stated that safe care should be a consistent and universal expectation for all patients. Commenters noted this position has also been taken by the NQF; patient safety measures were not included in the two-year trial period. Commenters recommended that CMS continue to collect a variety of data that could be analyzed over a 2-year period to establish a baseline that identifies how social risk factors impact populations and appropriately weigh those factors when measuring HACs.

Response: We appreciate the recommendations from the commenters about consideration of socioeconomic position; race, ethnicity and cultural context; gender; social relationships; residential and community context; and health literacy and will work to determine the feasibility of collecting these patient-level variables. We also will consider whether we should stratify hospitals into peer groups so that hospitals are compared to others with a similar patient mix or grouping such as number of beds.

We intend to explore options including, but not limited to, measure stratification by social risk factors in a consistent manner across programs, informed by considerations of stratification methods described in section IX.A.13. of the preamble of this final rule. We thank the commenters for this important feedback and will continue to consider options to account for social risk factors that would allow us to view disparities and potentially incentivize improvement in care for patients and beneficiaries. We also will consider providing feedback to providers on outcomes for individuals with social risk factors in confidential reports. As we consider the feasibility of collecting patient-level data and the impact of strategies to account for social risk factors through further analysis, we will continue to evaluate the reporting burden on providers. We also will consider the concerns commenters

raised about masking disparities associated with adjusting for social risk factors. Future proposals would be made after further research and continued stakeholder engagement.

We thank the commenters, and we will consider their views as we develop further policy regarding social risk factors in the HAC Reduction Program.

6. Request for Comments on Inclusion of Disability and Medical Complexity for CDC NHSN Measures

The intent of the HAC Reduction Program is to encourage all hospitals to reduce the incidence of HACs. We continue to believe that there is room for improvement in the incidence of HACs, regardless of the institution or hospital. The measures adopted in the HAC Reduction Program, which are risk-adjusted to account for the different patient populations that hospitals service, target important quality improvement areas. In its IMPACT Act report,[91] ASPE suggested payment strategies to improve the HAC Reduction Program. ASPE noted that it is well-proven that higher levels of medical risk are associated with a higher risk for many (although not all) patient safety events, particularly infections.[92] For example, diabetes is associated with roughly 70 percent higher odds of surgical site infections and diabetes, pulmonary disease, renal failure, and exposure to nursing homes are associated with a higher risk of MRSA.[93] Many of the same medical factors also confer a higher risk of *C. diff.* infection, as well as CAUTI and CLABSI.[94]

ASPE suggested that patient-level clinical data from the CDC healthcare-associated infection (HAI) measures should be examined and considered for additional risk-adjustment.[95] ASPE also noted that the clinical risk-adjustment of the patient safety and hospital-acquired infection measures should be improved to ensure the measures adequately adjust for differences in patients' clinical risk, so that fair comparisons for hospital accountability and performance assessment can be made to hold providers to the same fair standard.[96] ASPE recommended additional analyses for measure developers such as AHRQ and CDC to determine whether adjusting key components of the patient safety or HAI measures (for example frailty, functional limitations, prior hospitalizations or nursing home residence, or other markers of immune system deficiencies or unmeasured medical complexity) may better account for susceptibility to infection and patient safety events.[97]

Based on ASPE's analysis and considerations, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19899), we requested stakeholder feedback on risk-adjusting the CDC NHSN measures for disability or medical complexity. Although we did not propose any specific changes to the measures in the proposed rule, we will consider all comments as a guide to potential future action.

Comment: Many commenters supported the adjustment of the CDC NHSN measures to account for patient medical complexity. Commenters agreed that patients with certain medical conditions (for example, diabetes, pulmonary disease, adrenal failure) are at higher risk for infection, and that frailty and functional limitations are risk factors for some patient safety events. Commenters noted the complex linkages between socioeconomic factors and performance in the HAC Reduction Program; the program's measures, healthcare-associated infections (HAIs), and serious safety events largely reflect actions within a hospital's control. This contrasts with other outcome measures such as readmissions, cost or patient experience, where socioeconomic factors like poverty and access issues can affect outcomes. Commenters agreed with the findings of the ASPE report that patient disability and complexity have a significant impact on patient outcomes, and may not be adequately captured in the current measures.

Commenters encouraged CMS to work with CDC on gathering additional data on medical complexity for further evaluation as part of improved risk-adjustment as well as being able to trend the risks associated with infections for use in prevention strategies. Commenters recommended that any adjustments to the CDC NHSN measures should come directly from CDC based on their experience, testing, and feasibility of accurately obtaining the additional data.

One commenter recommended that CMS examine whether there are any broader community environmental factors that may impact a patient's risk for infections or other complications. For example, poorer communities can have environmental pollution, reduced access to resources to manage chronic conditions, and food deserts that impact nutrition. One commenter suggested that exposure to nursing homes increased the risk for infection, and urged CMS to consider this as a factor. Another commenter recommended that CMS adopt risk factors that can be extracted from EHRs or claims data rather than chart abstraction.

Response: We thank the commenters and we will consider their views as we develop further policy regarding risk-adjusting the CDC NHSN measures for disability or medical complexity in the HAC Reduction Program. We also appreciate the suggestion to examine whether broader community environmental factors have a differential bearing on the healthcare-associated infection (HAI) outcome measures. While community environmental factors are a plausible contributor to differential risks for HAIs, we are not aware of empirical data that establishes an association or associations. We will continue to partner with CDC to analyze whether we should include additional patient risk factors, preexisting or coexisting conditions, community environmental exposures or healthcare exposures to the CDC NHSN measures.

7. Extraordinary Circumstance Exception (ECE) Policy for the HAC Reduction Program

Many of our quality reporting and value-based purchasing programs share a common process for requesting an exception from program reporting due to an extraordinary circumstance not within a provider's control. The Hospital IQR, Hospital OQR, IPFQR, ASCQR, and PCHQR Programs, as well as the Hospital Readmissions Reduction Program, share common processes for Extraordinary Circumstance Exception (ECE) requests. In reviewing the policies for these programs, we recognized that there are five areas in which these programs have variance regarding ECE requests. These are: (1) Allowing the facilities or hospitals to submit a form signed by the facility's or hospital's CEO versus CEO or designated personnel; (2) requiring the form be submitted within 30 days following the date that the extraordinary circumstance occurred versus within 90 days following the date the extraordinary circumstance occurred; (3) inconsistency regarding specification of a timeline for us to provide our formal response notifying the facility or hospital of our decision; (4) inconsistency regarding specification of our authority to grant ECEs due to CMS data system issues; and (5)

[91] ASPE, ''Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.'' 21 Dec 2016. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[92] *Ibid.* 102.

[93] *Ibid.* 102.

[94] *Ibid.* 102.

[95] *Ibid.* 135.

[96] *Ibid.* 136.

[97] *Ibid.* 136.

referring to the program as ''extraordinary extensions/exemptions'' versus as ''extraordinary circumstances exceptions.'' We believe addressing these five areas, as appropriate, can improve administrative efficiencies for affected facilities or hospitals.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49579 through 49581), we adopted an ECE policy for the HAC Reduction Program beginning in FY 2016. This policy was similar to the ECE policy for the Hospital IQR Program, as finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651), modified in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836) (designation of a non-CEO hospital contact), and further modified in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277) (amended 42 CFR 412.140(c)(2) to refer to ''extension or exemption'' instead of the former ''extension or waiver''). In section IX.A.15. of the preamble of this final rule, we discuss our proposal to amend the Hospital IQR Program regulations at 42 CFR 412.140(c)(2) to refer to ''extraordinary circumstances exceptions'' and we will continue to use this nomenclature for the HAC Reduction Program.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19990), we proposed to modify the ECE policy for the HAC Reduction Program by: (1) Allowing the facility to submit a form signed by the facility's CEO or designated personnel; (2) specifying that we will strive to provide our formal response notifying the facility of our decision within 90 days of receipt of the facility's request; and (3) specifying that CMS may grant ECEs due to CMS data system issues which affect data submission. These proposed modifications generally align with policies in the Hospital IQR Program (76 FR 51651 through 51652; 78 FR 50836 through 50837; and 81 FR 57181 through 57182), the Hospital OQR Program (77 FR 68489 and 81 FR 79795), as well as other quality reporting programs. We proposed that these modifications would apply beginning in FY 2018 as related to extraordinary circumstances that occur on or after October 1, 2017.

We note that there may be circumstances in which it is not feasible for a facility's CEO to sign the ECE request form. In these circumstances, we believe that facilities affected by such circumstances should be able to submit ECE forms regardless of the CEO's availability to sign. Therefore, the first proposed modification would allow any hospital to designate an appropriate, non-CEO, contact at its discretion. This individual would be responsible for the submission, and would be the one signing the form. We would accept ECE forms which have been signed by designated personnel.

We also believe that it is important for facilities to receive timely feedback regarding the status of ECE requests. We strive to complete our review of each ECE request as quickly as possible. However, we recognize that the number of requests we receive, and the complexity of the information provided impacts the actual timeframe to make ECE determinations. To improve transparency of our process, we believe it is appropriate to clarify that we will strive to provide our response within 90 days of receipt.

Although we do not anticipate this situation will happen on a regular basis, there may be times where CMS experiences issues with its data systems that directly affects facilities' abilities to submit data. In these cases, we believe it would be inequitable to require facilities to report. Therefore, we proposed to allow CMS to grant ECEs to facilities if we determine that a systemic problem with one of our data collection systems directly affected the ability of the facilities to submit data. If we make the determination to grant ECEs, we proposed to communicate this decision through routine communication channels.

We invited public comment on these proposed modifications to the HAC Reduction Program's ECE policy.

Comment: Commenters supported the proposals to modify the extraordinary circumstances exceptions (ECE) policies to align across CMS quality reporting and value-based purchasing programs. One commenter recommended CMS communicate to other agencies when transmission or submission of data to CMS is affected so deadlines imposed by those agencies can be adjusted. One commenter further recommended that if dual eligible hospitals or providers are submitting eCQMs and Attestation data through the CMS portal, CMS work with and instruct State Medicaid agencies to accept the data from CMS regardless of deadlines or time frames, if reasonable. In addition, some commenters recommended a definition that includes circumstances of a health-related nature that make it more difficult to provide patient care, such as disease outbreaks, epidemics, drug or vaccine shortages.

Response: We appreciate the commenters' recommendations and we will take them into consideration as we determine operational decisions. As we discussed in the 2016 IPPS/LTCH PPS final rule (80 FR 49581), based on our experience with the Hospital VBP Program and the Hospital IQR Program, we anticipate providing exemptions to only a small number of hospitals where the ability to accurately or timely submits claims has been directly impacted as a direct result of experiencing a significant disaster or other extraordinary circumstance beyond the control of the hospital. We do not intend to modify the criteria for an extraordinary circumstance exception at this time.

Comment: A few commenters noted that there is currently no ECE policy for Indian Health Service or Tribally-operated programs, although tribal programs have requested an exception from CMS in previous fiscal years. Commenters requested an ECE specifically for IHS and tribal healthcare programs.

Response: We appreciate the commenters' concern; however, we note that sections 1886(p)(2)(A) and (B) of the Act defines applicable hospitals and requires all subsection (d) hospitals to be included in the HAC Reduction Program. The ECE policy was not designed to allow a category of hospital to seek exclusion from the HAC Reduction Program in its entirety, but to provide relief for a hospital whose ability to accurately collect quality measure data and/or to report those data in a timely manner has been negatively impacted as a direct result of experiencing a significant disaster or other extraordinary circumstance beyond the control of the hospital.

After consideration of the public comments we received we are finalizing the modifications to the Extraordinary Circumstances Exception (ECE) policy as proposed.

8. Maintenance of Technical Specifications for Quality Measures

Technical specifications for Patient Safety and Adverse Events Composite Measure in Domain 1 can be found at AHRQ's Web site at: *http://qualityindicators.ahrq.gov/Modules/PSI_TechSpec.aspx*. Technical specifications for the CDC NHSN HAI measures in Domain 2 can be found at CDC's NHSN Web site at: *http://www.cdc.gov/nhsn/acute-care-hospital/index.html*. Both Web sites provide measure updates and other information necessary to guide hospitals participating in the collection of HAC Reduction Program data.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50100), we described a policy under which we use a subregulatory process to make nonsubstantive updates to measures used for the HAC Reduction Program. In the FY 2018 IPPS/LTCH PPS proposed

rule (82 FR 19989), we did not propose any changes to this policy at this time.

L. Rural Community Hospital Demonstration Program

1. Introduction

The Rural Community Hospital Demonstration was originally authorized for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), and extended for another 5-year period by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148). Subsequently, section 15003 of the 21st Century Cures Act (Pub. L. 114–255), enacted December 13, 2016, amended section 410A of Public Law 108–173 to require a 10-year extension period (in place of the 5-year extension required by the Affordable Care Act, as further discussed below). Section 15003 also requires that no later than 120 days after enactment of Public Law 114–255 the Secretary must issue a solicitation for applications to select additional hospitals to participate in the demonstration program for the second 5 years of the 10-year extension period so long as the maximum number of 30 hospitals stipulated by the Affordable Care Act is not exceeded. In this final rule, we provide a summary of the previous legislative provisions and their implementation; a description of the provisions of section 15003 of Public Law 114–255; our proposals and final policies for implementation; and our proposals and finalized policies for budget neutrality, including a discussion of the budget neutrality methodology used in previous final rules, the budget neutrality methodology for the extension period authorized by section 15003 of Public Law 114–255, and the reconciliation of actual and estimated costs of the demonstration for previous years (2011, 2012, and 2013).

2. Background

Section 410A(a) of Public Law 108–173 required the Secretary to establish a demonstration program to test the feasibility and advisability of establishing ''rural community'' hospitals to furnish covered inpatient hospital services to Medicare beneficiaries. The demonstration pays rural community hospitals under a reasonable cost-based methodology for Medicare payment purposes for covered inpatient hospital services furnished to Medicare beneficiaries. A rural community hospital, as defined in section 410A(f)(1), is a hospital that—

- Is located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act;
- Has fewer than 51 beds (excluding beds in a distinct part psychiatric or rehabilitation unit) as reported in its most recent cost report;
- Provides 24-hour emergency care services; and
- Is not designated or eligible for designation as a CAH under section 1820 of the Act.

Section 410A(a)(4) of Public Law 108–173 specified that the Secretary was to select for participation no more than 15 rural community hospitals in rural areas of States that the Secretary identified as having low population densities. Using 2002 data from the U.S. Census Bureau, we identified the 10 States with the lowest population density in which rural community hospitals were to be located in order to participate in the demonstration: Alaska, Idaho, Montana, Nebraska, Nevada, New Mexico, North Dakota, South Dakota, Utah, and Wyoming (Source: U.S. Census Bureau, Statistical Abstract of the United States: 2003).

CMS originally solicited applicants for the demonstration in May 2004; 13 hospitals began participation with cost reporting periods beginning on or after October 1, 2004. In 2005, 4 of these 13 hospitals withdrew from the demonstration program and converted to CAH status. This left 9 hospitals participating at that time. In 2008, we announced a solicitation for up to 6 additional hospitals to participate in the demonstration program. Four additional hospitals were selected to participate under this solicitation. These 4 additional hospitals began under the demonstration payment methodology with the hospitals' first cost reporting period starting on or after July 1, 2008. At that time, 13 hospitals were participating in the demonstration.

Five hospitals (3 of the hospitals were among the 13 hospitals that were original participants in the demonstration program and 2 of the hospitals were among the 4 hospitals that began the demonstration program in 2008) withdrew from the demonstration program during CYs 2009 and 2010. In CY 2011, one hospital that was among the original set of hospitals that participated in the demonstration withdrew from the demonstration. These actions left 7 of the originally participating hospitals (that is, hospitals that were selected to participate in either 2004 or 2008) participating in the demonstration program as of June 1, 2011.

Sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148) amended section 410A of Public Law 108–173, changing the Rural Community Hospital Demonstration Program in several ways. First, the Secretary was required to conduct the demonstration program for an additional 5-year period, to begin on the date immediately following the last day of the initial 5-year period. Further, the Affordable Care Act required, in the case of a rural community hospital participating in the demonstration program as of the last day of the initial 5-year period, the Secretary to provide for the continued participation of such rural community hospital in the demonstration program during the 5-year extension period, unless the hospital made an election to discontinue participation.

In addition, the Affordable Care Act required that, during the 5-year extension period, the Secretary shall expand the number of States with low population densities determined by the Secretary to 20. Further, the Secretary was required to use the same criteria and data that the Secretary used to determine the States for purposes of the initial 5-year period. The Affordable Care Act also allowed not more than 30 rural community hospitals in such States to participate in the demonstration program during the 5-year extension period.

We published a solicitation for applications for additional participants in the Rural Community Hospital Demonstration program in the **Federal Register** on August 30, 2010 (75 FR 52960). The 20 States with the lowest population density that were eligible for the demonstration program were: Alaska, Arizona, Arkansas, Colorado, Idaho, Iowa, Kansas, Maine, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Utah, and Wyoming (Source: U.S. Census Bureau, Statistical Abstract of the United States: 2003). Sixteen new hospitals began participation in the demonstration with the first cost reporting period beginning on or after April 1, 2011.

In addition to the 7 hospitals that were selected in either 2004 or 2008, the new selection led to a total of 23 hospitals in the demonstration. During CY 2013, one additional hospital among the set selected in 2011 withdrew from the demonstration, which left 22 hospitals participating in the demonstration, effective July 1, 2013, all of which continued their participation through December 2014. Starting from that date and extending through the end

of FY 2015, the 7 ''originally participating'' hospitals, that is, hospitals that were selected in either 2004 or 2008, ended on a rolling basis their scheduled 5-year periods of performance authorized by the Affordable Care Act (referred to hereafter as ''Cohort 1'' hospitals). Likewise, the participation period for the 14 hospitals that entered the demonstration following the mandate of the Affordable Care Act and that were still participating (referred to as ''Cohort 2'' hospitals) ended their scheduled periods of performance on a rolling basis according to the end dates of the hospitals' cost report periods, respectively, from April 30, 2016 through December 31, 2016. (One hospital among the Cohort 2 hospitals closed in October 2015.)

3. Provisions of the 21st Century Cures Act (Pub. L. 114–255) and Proposals and Finalized Policies for Implementation

a. Statutory Provisions

As stated earlier, section 15003 of Public Law 114–255 further amended section 410A of Public Law 108–173 to require the Secretary to conduct the Rural Community Hospital Demonstration for a 10-year extension period (in place of the 5-year extension period required by the Affordable Care Act), beginning on the date immediately following the last day of the initial 5-year period under section 410A(a)(5) of Public Law 108–173. Thus, the Secretary is required to conduct the demonstration for an additional 5-year period. Specifically, section 15003 of Public Law 114–255 amended section 410A(g)(4) of Public Law 108–173 to require that, for hospitals participating in the demonstration as of the last day of the initial 5-year period, the Secretary shall provide for continued participation of such rural community hospitals in the demonstration during the 10-year extension period, unless the hospital makes an election, in such form and manner as the Secretary may specify, to discontinue participation. In addition, section 15003 of Public Law 114–255 amended section 410A(g)(4)(B) (Pub. L. 108–173) to provide that in calculating the amount of payment under the demonstration program to the rural community hospital for covered inpatient hospital services furnished by the hospital during each 5-year period of such 10 year extension period, the amount of payment (for the first cost reporting period) is the reasonable costs of providing such services for discharges occurring in the first cost reporting period beginning on or after the first day of each applicable 5-year period in the 10-year extension period. Furthermore, section 15003 of Public Law 114–255 added subsection (g)(5) to section 410A of Public Law 108–173 to require that, during the second 5 years of the 10-year extension period, the Secretary shall apply the provisions of section 410A(g)(4) of Public Law 108–173 to rural community hospitals that are not described in subsection (g)(4) but that were participating in the demonstration as of December 30, 2014, in a similar manner as such provisions apply to hospitals described in subsection (g)(4). We interpret this as providing for participation in and payment under the demonstration during the second 5 years of the 10-year extension period for hospitals that are not described in section 410A(g)(4) of Public Law 108–173 (as amended) but that were participating in the demonstration as of December 30, 2014, in a similar manner as such extension and payment applies to hospitals described in section 410A(g)(4) of Public Law 108–173 (as amended), unless a hospital makes an election, in such form and manner as the Secretary may specify, to discontinue participation.

In addition, section 15003 of Public Law 114–255 amended section 410A of Public Law 108–173 to add paragraph (g)(6)(A) which requires that, no later than 120 days after enactment of paragraph (g)(6), the Secretary shall issue a solicitation for applications to select additional rural community hospitals located in any State to participate in the demonstration program for the second 5 years of the 10-year extension period, without exceeding the maximum number of hospitals (that is, 30) permitted under section 410A(g)(3) of Public Law 108–173 (which was added by the Affordable Care Act). Section 15003 also amended section 410A of Public Law 108–173 to add paragraph (g)(6)(B) which provides that, in determining which hospitals submitting an application pursuant to this solicitation are to be selected for participation in the demonstration, the Secretary shall give priority to rural community hospitals located in one of the 20 States with the lowest population densities, as determined using the 2015 Statistical Abstract of the United States. In addition, in determining which among the hospitals submitting an application pursuant to this solicitation are to be selected for participation in the demonstration, section 410A(g)(6)(B) specifies that the Secretary may consider closures of hospitals located in rural areas in the State in which an applicant hospital is located during the 5-year period immediately preceding the date of enactment of section 410A(g)(6) of Public Law 108–173, as well as the population density of the State in which the rural community hospital is located.

b. Terms of Continuation for Previously Participating Hospitals

As discussed earlier, section 15003 of Public Law 114–255 (the 21st Century Cures Act) amended section 410A of Public Law 108–173 to provide for a 10-year extension of the demonstration (in place of the 5-year extension required by the Affordable Care Act) beginning on the date immediately following the last day of the initial 5-year period under section 410A(a)(5) of Public Law 108–173. Thus, section 15003 of Public Law 114–255 requires an additional 5-year extension of the demonstration beyond the extension required by the Affordable Care Act. Given the timing of the enactment of Public Law 114–255, for most of the previously participating hospitals, there is a gap between the end date of each hospital's participation in the first 5-year extension period and enactment of Public Law 114–255 on December 13, 2016. For these hospitals, this gap is for a period of between 2 to 23 months. Section 15003 of Public Law 114–255 does not address how the second 5 years of the 10-year extension is to be implemented in the event of a gap between the end of the first 5 years of the 10-year extension period for a participating hospital and the enactment of Public Law 114–255 authorizing the second 5 years of the 10-year extension period. As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19992), given this gap and the lack of specific direction in the statute regarding how to implement the extension in this situation for these previously participating hospitals, and the mandate under section 15003 of Public Law 114–255 to issue a solicitation for additional participants for the second 5 years of the 10-year extension, we considered how to implement the second 5 years of the 10-year extension period. In the FY 2018 IPPS/LTCH PPS proposed rule, for each previously participating hospital that decides to participate in the second 5 years of the 10-year extension period, we proposed that the start date for the period of performance under the second 5-year extension period would be the start of the first cost reporting period on or after October 1, 2017 following upon the announcement of the selection of the additional hospitals for the demonstration. In this manner, we proposed to align the periods of performance for the previously

participating hospitals that decide to participate in the second 5-year extension period with the periods of performance for the additional hospitals authorized by section 15003 of Public Law 114–255. In the FY 2018 IPPS/LTCH PPS proposed rule, we stated that we believe the approach we proposed above is consistent with section 410A of Public Law 108–173, as amended by Public Law 114–255. We also stated that aligning, to the extent possible, the periods of performance of the previously participating hospitals with those of those newly selected under the demonstration was reasonable, given the need for time to carry out demonstration administration activities, evaluation considerations, and the necessity for the calculation of budget neutrality offset amounts.

We invited public comments on the proposed approach discussed earlier for implementing the second 5-year period of the 10-year extension required under section 15003 of Public Law 114–255 for the previously participating hospitals. In addition, we invited public comments on alternative approaches under the statute for implementing the extension, particularly with respect to the commencement of the second 5-year period of the extension for previously participating hospitals.

We described an alternative approach according to which each previously participating hospital would begin the second 5 years of the 10-year extension period and the cost-based payment methodology under section 410A of Public Law 108–173 (as amended by section 15003 of Pub. L. 114–255), on the date immediately after the date the period of performance under the first 5-year extension period ended. For example, for a hospital whose 5-year period of performance authorized by the Affordable Care Act ended June 30, 2015, the extension period under section 15003 of Public Law 114–255 would be effective July 1, 2015, and it would extend through June 30, 2020. Likewise, for a hospital whose 5-year period of performance ended June 30, 2016, the extension period under section 15003 of Public Law 114–255 would be effective July 1, 2016, and it would extend through June 30, 2021. The methodology we considered for calculating the budget neutrality offset amount under this alternative approach is described in section V.L.4.d. of the preamble of the proposed rule. We stated that this alternative approach would also be consistent with the language of section 410A of Public Law 108–173 (as amended), and, unlike the proposed approach, would not provide for a gap in the reasonable cost payment methodology between the end of the first and start of the second 5-year periods of the 10-year extension period. We also sought public comments on this alternative approach to implementing the extension to the demonstration under section 15003 of Public Law 114–255 and the corresponding alternative budget neutrality calculation described in section V.L.4.d. of the preamble of the proposed rule.

Comment: Several commenters expressed concern about our proposed approach, stating that section 15003 of Public Law 114–255, which authorizes the second 5-year extension, changes the language in Public Law 111–148 from 5 years to 10 years, beginning on the date immediately following the last day of the initial 5-year period, and that thus the alternative approach should be implemented so as to apply the cost-based payment methodology continuously for the previously participating hospitals. The commenters added that adopting our proposed approach would create financial hardship for some of the previously participating hospitals. They noted that, in certain cases, these hospitals play a vital role in providing health services in remote communities, and that the gap in applying the cost-based payment under our proposed approach would jeopardize access to essential health care services.

Response: We believe that our proposed approach to align the periods of participation for all participating hospitals for the second 5-year extension period is consistent with the statute and reasonable, given the gap between the end of the first 5-year extension period for previously participating hospitals and the enactment of Public Law 114–255 authorizing the second 5-year extension period. Nevertheless, we acknowledge that we have administered this demonstration program for the previous 5-year periods, as authorized by section 410A of Public Law 108–173 and sections 3123 and 10313 of Public Law 111–148, respectively, by aligning the period of participation for each of the hospitals with the start of the first cost report year upon selection to the demonstration program. Considering this previous experience for the demonstration program, we believe that implementing the periods of performance for the second 5-year extension period in accordance with the alternative approach would also be consistent with the language of the authorizing statutes and reasonable.

We have considered the concerns expressed about the negative impact that our proposed approach of a gap in the cost-based payment methodology would have on the ability of the previously participating hospitals to provide essential health care services. We believe these are important concerns to balance against any considerations under the proposed approach in undertaking the administrative, evaluation, and budget neutrality functions for the demonstration. Therefore, we are finalizing the alternative approach with regard to the effective date for the application of the demonstration payment methodology for those previously participating hospitals that choose to participate in the second 5-year extension period. Thus, each previously participating hospital would begin the second 5 years of the 10-year extension period and the cost-based payment methodology under section 410A of Public Law 108–173 (as amended by section 15003 of Pub. L. 114–255) on the date immediately after the date the period of performance under the first 5-year extension period ended.

c. Solicitation for Additional Participants

We stated in the FY 2018 IPPS/LTCH PPS proposed rule that, as required under section 15003 of Public Law 114–255, we would issue a solicitation for additional hospitals to participate in the demonstration. We released this solicitation on April 17, 2017, with applications due May 17, 2017. Among other things, the solicitation asked hospitals to describe challenges experienced with the current method of Medicare payment, the impact of rural hospital closures within the State or surrounding area, and a strategy for financial viability and improving the health care of the population.

Section 15003 of Public Law 114–255, adding section 410A(g)(6)(B) to Public Law 108–173, provides that, in determining which rural community hospitals that submitted an application pursuant to the solicitation under section 410A(g)(6)(A) to select for participation in the demonstration program, the Secretary shall give priority to rural community hospitals located in one of the 20 States with the lowest population densities (as determined by the Secretary using the 2015 Statistical Abstract of the United States). We note that the U.S. Census Bureau ceased publishing the Statistical Abstract of the United States in 2011, and that in the years since then, ProQuest, LLC, a private vendor, has produced a volume intended to serve the same function as a comprehensive collection of national statistics, compiling data from different sources

including published reports from the Census Bureau. Thus, we used ProQuest Statistical Abstract of the United States, 2015 in determining which States to give priority in selecting additional participants for the demonstration. We believe that, in the absence of a volume produced by the Census Bureau, using this compendium is consistent with the intent of the statute, and is appropriate for the purpose of designating States to which priority is to be given under section 410A(g)(6)(B)(i) of Public Law 108–173.

In the FY 2018 IPPS/LTCH PPS proposed rule, we noted that the table in this compendium presenting information on State population density includes separate sets of statistics for 2010 and 2013. Both data sources are available on the Census Bureau Web site. The source for the 2010 statistics is ''2010 Census Briefs, Population Distribution and Change: 2000 to 2010, March 2011'' (*http://www.census.gov/prod/cen2010/briefs/c2010br-01.pdf*); the source for 2013 is ''Annual Estimates of the Population for the United States, Regions, States, and Puerto Rico: April 1, 2010 to July 1, 2013'' (*http://www.census.gov/popest/data/state/totals/2013/index.html*). Consistent with our policy for the previous solicitations, we chose the more recent data source to identify the 20 States to which priority is to be given. These States are: Alaska, Arizona, Arkansas, Colorado, Idaho, Iowa, Kansas, Maine, Mississippi, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Utah, Vermont, and Wyoming.

We noted that section 410A(g)(6)(B)(ii)(II) of Public Law 108–173 as added by section 15003 of Public Law 114–255 also states that, in selecting additional participants, the Secretary may consider the population density of the State in which the rural community hospital is located. We are doing so because the demonstration may have differing effects for health care services and populations depending on State population density. In addition, as permitted by section 410A(g)(6)(B)(ii)(I) of Public Law 108–173, in selecting additional participants under this solicitation, we will consider the impact of closures of hospitals located in rural areas in the State in which the hospital is located during the 5-year period immediately preceding December 13, 2016. We believe that this consideration is reasonable, given the possibility that enhanced Medicare payment through the demonstration may increase access to health care services for populations thus affected by hospital closures.

We stated that our goal was to finalize this selection by June 2017, in time to include in the FY 2018 IPPS/LTCH PPS final rule an estimate of the costs of the demonstration during FY 2018 and the resulting budget neutrality offset amount for these newly participating hospitals (referred to as ''Cohort 3'' hospitals), as well as for those hospitals among the previously participating hospitals that decide to participate in the extension period (Cohorts 1 and 2 hospitals). Upon announcing the selection of new participants, we indicated that we would confirm the start dates for the periods of performance for these newly selected hospitals and for previously participating hospitals. We stated that in accordance with the proposed implementation approach discussed in section V.L.3.b. of the preamble of the FY 2018 IPPS/LTCH PPS proposed rule, if the selection were to be announced by June 2017, we would expect that we would determine the periods of performance for all of the participating hospitals to begin with the first cost reporting period on or after October 1, 2017, and we would include an estimate of the costs for the demonstration for FY 2018 for Cohorts 1, 2, and 3 hospitals in the FY 2018 IPPS/LTCH PPS final rule.

We stated, on the other hand, that if final selection of the Cohort 3 hospitals were not to occur by June 2017, under our proposed approach, we would not be able to include an estimate of the costs of the demonstration or an estimate of the budget neutrality offset amount for FY 2018 for either these Cohort 3 hospitals or the previously participating Cohorts 1 and 2 hospitals in the FY 2018 IPPS/LTCH PPS final rule. Considering that periods of performance for the Cohorts 1 and 2 hospitals would not be determined until after the selection of the Cohort 3 hospitals, we would not know precisely when the periods of performance would begin for the Cohorts 1 and 2 hospitals, or to what extent they would overlap with the 12 months in FY 2018 until the Cohort 3 hospitals were selected. Therefore, if the announcement of the final selection of the Cohort 3 hospitals were not to occur by June 2017, we would not be able to include an estimate of the demonstration costs or budget neutrality offset amount for FY 2018 for the Cohorts 1 and 2 hospitals in the FY 2018 IPPS/LTCH PPS final rule. As a result, if the announcement of the final selection of the Cohort 3 hospitals were not to occur by June 2017, we would specify the dates on which all participating hospitals would start in the second 5 years of the 10-year extension period at the time the selection was announced in accordance with our proposal. We proposed that if the selection of the Cohort 3 hospitals was not announced in June 2017, we would include the estimated costs of the demonstration for all participating hospitals for FY 2018 in the budget neutrality offset amount to be calculated in the FY 2019 IPPS/LTCH PPS proposed and final rules.

Comment: One commenter supported CMS' goal of aligning performance periods across all of the hospitals participating in the demonstration program. However, the commenter recommended that CMS achieve this end by implementing a retroactive reimbursement policy for the hospitals newly entering the demonstration program as well, so that all hospitals participating in the second 5-year extension period are subject to the demonstration payment methodology for the gap period occurring between the end of the first 5 years of the 10-year extension period and the enactment of Public Law 114–255 authorizing the second 5 years of the 10-year extension period.

Response: We appreciate the commenter's support and recommendation. As of the time of the publication of this final rule, we have not finalized the selection of additional participants (Cohort 3 hospitals) to participate in the demonstration. Once we announce selections, we will also announce the start dates for the 5-year extension period for the additional hospitals selected (Cohort 3). In addition, for the previously participating Cohorts 1 and 2 hospitals, as discussed in section V.L.3.b. of the preamble of this final rule, we are not finalizing the proposed approach under which the start date for the period of performance under the second 5-year extension period would be the start of the first cost reporting period on or after October 1, 2017, following upon the announcement of the selection of the additional hospitals for the demonstration. We are finalizing the alternative approach, under which the start date of each previously participating Cohort 1 and 2 hospital for the second 5 years of the 10-year extension period would be the date immediately after the date the period of performance under the first 5-year extension period ended. We will confirm the start dates for these hospitals after verifying which among them will continue to participate in the second 5-year extension period.

Inasmuch as the selection of the Cohort 3 hospitals was not announced in June 2017, we are finalizing our

proposal to include the estimated costs of the demonstration for all participating hospitals (Cohorts 1, 2, and 3) for FY 2018 in the budget neutrality offset amount to be calculated in the FY 2019 IPPS/LTCH PPS proposed and final rules. We refer readers to section V.L.4.d. of the preamble of this final rule for a discussion of our finalized calculation methodology for the budget neutrality offset amount for FY 2018.

4. Budget Neutrality

a. Statutory Budget Neutrality Requirement

Section 410A(c)(2) of Public Law 108–173 requires that, in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented. This requirement is commonly referred to as ''budget neutrality.'' Generally, when we implement a demonstration program on a budget neutral basis, the demonstration program is budget neutral on its own terms; in other words, the aggregate payments to the participating hospitals do not exceed the amount that would be paid to those same hospitals in the absence of the demonstration program. Typically, this form of budget neutrality is viable when, by changing payments or aligning incentives to improve overall efficiency, or both, a demonstration program may reduce the use of some services or eliminate the need for others, resulting in reduced expenditures for the demonstration program's participants. These reduced expenditures offset increased payments elsewhere under the demonstration program, thus ensuring that the demonstration program as a whole is budget neutral or yields savings. However, the small scale of this demonstration program, in conjunction with the payment methodology, makes it extremely unlikely that this demonstration program could be held to budget neutrality under the methodology normally used to calculate it—that is, cost-based payments to participating small rural hospitals are likely to increase Medicare outlays without producing any offsetting reduction in Medicare expenditures elsewhere. In addition, a rural community hospital's participation in this demonstration program would be unlikely to yield benefits to the participants if budget neutrality were to be implemented by reducing other payments for these same hospitals. Therefore, in the 12 IPPS final rules spanning the period from FY 2005 through FY 2016, we adjusted the national inpatient PPS rates by an amount sufficient to account for the added costs of this demonstration program, thus applying budget neutrality across the payment system as a whole rather than merely across the participants in the demonstration program. (In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57034), we described a different methodology which we specify below.) As we discussed in the FYs 2005 through 2017 IPPS final rules (69 FR 49183; 70 FR 47462; 71 FR 48100; 72 FR 47392; 73 FR 48670; 74 FR 43922, 75 FR 50343, 76 FR 51698, 77 FR 53449, 78 FR 50740, 77 FR 50145; 80 FR 49585; and 81 FR 57034, respectively), we believe that the language of the statutory budget neutrality requirements permits the agency to implement the budget neutrality provision in this manner.

b. Methodology Used In Previous Final Rules

We generally incorporated two components into the budget neutrality offset amounts identified in the final IPPS rules in previous years. First, we estimated the costs of the demonstration for the upcoming fiscal year, generally determined from historical, ''as submitted'' cost reports for the hospitals participating in that year. Update factors representing nationwide trends in cost and volume increases were incorporated into these estimates, as specified in the methodology described in the final rule for each fiscal year. Second, as finalized cost reports became available, we determined the amount by which the actual costs of the demonstration for an earlier, given year differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year, and we incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. If the actual costs for the demonstration for the earlier fiscal year exceeded the estimated costs of the demonstration identified in the final rule for that year, this difference was added to the estimated costs of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming fiscal year. Conversely, if the estimated costs of the demonstration set forth in the final rule for a prior fiscal year exceeded the actual costs of the demonstration for that year, this difference was subtracted from the estimated cost of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming fiscal year. (We note that we have calculated this difference for FYs 2005 through 2010 between the actual costs of the demonstration as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.)

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57036), we finalized a different methodology as compared to previous years for analyzing the costs attributable to the demonstration for FY 2017. We noted in the FY 2017 IPPS/LTCH PPS final rule that, in accordance with the extension mandated by the Affordable Care Act, the demonstration would have substantially phased out by the beginning of FY 2017. In addition to the 7 originally participating hospitals (Cohort 1 hospitals) having ended their scheduled period of performance in the 5-year extension period prior to the start of FY 2016, we noted that the participation periods for the 14 hospitals that entered the demonstration following the extension mandated by the Affordable Care Act (Cohort 2 hospitals) that were still participating were to end on a rolling basis according to the end dates of the hospitals' cost report periods, respectively, from April 30, 2016 through December 31, 2016. (As noted earlier, 1 hospital among the Cohort 2 hospitals closed in October 2015.) Of these 14 hospitals, 10 ended participation on or before September 30, 2016, leaving 4 hospitals participating for the last 3 months of CY 2016 (that is, the first 3 months of FY 2017). We stated that, given the small number of participating hospitals and the limited time of participation for such hospitals during FY 2017, a revised methodology was appropriate for determining the costs of the demonstration during this period. We noted that, for the 4 hospitals that would end their participation in the demonstration effective December 31, 2016, the financial experience of the last 3 months of the calendar year (that is, the first 3 months of FY 2017) would be included in the finalized cost reports for FY 2016. We stated that examining the finalized cost reports for FY 2016 for these hospitals would lead to a more accurate and administratively feasible calculation of budget neutrality for the demonstration in FY 2017 than conducting an estimate of the costs of the demonstration for this 3-month period based on ''as submitted cost reports'' (as would occur according to the budget neutrality methodology used

prior to the FY 2017 IPPS/LTCH PPS final rule).

Thus, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57037), we finalized the proposal to forego the process of estimating the costs attributable to the demonstration for FY 2017, and to instead calculate the costs of the demonstration and the resulting budget neutrality adjustment factor for the demonstration for FY 2017 once the finalized cost reports for cost reporting periods beginning in FY 2016 became available.

c. Budget Neutrality Methodology for Extension Period Authorized by the 21st Century Cures Act (Pub. L. 114–255)

For the implementation approach that we proposed in section V.L.3.b. of the preamble of the FY 2018 IPPS/LTCH PPS proposed rule, we proposed that a budget neutrality offset methodology similar to previous years (prior to FY 2017) would be applied to the periods of performance under the second 5 years of the 10-year extension period authorized by section 15003 of Public Law 114–255. With the potential exception of the demonstration costs for FY 2018 as discussed below, for the periods of performance under the second 5 years of the 10-year extension period, an estimate of the costs of the demonstration, generally determined from historical, ''as submitted'' cost reports for the participating hospitals and the appropriate update factors, would be incorporated into a budget neutrality offset amount to be applied to the national IPPS rates for the upcoming fiscal year. We proposed that we would implement this adjustment through the corresponding proposed and final IPPS rules. In addition, we proposed that we would include as a second component to the budget neutrality offset amount, the amount by which the actual costs of the demonstration for an earlier, given year (as determined from finalized cost reports when available) differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year.

Regarding demonstration costs specifically for FY 2018, as described in section V.L.3.c. of the preamble of the FY 2018 IPPS/LTCH PPS proposed rule, we proposed that if the selection of additional hospitals pursuant to section 410A(g)(6) of Public Law 108–173 (as added by section 15003 of Pub. L. 114–255) were to be announced by June 2017, we would include in this FY 2018 IPPS/LTCH PPS final rule an estimate of the costs of the demonstration for FY 2018 and the resulting estimated budget neutrality offset amount for the newly selected hospitals (Cohort 3 hospitals) and for the previously participating hospitals (Cohorts 1 and 2 hospitals). As discussed earlier, if the final selection of the additional hospitals were not to occur by June 2017, we stated in the proposed rule that we would not be able to include an estimate of the costs of the demonstration for any participating hospitals or an estimated budget neutrality adjustment for FY 2018 in the FY 2018 IPPS/LTCH PPS final rule. In that situation, we proposed to include the estimated costs of the demonstration for FY 2018 for all participating hospitals (Cohorts 1, 2 and 3 hospitals) in the budget neutrality offset adjustment in the FY 2019 IPPS/LTCH PPS proposed and final rules. The budget neutrality offset adjustment for the FY 2019 IPPS/LTCH PPS proposed and final rules would also include the estimated costs of the demonstration for FY 2019 for all participating hospitals based on historical, ''as submitted'' cost reports and the appropriate update factors.

Under our proposed implementation approach for the second 5-year extension period as described in section V.L.3.b. of the preamble of the FY 2018 IPPS/LTCH PPS proposed rule, if the selection of the new hospitals were to be announced by June 2017, we stated that we would continue to use the general methodology finalized in previous final rules (prior to FY 2017) to calculate the estimated budget neutrality adjustment factor to be applied to the FY 2018 national IPPS rates. (We noted that the same general methodology would be used if the announcement of the selection of additional hospitals did not occur by June 2017, and thus the budget neutrality offset amount reflecting the costs of the demonstration for hospitals participating in FY 2018 would be applied to the national IPPS rates for FY 2019.)

We did not receive any public comments on this issue.

Consistent with the approach adopted in the FY 2016 IPPS/LTCH PPS final rule, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19996), we proposed a specific calculation to account for the fact that the periods of performance for the participating hospitals would start at different points of time during FY 2018. That is, we proposed to prorate estimated reasonable cost amounts and amounts that would be paid without the demonstration for FY 2018 according to the fraction of the number of months that the hospital would be participating out of the 12 months within FY 2018. For example, if a hospital would be starting this second 5-year period of the 10-year extension period on January 1, 2018, we would multiply the estimated cost and payment amounts, derived as described below, by a factor of 0.75. (In this discussion of how the overall calculations are conducted, this factor is referred to as ''the hospital-specific prorating factor''.) Our proposed methodology for calculating the budget neutrality offset amount proceeds in several steps, as set forth below:

Step 1: For each of the participating hospitals, we proposed to identify the reasonable cost amount calculated under the reasonable cost methodology for covered inpatient hospital services, as indicated on the ''as submitted'' cost report for the most recent cost reporting period available. (We stated that we expected that, for most of the hospitals, these ''as submitted'' cost reports would be those with cost report period end dates in CY 2015. In the solicitation for additional participants, we requested that applicants submit cost report information from the most recent year available. For the selected additional hospitals (that is, Cohort 3), we stated that we would be using the submitted information for the calculation of the budget neutrality offset amount for FY 2018.) We stated that we believed the most recent available cost reports to be an accurate predictor of the costs of the demonstration in FY 2018 because they would give us a recent picture of the participating hospitals' costs.

Because section 410A of Public Law 108–173 stipulates swing-bed services are to be included among the covered inpatient hospital services for which the demonstration payment methodology applies, we proposed to include the cost of these services, as reported on the cost reports for the hospitals that provide swing-bed services, in estimating the total reasonable cost amount for covered inpatient hospital services under the demonstration. Similar to what is stated above, we proposed to use the most recently available ''as submitted'' cost reports for this calculation.

For each hospital, we proposed to sum the two above-referenced amounts, and then multiply this sum by the hospital-specific prorating factor (described above), to obtain an unadjusted hospital-specific amount, calculated for each hospital prior to applying adjustments for increases in cost or volume, as described below. (In the discussion below, we refer to this amount as the ''unadjusted hospital-specific amount''.) We proposed to sum these unadjusted hospital-specific amounts for all participating hospitals to obtain an unadjusted total estimated reasonable cost amount for covered inpatient hospital services (for all participating hospitals) to which update

factors representing increases in costs and volume would be applied.

Accordingly, we proposed to multiply this sum (that is, the unadjusted total estimated reasonable cost amount for covered inpatient hospital services for all participating hospitals) by the FY 2016, FY 2017, and final FY 2018 IPPS market basket percentage increases, which are formulated by the CMS Office of the Actuary. We proposed to use the market basket percentage increases for these particular years because we expect that most of the ''as submitted'' cost reports that would be used in determining the unadjusted hospital-specific amounts will end in FY 2015. If a majority of these ''as submitted'' cost reports end in FY 2016, we stated that we would apply only the FY 2017 and final FY 2018 market basket percentage increases. We recognized that applying the set of FY 2016, FY 2017, and FY 2018 market basket percentage increases to a sum that may include information from ''as submitted'' cost reports ending in FY 2016 (or, conversely, applying these update factors for FY 2017 and FY 2018 to a sum that may include information from ''as submitted'' cost reports ending in FY 2015) might appear to reduce the precision of the estimate. However, we stated that we believed that the potential margin of error in estimating the total costs for the demonstration hospitals inherent in using a uniform set of update factors would be justifiable for purposes of streamlining and applying a consistent calculation method for all participating hospitals. In addition, we noted that, as in previous years, we proposed to reconcile the actual costs of the demonstration as determined from finalized cost reports when available with the estimate of the costs of the demonstration in FY 2018 as included in the budget neutrality offset amount, which would ultimately address any potential error in estimating the costs of the demonstration for FY 2018, thereby enhancing the accuracy of the calculation.

In the proposed rule, we stated that the current estimate of the FY 2018 IPPS market basket percentage increase provided by the CMS Office of the Actuary is specified in section V.B.1. of the preamble of the proposed rule. We also proposed to then multiply the product of the unadjusted total estimated reasonable cost amount for all participating hospitals and the market basket percentage increases applicable to the years involved by a 3-percent annual volume adjustment for each of FYs 2016 through 2018 (or only FYs 2017 and 2018, in accordance with the discussion above). The result would be the general total estimated FY 2018 reasonable cost amount for covered inpatient hospital services for all participating hospitals.

We proposed to apply the IPPS market basket percentage increases applicable for FYs 2016 through 2018 (or FYs 2017 and 2018, in accordance with the discussion above) to the applicable total estimated reasonable cost amount described above to model the estimated FY 2018 reasonable cost amount under the demonstration. We proposed to use the IPPS market basket percentage increases because we believe that these update factors appropriately indicate the trend of increase in inpatient hospital operating costs under the reasonable cost methodology for the years involved. The 3-percent annual volume adjustment was stipulated by the CMS Office of the Actuary and was proposed because it is intended to accurately reflect the tendency of hospitals' inpatient caseloads to increase. We acknowledged the possibility that inpatient caseloads for small hospitals may fluctuate, and thus proposed to incorporate into the estimate of demonstration costs a factor to allow for a potential increase in inpatient hospital services.

Step 2: For each of the participating hospitals, we proposed to identify the general estimated amount that would otherwise be paid in FY 2018 under applicable Medicare payment methodologies for covered inpatient hospital services (as indicated on the same set of ''as submitted'' cost reports as in Step 1) if the demonstration was not implemented. Similarly, as in Step 1, for the hospitals that provide swing-bed services, we proposed to identify the estimated amount that generally would otherwise be paid for these services (using the same ''as submitted'' cost reports as in Step 1) and include it in estimating the total FY 2018 general amount that would otherwise be paid for covered inpatient hospital services without the demonstration. Similar to Step 1, we proposed to multiply this sum for each participating hospital by the hospital-specific prorating factor. We then proposed to add together the resulting amounts for all participating hospitals to obtain an estimate of the amount that would otherwise be paid for covered inpatient hospital services for all participating hospitals without the demonstration, to which update factors representing increases in costs and volume would be applied.

Accordingly, we proposed to then multiply this amount by the FYs 2016 through 2018 (or only FYs 2017 and 2018, in accordance with the discussion above) IPPS applicable percentage increases, depending on whether the majority of the ''as submitted'' cost reports end in FY 2015 or FY 2016, as discussed in Step 1. This methodology differs from Step 1, in which we proposed to apply the market basket percentage increases to the sum of the hospitals' applicable total estimated reasonable cost amount for covered inpatient hospital services. We stated that we believed that the IPPS applicable percentage increases are appropriate factors to update the estimated amounts that generally would otherwise be paid without the demonstration. This is because IPPS payments would constitute the majority of payments that would otherwise be made without the demonstration and the applicable percentage increase is the factor used under the IPPS to update the inpatient hospital payment rates. Most of the hospitals participating in the demonstration would be paid under the IPPS payment methodology if they were not in the demonstration. Then, for the same reasons discussed in Step 1, we proposed to multiply the product of the applicable estimated total payments that generally would otherwise be made without the demonstration and the IPPS applicable percentage increases applicable to the years involved by the 3-percent annual volume adjustment for each of FYs 2016 through 2018 (or FYs 2017 and 2018, in accordance with the discussion above). The result would be the general total estimated payment amount that would otherwise be paid without the demonstration for FY 2018 to participating hospitals for covered inpatient hospital services.

Step 3: We proposed to subtract the amount derived in Step 2 (representing the sum of estimated amounts that generally would otherwise be paid to the participating hospitals for covered inpatient hospital services for FY 2018 if the demonstration were not implemented) from the amount derived in Step 1 (representing the sum of the estimated reasonable cost amounts that generally would be paid under the demonstration to all participating hospitals for covered inpatient hospital services for FY 2018). We proposed that the resulting difference would be the estimated amount of the costs of the demonstration for FY 2018, which would be incorporated into an adjustment to the national IPPS rates.

Similar to previous years, in order to meet the budget neutrality requirement in section 410A(c)(2) of Public Law 108–173, we proposed that when finalized cost reports for each of the second 5 years of the 10-year extension period become available, we would determine the difference between the

actual costs of the demonstration as determined from these finalized cost reports and the estimated cost indicated in the corresponding fiscal year IPPS final rule, and include that difference either as a positive or negative adjustment in the upcoming year's final rule.

Specifically for FY 2018, when the finalized cost reports beginning in FY 2018 are available, we stated that we would determine the difference between the actual costs of the demonstration as determined from these finalized cost reports and the estimated cost indicated in the FY 2018 (or FY 2019, as discussed above) IPPS/LTCH PPS final rule, and include that difference either as a positive or negative adjustment in the applicable year's final rule.

Thus, in keeping with the methodologies used in previous final rules, we stated that we would continue to use a methodology for calculating the budget neutrality offset amount for the second 5-years of the 10-year extension period consisting of two components: (1) The estimated demonstration costs in the upcoming fiscal year (as described above); and (2) the amount by which the actual demonstration costs corresponding to an earlier, given year (which would be known once finalized cost reports became available for that year) differed from the budget neutrality offset amount finalized in the corresponding year's IPPS final rule.

We invited public comments on the budget neutrality calculation methodology proposed above. In addition, we invited public comments on other approaches that would be consistent with section 410A(c)(2) of Public Law 108–173, and that would provide a reasonable determination of budget neutrality for the demonstration.

We did not receive any public comments on the budget neutrality calculation that we proposed, which would apply in accordance with our proposed implementation approach. However, because we are not finalizing our proposed implementation approach, we are not finalizing the proposed budget neutrality calculation methodology. As subsequently discussed in section V.L.4.d. of the preamble of this final rule, we are finalizing the alternative budget neutrality methodology that was described in section V.L.4.d. of the preamble of the FY 2018 IPPS/LTCH PPS proposed rule.

d. Finalized Budget Neutrality Approach

In section V.L.3.b. of the preamble of the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19993), we described an alternative approach that we considered for implementing the extension of the demonstration pursuant to section 15003 of Public Law 114–255, and we invited public comments on this alternative approach. Under this alternative approach, for each previously participating hospital that decided to participate in the second 5 years of the 10-year extension period, the cost-based payment methodology under section 410A of Public Law 108–173 (as amended by section 15003 of Pub. L. 114–255) would begin on the date immediately following the end date of its period of performance for the first 5-year extension period.

As discussed above, we are finalizing and adopting this alternative implementation approach in this final rule. Depending on which among the Cohort 1 and 2 hospitals choose to participate in this second 5-year extension period, the demonstration's cost-based payment methodology would be applied to dates as far back as January 1, 2015 and as late as January 1, 2017. This will require reconciling the reasonable costs associated with furnishing Medicare covered inpatient hospital services as reported on cost reports with the amounts already paid under the other Medicare payment methodologies applied since the end of their periods of performance for the first 5-year extension. Under this approach, any additional amounts associated with the cost-based payment methodology for this period would be paid to the hospitals.

In general, as described in the proposed rule, the methodology for calculating the budget neutrality offset under this approach would involve the following steps:

- To reflect the costs of the demonstration for fiscal years before FY 2018, for the previously participating hospitals (Cohorts 1 and 2) that decide to participate in the 5-year extension period authorized by section 15003 of Public Law 114–255, when finalized cost reports become available, we indicated that we would determine the actual costs of the demonstration for cost report periods beginning on the day after the last day of the hospitals' periods of performance in the first 5-year extension period and extending through the last day of the cost report periods ending in FY 2018 (or FY 2017 for hospitals with an October 1 cost report start date, as explained below), and incorporate these amounts in the budget neutrality offset amount to be included in a future IPPS final rule. Thus, we would determine the actual costs for the previously participating hospitals for the period prior to the start of FY 2018. Similar to our proposed approach for implementation and budget neutrality, as described in sections V.L.3.b. and V.L.4.c. of the preamble of the proposed rule, under this methodology, we would begin our estimation of the costs of the demonstration for all hospitals in the same fiscal year (that is, in FY 2018, with each hospital's first cost reporting period beginning on or after October 1, 2017).

Thus, under this approach, for a Cohort 1 hospital whose period of performance in the first extension period ended June 30, 2015, we would determine the actual costs of the demonstration for the cost reporting periods from July 1, 2015 through June 30, 2016, from July 1, 2016 through June 30, 2017, and from July 1, 2017 through June 30, 2018. For a Cohort 2 hospital whose period of performance in the first extension period ended June 30, 2016, under this approach, we would determine the actual costs of the demonstration for the cost reporting periods from July 1, 2016 through June 30, 2017, and from July 1, 2017 through June 30, 2018. We noted that for both of these Cohorts 1 and 2 hospitals, this last cost report period would encompass services occurring since the enactment of Public Law 114–255, which authorizes the second extension period. However, we stated that we believed that applying a uniform method for determining costs across a cost report year would be more reasonable from the standpoint of operational feasibility and consistent application of cost determination principles. (We noted that, for hospitals (either Cohort 1 or 2) with an October 1 cost report start date, the estimation of costs for FY 2018 would apply for the period starting October 1, 2017, that is, the first day of FY 2018. Therefore, for these hospitals, we would determine actual costs from finalized cost reports when available for the period starting from the day after the last day of the period of performance under the first 5-year extension period and concluding with the last day of FY 2017.) For all hospitals, under this approach, we stated that we would incorporate these amounts into a single amount to be included in the calculation of the budget neutrality offset amount to the national IPPS rates in a future final rule after such finalized cost reports become available.

- To reflect the costs of the demonstration for the upcoming fiscal year (that is, FY 2018) for Cohorts 1 and 2 hospitals that have decided to participate in the second 5-years of the 10-year extension period, we indicated that we would estimate the costs of the

demonstration for FY 2018, based on historical ''as submitted'' cost reports, applying prorating factors and updates as appropriate, as described below. Similar to the proposed methodology described in section V.L.4.c. of the preamble of the FY 2018 IPPS/LTCH PPS proposed rule for estimating the costs of the demonstration for FY 2018, we stated that the methodology for this approach for estimating the costs of the demonstration for FY 2018 would follow 3 steps:

Step 1: We stated that we would determine the total estimated reasonable cost amount for covered inpatient hospital services (as indicated on the ''as submitted'' cost reports for the most recent cost reporting period available) for all participating hospitals for FY 2018 calculated under the demonstration's reasonable cost-based payment methodology. We stated that these calculations would be identical to those described for our proposed methodology in section V.L.4.c. of the preamble of the proposed rule, with the exception that the formulation of the ''hospital-specific prorating factor,'' to be applied to each participating hospital's reasonable cost amounts as derived from its most recently available ''as submitted'' cost report, would be different. Under the different methodology for the formulation of the hospital-specific prorating factor, for hospitals with a cost report start date other than October 1, we indicated that the hospital-specific prorating factor would be the ratio of the number of months between the end of the cost reporting period ending in FY 2018, on the basis of which actual costs are determined (as described above), and the end of the fiscal year, out of the total number of months in the fiscal year. Therefore, for a hospital (either Cohort 1 or 2) for which the end of the period on which we would determine actual costs (that is, the end date of the hospital's cost report year) would be June 30, 2018, there would be 3 months remaining in FY 2018, and the hospital-specific prorating factor would be .25. (We noted that hospitals with an October 1 cost report start date would participate in the demonstration for the full 12 months of FY 2018 and thus would have a hospital-specific prorating factor of 1.0.) We stated that we would then follow the same calculations as in our proposed budget neutrality calculation described in section V.L.4.c. of the preamble of the proposed rule, including application of the same update factors to reflect increases in cost and volume.

Step 2: We stated that we would estimate the amount that would otherwise be paid for Medicare covered inpatient hospital services to all participating hospitals in FY 2018 without the demonstration. These calculations would be identical to those described for our proposed methodology in section V.L.4.c. of the preamble of the proposed rule, except for the difference that the hospital-specific prorating factor, to be applied to the estimated amount that the hospital would be paid without the demonstration, as derived from its most recently available ''as submitted'' cost report, would be formulated in the same manner as described in Step 1 above under this methodology.

Step 3: We stated that we would then subtract the amount derived in Step 2 (representing the estimated amount that would otherwise be paid to the participating hospitals for covered inpatient hospital services for FY 2018 if the demonstration were not implemented) from the amount derived in Step 1 (representing the estimated reasonable cost amounts that generally would be paid under the demonstration to all participating hospitals for covered inpatient hospital services for FY 2018). The resulting difference would be the estimated amount of the costs of the demonstration for FY 2018, which would be incorporated into an adjustment to the national IPPS rates.

- For the Cohort 3 hospitals, we indicated that we would follow the identical methodology for estimating the costs of the demonstration for FY 2018 as described for the proposed budget neutrality methodology discussed in section V.L.4.c. of the preamble of the proposed rule under the proposed implementation approach. In the proposed rule, we noted that if the selection of additional participants under the solicitation authorized by Public Law 114–255 were not announced by June 2017, we would not be able to include the estimates of the costs of the demonstration for FY 2018 for the Cohort 3 hospitals in the budget neutrality offset adjustment for FY 2018, and similar to our proposed methodology in that situation, we would incorporate this estimate in the budget neutrality offset adjustment in the FY 2019 IPPS/LTCH PPS final rule. We noted that, under these circumstances, the budget neutrality offset adjustment for the FY 2019 IPPS proposed and final rules would also include the estimated costs of the demonstration for FY 2019 for these Cohort 3 hospitals based on historical, ''as submitted'' cost reports and the appropriate update factors.
- Consistent with our approach in previous final rules, when the finalized cost reports for cost reporting periods beginning in FY 2018 are available, we stated that we would determine the difference between the actual costs of the demonstration as determined from these finalized cost reports and the estimated cost indicated in the FY 2018 IPPS/LTCH PPS final rule (or the FY 2019 IPPS/LTCH PPS final rule, as explained earlier), and include that difference either as a positive or negative adjustment in the upcoming year's final rule.
- For future years, we stated that we would continue to incorporate the estimated costs of the demonstration for all participating hospitals for the upcoming fiscal year in the budget neutrality offset adjustment in the IPPS final rule of the corresponding fiscal year. For these hospitals, we indicated that we also would determine the actual costs of the demonstration when finalized cost reports become available, and include the difference between the estimated and actual costs of the demonstration in the calculation of the budget neutrality offset amount to the national IPPS rates in the final rule for a future year.

We noted that, under this approach, although we would not be able to include an estimate of the costs of the demonstration for FY 2018 Cohort 3 hospitals in the budget neutrality offset adjustment in the FY 2018 final rule if we were not able to announce the selection of additional hospitals by June 2017, we would do so for the Cohorts 1 and 2 hospitals.

We invited public comments on this alternative budget neutrality calculation methodology, as discussed earlier.

We did not receive any public comments on this alternative methodology.

Because we are finalizing the alternative implementation approach described in section V.L.3.b. of the preamble of this final rule, according to which each previously participating hospital would begin the second 5 years of the 10-year extension period and the cost-based payment methodology under section 410A of Public Law 108–173 (as amended by section 15003 of Pub. L. 114–255) on the date immediately after the date the period of performance under the first 5-year extension period ended, we are finalizing the alternative budget neutrality methodology from the proposed rule, as described in section V.L.4.d. of the preamble of this final rule specific to this approach. We note that in advance of finalizing our policy about the start date for the period of performance for the second 5-year extension period for the previously participating hospitals (Cohorts 1 and

2), at the time of publication of this final rule, we have not been able to verify which among these hospitals will continue to participate in the second 5-year extension period. Therefore, we are not including an estimate of the costs of the demonstration for any of the previously participating Cohort 1 or 2 hospitals for FY 2018 in the budget neutrality offset adjustment in this FY 2018 IPPS/LTCH PPS final rule. In addition, because the selection of additional participants under the solicitation authorized by Public Law 114–255 was not announced by June 2017, we also are not able to include the estimates of the costs of the demonstration for the Cohort 3 hospitals for FY 2018 in the budget neutrality offset adjustment in this FY 2018 IPPS/LTCH PPS final rule. As a result, there will be no budget neutrality offset adjustment for the demonstration in this FY 2018 IPPS/LTCH PPS final rule. We will include the estimated costs of the demonstration for all participating hospitals (Cohorts 1, 2, and 3) for FY 2018 in the budget neutrality offset amount in the FY 2019 IPPS proposed and final rules.

e. Reconciling Actual and Estimated Costs of the Demonstration for Previous Years (2011, 2012, and 2013)

As described earlier, we have calculated the difference for FYs 2005 through 2010 between the actual costs of the demonstration, as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57037), we finalized a proposal to reconcile the budget neutrality offset amounts identified in the IPPS final rules for FYs 2011 through 2016 with the actual costs of the demonstration for those years, considering the fact that the demonstration was scheduled to end December 31, 2016. In that final rule, we stated that we believed it would be appropriate to conduct this analysis for FYs 2011 through 2016 at one time, when all of the finalized cost reports for cost reporting periods beginning in FYs 2011 through 2016 are available. We stated that such an aggregate analysis encompassing the cost experience through the end of the period of performance of the demonstration would represent an administratively streamlined method, allowing for the determination of any appropriate adjustment to the IPPS rates and obviating the need for multiple, fiscal year-specific calculations and regulatory actions. Given the general lag of 3 years in finalizing cost reports, we stated that we expected any such analysis would be conducted in FY 2020.

With the extension of the demonstration for another 5-year period, as authorized by section 15003 of Public Law 114–255, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20000), we proposed to modify the plan outlined in the FY 2017 IPPS/LTCH PPS final rule, and instead return to the general procedure in previous final rules; that is, as finalized cost reports become available, to determine the amount by which the actual costs of the demonstration for an earlier, given year differ from the estimated costs for the demonstration set forth in the IPPS final rule for the corresponding fiscal year, and then incorporate that amount into the budget neutrality offset amount for an upcoming fiscal year. We proposed that if the actual costs of the demonstration for the earlier fiscal year exceed the estimated costs of the demonstration identified in the final rule for that year, this difference would be added to the estimated costs of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the final rule. Conversely, we proposed that if the estimated costs of the demonstration set forth in the final rule for a prior fiscal year exceed the actual costs of the demonstration for that year, this difference would be subtracted from the estimated cost of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for an upcoming fiscal year. However, given that this adjustment for specific years could be positive or negative, we proposed to combine this reconciliation for multiple prior years into one adjustment to be applied to the budget neutrality offset amount for a single fiscal year, thus reducing the possibility of both positive and negative adjustments to be applied in consecutive years, and enhancing administrative feasibility. Specifically, we proposed that when finalized cost reports for FYs 2011, 2012, and 2013 are available, we would include this difference for these years in the budget neutrality offset adjustment to be applied to the national IPPS rates in a future final rule. We stated that we expected that this would occur in FY 2019. We also proposed that when finalized cost reports for FYs 2014 through 2016 are available, we would include the difference between the actual costs as reflected on these cost reports and the amounts included in the budget neutrality offset amounts for these fiscal years in a future final rule. We stated in the proposed rule that we plan to provide an update in a future final rule regarding the year that we would expect that this analysis would occur.

We invited public comments on this proposal.

We did not receive any public comments on this proposal. We are finalizing our proposal for reconciling the actual and estimated costs of the demonstration for 2011 through 2013.

M. Adjustment to IPPS Rates Resulting From 2-Midnight Policy for FY 2018

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50906 through 50954), we adopted the 2-midnight policy, effective for dates of admission on or after October 1, 2013. As discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57058 through 57060), under the 2-midnight policy, an inpatient admission is generally appropriate for Medicare Part A payment if the physician (or other qualified practitioner) admits the patient as an inpatient based upon the reasonable expectation that the patient will need hospital care that crosses at least 2 midnights. In assessing the expected duration of necessary care, the physician (or other qualified practitioner) may take into account outpatient hospital care received prior to inpatient admission. If the patient is expected to need less than 2 midnights of care in the hospital, the services furnished should generally be billed as outpatient services. We note that revisions were made to this policy in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70545). Our actuaries estimated that the 2-midnight policy would increase expenditures by approximately $220 million in FY 2014 due to an expected net increase in inpatient encounters. We used our authority under section 1886(d)(5)(I)(i) of the Act to make a reduction of 0.2 percent to the standardized amount, the Puerto Rico standardized amount, and the hospital-specific payment rates, and we used our authority under section 1886(g) of the Act to make a reduction of 0.2 percent to the national capital Federal rate and the Puerto Rico-specific capital rate, in order to offset this estimated $220 million in additional IPPS expenditures in FY 2014.

For the reasons outlined in the FY 2017 IPPS/LTCH PPS proposed and final rules (81 FR 25136 through 25138 and 81 FR 57058 through 57060), we used our authority under sections 1886(d)(5)(I)(i) and 1886(g) of the Act to prospectively remove, beginning in FY 2017, the 0.2 percent reduction to the rates put in place beginning in FY 2014. The 0.2 percent reduction was

implemented by including a factor of 0.998 in the calculation of the FY 2014 standardized amount, hospital-specific payment rates, and the national capital Federal rate, permanently reducing the rates for FY 2014 and future years until the 0.998 is removed. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57281 and 57294), we permanently removed the 0.998 reduction beginning in FY 2017 by including a factor of (1/0.998) in the calculation of the FY 2017 standardized amount, the hospital-specific payment rates, and the national capital Federal rate.

We also stated in the FY 2017 IPPS/LTCH PPS proposed and final rules that, for the reasons outlined in those rules, we believe it would be appropriate to use our authority under sections 1886(d)(5)(I)(i) and 1886(g) of the Act to temporarily increase the rates, only for FY 2017, to address the effect of the 0.2 percent reduction to the rates in effect for FY 2014, the 0.2 percent reduction to the rates in effect for FY 2015 (recall the 0.998 factor included in the calculation of the FY 2014 rates permanently reduced the rates for FY 2014 and future years until it is removed), and the 0.2 percent reduction to the rates in effect for FY 2016. We stated that we believe the most transparent, expedient, and administratively feasible method to accomplish this was a temporary one-time prospective increase to the FY 2017 rates of 0.6 percent (= 0.2 percent + 0.2 percent + 0.2 percent). Specifically, we finalized our proposal to include a factor of 1.006 in the calculation of the standardized amount, the hospital-specific payment rates, and the national capital Federal rate in FY 2017 and then to remove this temporary one-time prospective increase by including a factor of (1/1.006) in the calculation of the rates for FY 2018. We stated that while we generally did not believe it is appropriate in a prospective system to retrospectively adjust rates, we took this action in the specific context of this unique situation.

In summary, for the reasons described in the FY 2017 IPPS/LTCH PPS proposed and final rules, we finalized our proposal to include a permanent factor of (1/0.998) and a temporary one-time factor of (1.006) in the calculation of the FY 2017 standardized amount, hospital-specific payment rates, and national capital Federal rate and to include a factor of (1/1.006) in the calculation of the FY 2018 standardized amount, hospital-specific payment rates, and national capital Federal rate to remove the temporary one-time factor of 1.006.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20001), we stated that we were including a factor of (1/1.006) in the calculation of the FY 2018 standardized amount, hospital-specific payment rates, and national capital Federal rate to remove the temporary one-time factor of 1.006, as explained in detail in section II. of the Addendum to the proposed rule.

We noted that, in the FY 2017 IPPS/LTCH PPS final rule, in our response to public comments, we recognized that for closed, converted, or new hospitals, our prospective method generally may have had a differential positive or negative impact compared to hospitals that were IPPS hospitals for all of the FY 2014 through FY 2017 time period. We stated that we generally believe that, given the prospective nature of our method and our goal to adopt a transparent, expedient, and administratively feasible approach, these differential impacts would be an appropriate consequence. However, after consideration of the public comments received, we agreed that we should provide a process to address the situation of closed or converted hospitals. Due to the small number of hospitals impacted, we stated that we will address closed and converted hospitals as part of the cost report settlement process. We stated that these hospitals should identify themselves to their MACs so that the appropriate cost report adjustment can be applied.

Comment: One commenter opposed the removal of the one-time 1.006 adjustment, stating that the original reduction was improper. Another commenter indicated that CMS should recalculate an adjustment to the IPPS rates using both medical and surgical Medicare claims data and recalculate the FY 2018 IPPS rates accordingly.

Response: We did not propose to make any adjustment to the FY 2018 rates related to the 2-midnight policy. We note that in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57060), we finalized the policy to remove the one-time 1.006 adjustment in the FY 2018 rates. We also refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57060), where we responded to similar comments.

As we finalized in the FY 2017 IPPS/LTCH PPS final rule, we are including a factor of (1/1.006) in the calculation of the FY 2018 standardized amount, hospital specific payment rates, and national capital Federal rate to remove the temporary one-time factor of 1.006 that was in place for FY 2017.

N. Provider-Based Status of Indian Health Service and Tribal Facilities and Organizations

As we discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20001 through 20002), since the beginning of the Medicare program, some providers, which we refer to as ''main providers,'' have functioned as a single entity while owning and operating multiple departments, locations, and facilities. We have maintained that having clear criteria for provider-based status is important because a provider-based status designation can result in additional Medicare payments under the OPPS for services provided at the provider-based facility, as well as increased beneficiary coinsurance liability for Medicare beneficiaries.

The Medicare criteria for provider-based status are set forth in our regulations at 42 CFR 413.65. In the April 7, 2000 OPPS final rule (65 FR 18507), CMS (then HCFA), responded to several commenters who were concerned that the implementation of the proposed provider-based regulations would have the effect of denying Medicare participation as provider-based entities to a number of Indian Health Service (IHS) facilities that were being operated by Indian Tribes under the auspices of the Indian Self-Determination and Education Assistance Act (Pub. L. 93–638). Other commenters were concerned that the regulations would jeopardize statutorily authorized contracting and compacting relationships and would severely restrict a number of IHS and Tribal clinics from receiving payments for outpatient services. The IHS itself strongly recommended that the proposed regulations not apply to IHS and the Tribal health system. In response to these concerns, we stated in that final rule (68 FR 18507): ''We recognize that the provision of health services to members of federally recognized Tribes is based on a special and legally recognized relationship between Indian Tribes and the United States Government. To address this relationship, the IHS has developed an integrated system to provide care that has its foundation in IHS hospitals. Because of these special circumstances, not present in the case of private, non-Federal facilities and organizations that serve patients generally, we agree that it would not be appropriate to apply the provider-based criteria to IHS facilities or organizations or to most tribal facilities or organizations.''

In the April 7, 2000 OPPS final rule (65 FR 18507), we finalized a policy at § 413.65(m) of our regulations under

which facilities and organizations operated by the IHS or Tribes would be considered to be ''departments of hospitals operated by the IHS or Tribes,'' and thereby grandfathered from application of the provider-based rules, if on or before April 7, 2000, they furnished only services that were billed as if they had been furnished by a department of a hospital operated by the IHS or a Tribe and they are: (1) Owned and operated by the IHS; (2) owned by the Tribe but leased from the Tribe by the IHS under the Indian Self-Determination and Education Assistance Act in accordance with applicable regulations and policies of the IHS in consultation with Tribes; or (3) owned by the IHS but leased and operated by the Tribe under the Indian Self-Determination and Education Assistance Act in accordance with applicable regulations and policies of the IHS in consultation with Tribes.

In order to qualify for grandfathering under § 413.65(m), we required that the services be furnished by the facility or organization on or before April 7, 2000 because of our concern that, without such a date limitation, this provision would create an incentive for IHS or Tribal hospitals to establish new outpatient departments that were not sufficiently integrated with the main provider to support payment under the OPPS for the services that they furnished. Our intent was to implement a policy that both addressed a primary concern (that is, the rapid growth of off-campus provider-based clinics) that necessitated the provider-based regulations and recognized longstanding and complex IHS and Tribal arrangements. Since we finalized the policy at § 413.65(m), we have issued guidance on circumstances that would and would not result in a facility or organization losing its grandfathered status. In particular, we recognized the special relationship between Tribes and the IHS under the Self-Determination and Education Assistance Act and stated that changes in the status of a hospital or a facility from IHS to Tribal operation, or vice versa, or the realignment of a facility from one IHS or Tribal hospital to another IHS or Tribal hospital, would not be a basis for losing such a grandfathered status, so long as the resulting configuration is one that would have qualified for grandfathering under § 413.65(m) had it been in effect on April 7, 2000.

In the years since we implemented § 413.65(m) and issued the guidance described earlier, we have considered whether it remains necessary to require that facilities and organizations be furnishing the services on or before April 7, 2000 in order to qualify for grandfathering. We have concluded that it does not because IHS policies and procedures (for example, as specified in the Indian Health Manual available on the IHS Web site at: *https://ihs.gov/aboutihs/indianhealthmanual/*) regarding the planning, operation, and funding of such facilities and organizations are resulting in appropriate Medicare payments to them. Therefore, after further consideration of the position CMS has set out in prior guidance, the special and legally recognized relationship between Indian Tribes and the U.S. Government, as well as current IHS policies and procedures, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20002), we proposed to remove the date limitation in § 413.65(m) that restricted the grandfathering provision to IHS or Tribal facilities and organizations furnishing services on or before April 7, 2000.

We also proposed to make a technical change to the billing reference in § 413.65(m) by replacing ''were billed'' with ''are billed using the CCN of the main provider and with the consent of the main provider.'' We stated that we believe this proposed change will make the regulation text more consistent with our current rules that require these facilities to comply with all applicable Medicare conditions of participation that apply to the main provider. In the proposed rule, we did not propose to otherwise change the requirement that the only services furnished at the facility or organization must be hospital outpatient services, or to change the other requirements for grandfathering in paragraphs (m)(1) through (3) of § 413.65. Therefore, under our proposal, a facility or organization operated by the IHS or a Tribe will be considered to be a department of a hospital operated by the IHS or a Tribe if it furnishes only hospital outpatient services that are billed using the CMS Certification Number (CCN) of the main provider with the consent of the main provider, and it also meets one of the conditions in § 413.65(m)(1) through (3).

We welcomed public comments on our proposals.

Comment: Commenters supported both CMS proposals to remove the date limitation and to clarify that only hospital outpatient services can be billed using the CCN of the main provider and with the consent of the main provider. Commenters requested that CMS further revise § 413.65(m)(1) through (3) to add an additional condition for facilities owned and operated by a Tribe or Tribal Organization pursuant to a contract or compact under the Indian Self-Determination Act (ISDA). Commenters contended that it is clear in the ISDA that Congressional intent was that the same resources available to the IHS be also available to Tribes to operate the same programs and services. Therefore, the commenters believed that the provisions in § 413.65(m) should be applied uniformly. Finally, commenters requested CMS to consider making regulatory changes to create flexibility in applying requirements at 42 CFR part 482, the conditions of participation (CoP) for provider-based IHS and Tribal facilities, and to similarly remove the April 7, 2000 date restriction for Tribal Grandfathered FQHC requirements.

Response: We appreciate the commenters' support for our proposals. Regarding the commenters' request to add an additional condition for exemption under § 413.65(m)(1) through (3), we did not propose to change the other requirements for grandfathering in paragraphs (m)(1) through (3) of § 413.65. However, we will take this comment under consideration and, if appropriate, address it in future rulemaking.

We appreciate the views shared by commenters regarding compliance with the hospital Conditions of Participation (CoPs) set out at 42 CFR part 482, and how the hospital CoPs might apply to provider-based facilities. We reiterate that the provider-based rules at § 413.65 govern whether a facility or organization is considered to be part of the main provider for purposes of Medicare payment, and those rules do not exempt any provider-based facilities from the need to comply with hospital requirements under the CoPs at Part 482. We also did not propose any changes to the Tribal grandfathered FQHC policy. As discussed in the CY 2016 Medicare Physician Fee Schedule final rule (80 FR 71089 through 71096), in order to qualify for the ''grandfathered'' Tribal FQHC payment rate, a Tribal facility is required to have billed as a department of a provider prior to April 7, 2000. While we are finalizing our proposed removal of the April 7, 2000 date from § 413.65(m) in this final rule, this date requirement will remain in effect for Tribal FQHCs. However, we will take these views into consideration for future rulemaking.

After consideration of public comments we received, we are finalizing the proposed revisions to § 413.65(m). We are removing the date limitation in § 413.65(m) that restricted the grandfathering provision to IHS or Tribal facilities and organizations furnishing services on or before April 7, 2000. We also are finalizing the

technical change to the billing reference in § 413.65(m) by replacing ''were billed'' with ''are billed using the CCN of the main provider and with the consent of the main provider.''

VI. Changes to the IPPS for Capital-Related Costs

A. Overview

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient acute hospital services in accordance with a prospective payment system established by the Secretary. Under the statute, the Secretary has broad authority in establishing and implementing the IPPS for acute care hospital inpatient capital-related costs. We initially implemented the IPPS for capital-related costs in the FY 1992 IPPS final rule (56 FR 43358). In that final rule, we established a 10-year transition period to change the payment methodology for Medicare hospital inpatient capital-related costs from a reasonable cost-based payment methodology to a prospective payment methodology (based fully on the Federal rate).

FY 2001 was the last year of the 10-year transition period that was established to phase in the IPPS for hospital inpatient capital-related costs. For cost reporting periods beginning in FY 2002, capital IPPS payments are based solely on the Federal rate for almost all acute care hospitals (other than hospitals receiving certain exception payments and certain new hospitals). (We refer readers to the FY 2002 IPPS final rule (66 FR 39910 through 39914) for additional information on the methodology used to determine capital IPPS payments to hospitals both during and after the transition period.)

The basic methodology for determining capital prospective payments using the Federal rate is set forth in the regulations at 42 CFR 412.312. For the purpose of calculating capital payments for each discharge, the standard Federal rate is adjusted as follows:

(Standard Federal Rate) × (DRG Weight) × (Geographic Adjustment Factor (GAF)) × (COLA for hospitals located in Alaska and Hawaii) × (1 + Capital DSH Adjustment Factor + Capital IME Adjustment Factor, if applicable).

In addition, under § 412.312(c), hospitals also may receive outlier payments under the capital IPPS for extraordinarily high-cost cases that qualify under the thresholds established for each fiscal year.

B. Additional Provisions

1. Exception Payments

The regulations at 42 CFR 412.348 provide for certain exception payments under the capital IPPS. The regular exception payments provided under §§ 412.348(b) through (e) were available only during the 10-year transition period. For a certain period after the transition period, eligible hospitals may have received additional payments under the special exceptions provisions at § 412.348(g). However, FY 2012 was the final year hospitals could receive special exceptions payments. For additional details regarding these exceptions policies, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725).

Under § 412.348(f), a hospital may request an additional payment if the hospital incurs unanticipated capital expenditures in excess of $5 million due to extraordinary circumstances beyond the hospital's control. Additional information on the exception payment for extraordinary circumstances in § 412.348(f) can be found in the FY 2005 IPPS final rule (69 FR 49185 and 49186).

2. New Hospitals

Under the capital IPPS, the regulations at 42 CFR 412.300(b) define a new hospital as a hospital that has operated (under previous or current ownership) for less than 2 years and lists examples of hospitals that are not considered new hospitals. In accordance with § 412.304(c)(2), under the capital IPPS, a new hospital is paid 85 percent of its allowable Medicare inpatient hospital capital-related costs through its first 2 years of operation, unless the new hospital elects to receive full prospective payment based on 100 percent of the Federal rate. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725) for additional information on payments to new hospitals under the capital IPPS.

3. Payments for Hospitals Located in Puerto Rico

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57061), we revised the regulations at 42 CFR 412.374 relating to the calculation of capital IPPS payments to hospitals located in Puerto Rico beginning in FY 2017 to parallel the change in the statutory calculation of operating IPPS payments to hospitals located in Puerto Rico, for discharges occurring on or after January 1, 2016, made by section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113). Section 601 of Public Law 114–113 increased the applicable Federal percentage of the operating IPPS payment for hospitals located in Puerto Rico from 75 percent to 100 percent and decreased the applicable Puerto Rico percentage of the operating IPPS payments for hospitals located in Puerto Rico from 25 percent to zero percent, applicable to discharges occurring on or after January 1, 2016. As such, under revised § 412.374, for discharges occurring on or after October 1, 2016, capital IPPS payments to hospitals located in Puerto Rico are based on 100 percent of the capital Federal rate.

C. Annual Update for FY 2018

The annual update to the national capital Federal rate, as provided for at § 412.308(c), for FY 2018 is discussed in section III. of the Addendum to this final rule.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50906 through 50954), we adopted the 2-midnight policy effective for dates of admission on or after October 1, 2013, under which an inpatient admission is generally appropriate for Medicare Part A payment if the physician (or other qualified practitioner) admits the patient as an inpatient based upon the reasonable expectation that the patient will need hospital care that crosses at least 2 midnights. At that time, our actuaries estimated that the 2-midnight policy would increase expenditures by approximately $220 million in FY 2014 due to an expected net increase in inpatient encounters. Using our authority under section 1886(g) of the Act, and consistent with the approach taken for the operating IPPS standardized amount, the Puerto Rico-specific standardized amount and the hospital-specific payment rates, we made a reduction of 0.2 percent (an adjustment factor of 0.998) to the national capital Federal rate and the Puerto Rico-specific capital rate to offset the estimated increase in capital IPPS expenditures associated with the projected increase in inpatient encounters that was expected to result from the new inpatient admission guidelines (78 FR 50746 through 50747). (As explained in section V.B.3. of the FY 2017 IPPS/LTCH PPS final rule, we discontinued use of the Puerto Rico capital rate in the calculation of capital IPPS payments to hospitals located in Puerto Rico beginning in FY 2017.)

For the reasons discussed in the FY 2017 IPPS/LTCH PPS proposed and final rules (81 FR 25136 through 25138 and 57058 through 57060) and consistent with our approach for the operating IPPS rates, we used our authority under section 1886(g) of the Act to permanently remove the 0.2 percent reduction to the national capital

Federal rate beginning in FY 2017. Specifically, we made an adjustment of (1/0.998) to the national capital Federal rate to remove the 0.2 percent reduction, consistent with the adjustment to the operating IPPS standardized amount and the hospital-specific payment rates.

In addition, consistent with our approach for the operating IPPS standardized amount and hospital-specific payment rates, and for the reasons discussed in the FY 2017 IPPS/LTCH PPS proposed and final rules, we finalized our proposal to use our authority under section 1886(g) of the Act to adjust the FY 2017 national capital Federal rate to address the effects of the 0.2 percent reduction to the national capital Federal rates in effect for FY 2014, FY 2015, and FY 2016 by making a one-time prospective adjustment of 1.006 in FY 2017 to the national capital Federal rate and, for FY 2018, to remove the effects of this one-time prospective adjustment through an adjustment of (1/1.006) to the national capital Federal rate. Therefore, consistent with our finalized policy, and as discussed in the FY 2018 IPPS/LTCH PPS proposed rule, for FY 2018, we are including a factor of (1/1.006) in the calculation of the FY 2018 operating IPPS standardized amount, the hospital-specific payment rates, and the national capital Federal rate to remove the temporary one-time factor of 1.006. (For additional details, we refer readers to section IV.P. of the preamble of the FY 2017 IPPS/LTCH PPS final rule (81 FR 57058 through 57060 and 57062 through 57063) and to section V.M. of the preamble of this final rule.)

In section II.D. of the preamble of this final rule, we present a discussion of the MS–DRG documentation and coding adjustment, including previously finalized policies and historical adjustments, as well as the adjustment to the standardized amount under section 1886(d) of the Act that we proposed, and are finalizing, for FY 2018 in accordance with the amendments made to section 7(b)(1)(B) of Public Law 110–90 by section 414 of the MACRA and section 15005 of the 21st Century Cures Act. Because these provisions require us to make an adjustment only to the operating IPPS standardized amount, we are not making a similar adjustment to the national capital Federal rate (or to the hospital-specific rates).

VII. Changes for Hospitals Excluded From the IPPS

A. Rate-of-Increase in Payments to Excluded Hospitals for FY 2018

Certain hospitals excluded from a prospective payment system, including children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling. A per discharge limit (the target amount as defined in § 413.40(a) of the regulations) is set for each hospital based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. For each cost reporting period, the updated target amount is multiplied by total Medicare discharges during that period and applied as an aggregate upper limit (the ceiling as defined in § 413.40(a)) of Medicare reimbursement for total inpatient operating costs for a hospital's cost reporting period. In accordance with § 403.752(a) of the regulations, religious nonmedical health care institutions (RNHCIs) also are subject to the rate-of-increase limits established under § 413.40 of the regulations discussed previously. Furthermore, as discussed in VIII.J. of the preamble of this final rule, in accordance with § 412.526(c)(3) of the regulations, extended neoplastic disease care hospitals (formerly termed long-term care neoplastic disease hospitals) also are subject to the rate-of-increase limits established under § 413.40 of the regulations discussed previously.

As explained in the FY 2006 IPPS final rule (70 FR 47396 through 47398), beginning with FY 2006, we have used the percentage increase in the IPPS operating market basket to update the target amounts for children's hospitals, cancer hospitals, and RNHCIs. Consistent with §§ 412.23(g), 413.40(a)(2)(ii)(A), and 413.40(c)(3)(viii), we also have used the percentage increase in the IPPS operating market basket to update the target amounts for short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. In the FYs 2014 and 2015 IPPS/LTCH PPS final rules (78 FR 50747 through 50748 and 79 FR 50156 through 50157, respectively), we adopted a policy of using the percentage increase in the FY 2010-based IPPS operating market basket to update the target amounts for FY 2014 and subsequent fiscal years for children's hospitals, cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. However, as discussed in section IV. of the preamble of the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20004), we proposed to rebase and revise the IPPS operating basket to a 2014 base year. Therefore, we proposed to use the percentage increase in the 2014-based IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa for FY 2018 and subsequent fiscal years. Accordingly, for FY 2018, the rate-of-increase percentage to be applied to the target amount for these hospitals would be the FY 2018 percentage increase in the 2014-based IPPS operating market basket. We did not receive any public comments on these proposals. Therefore, we are finalizing these policies as proposed. Based on IGI's 2016 fourth quarter forecast, for the proposed rule, we estimated that the 2014-based IPPS operating market basket update for FY 2018 would be 2.9 percent (that is, the estimate of the market basket rate-of-increase). We indicated in the proposed rule that if more recent data became available for the final rule, we would use them to calculate the IPPS operating market basket update for FY 2018. For this FY 2018 IPPS/LTCH PPS final rule, based on IGI's 2017 second quarter forecast (which is the most recent data available), we calculated the 2014-based IPPS operating market basket update for FY 2018 to be 2.7 percent. Therefore, the FY 2018 rate-of-increase percentage that is applied to the FY 2017 target amounts in order to calculate the FY 2018 target amounts for children's hospitals, cancer hospitals, RNCHIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is 2.7 percent, in accordance with the applicable regulations at 42 CFR 413.40.

In addition, as discussed in section VIII.J. of the preamble of this final rule, as originally enacted section 1886(d)(1)(B)(iv) of the Act established an IPPS-excluded category of hospitals that experience extended average inpatient length-of-stays, which are known as LTCHs under the Medicare program. Historically, section 1886(d)(1)(B)(iv) of the Act consisted of

two subclauses (I) and (II) (that is, sections 1886(d)(1)(B)(iv)(I) and (d)(1)(B)(iv)(II) of the Act), and the two categories of hospitals were generally referred to as ''subclause (I)'' and ''subclause (II)'' LTCHs. Section 15008 of the 21st Century Cures Act (Pub. L. 114–255) amended section 1886(d)(1)(B) of the Act by redesignating the ''subclause (II) LTCH'' provision in section 1886(d)(1)(B)(iv)(II) of the Act to section 1886(d)(1)(B)(vi) of the Act. In addition, subsection (b) of section 15008 of Public Law 114–255 specifies that, for cost reporting periods beginning on or after January 1, 2015, hospitals classified under section 1886(d)(1)(B)(vi) of the Act are not subject to section 1886(m) of the Act, which sets forth the LTCH PPS. Section 15008(c) further specifies that, for cost reporting periods beginning on or after January 1, 2015, payment for inpatient operating costs for such hospitals is to be made as described in 42 CFR 412.526(c)(3), and payment for capital costs is to be made as described in 42 CFR 412.526(c)(4). In order to implement these requirements, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20029), we proposed to amend § 412.23 to codify the redesignation of such hospitals from section 1886(d)(1)(B)(iv)(II) of the Act to new section 1886(d)(1)(B)(vi) of the Act (which we referred to as ''long-term care neoplastic disease hospitals'') and the statutory payment requirements for inpatient operating and capital costs. (For additional information on ''subclause (II)'' LTCHs, including the statutory criteria and the establishment of the payment adjustment under § 412.526, and our changes to § 412.22 to implement the provisions of section 15008 of Public Law 114–255, we refer readers to section VIII.J. of the preamble of this final rule.)

Under the redesignation of subclause (II) LTCHs to long-term care neoplastic disease hospitals provided by section 15008 of Public Law 114–255 (described above), the statute specifies that payment for inpatient operating costs shall continue to be made on a reasonable cost basis in the manner provided in § 412.526(c)(3) of the regulations. Section 412.526(c)(3) provides that the hospital's Medicare allowable net inpatient operating costs for that period are paid on a reasonable cost basis, subject to that hospital's ceiling, as determined under § 412.526(c)(1), for that period. Under section 412.526(c)(1), for each cost reporting period, the ceiling was determined by multiplying the updated target amount, as defined in § 412.526(c)(2), for that period by the number of Medicare discharges paid during that period. Section 412.526(c)(2)(i) describes the method for determining the target amount for cost reporting periods beginning during FY 2015. Section 412.526(c)(2)(ii) specifies that, for cost reporting periods beginning during fiscal years after FY 2015, the target amount will equal the hospital's target amount for the previous cost reporting period updated by the applicable annual rate-of-increase percentage specified in § 413.40(c)(3) for the subject cost reporting period (79 FR 50197).

For FY 2018, in accordance with proposed § 412.23(j)(2) and existing § 412.526(c)(2)(ii) of the regulations, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20029), we proposed that, for cost reporting periods beginning during FY 2018, the update to the target amount for long-term care neoplastic disease hospitals (that is, hospitals described under proposed § 412.23(j)) would be the applicable annual rate-of-increase percentage specified in § 413.40(c)(3) for FY 2018, which would be equal to the percentage increase projected by the hospital market basket index, which, in the proposed rule, was estimated to be the percentage increase in the proposed 2014-based IPPS operating market basket (that is, the estimate of the market basket rate-of-increase). Accordingly, for the proposed rule, the update to a long-term care neoplastic disease hospital's target amount for FY 2018 was 2.9 percent, which was based on IGI, Inc.'s 2016 fourth quarter forecast. Furthermore, we proposed that if more recent data became available for the final rule, we would use that updated data to calculate the IPPS operating market basket update for FY 2018. For this final rule, based on IHS Global Insight, Inc.'s second quarter forecast (which is the most recent data available), the update to an extended neoplastic disease care hospital's target amount for FY 2018 is 2.7 percent.

Comment: Some commenters requested that CMS move the regulations concerning payment for these hospitals from proposed § 412.23 to § 412.22.

Response: We agree with these commenters and are finalizing our payment regulation at new paragraph (i) under § 412.22. We note that the language of this paragraph is identical (with the exception of minor technical editing for cross-references) to the language we proposed.

Comment: Some commenters pointed out that the proposed rule preamble description of hospitals excluded from the IPPS does not include these hospitals and requested their inclusion.

Response: We agree and have made conforming changes to the preamble of this final rule.

Comment: Some commenters requested that CMS change the name of these hospitals from ''long-term care neoplastic disease hospitals'' to ''hospital for the treatment of advanced cancer and other diseases.''

Response: We do not believe that the name suggested by the commenters is sufficiently descriptive to accurately capture a specific subset of hospitals. Most, if not all, hospitals treat advanced cancer and other diseases. However, given the commenters' concerns about the use of the term ''long-term care'' in the name of the new category of hospital, we are finalizing the name ''extended neoplastic disease care hospital.'' We believe this is appropriate because it distinguishes these hospitals from the 11 cancer hospitals and to account for the fact that these hospitals are still statutorily required to maintain a minimum average length of stay.

Comment: Some commenters requested CMS to add a claims processing provision to the Medicare payment regulations for these hospitals.

Response: We do not believe that it is appropriate to include claims processing information in our regulations and, therefore, are not adding the additional language requested by commenters.

Comment: Some commenters requested that CMS include sunset dates to § 412.526.

Response: As we have added a sunset date to § 412.22 (proposed § 412.23(e)(ii)), we do not believe that it is necessary to include separate sunset dates in § 412.526.

After consideration of the public comments we received, we are finalizing our proposals with the minor technical changes noted above.

B. Changes to the Hospital-Within-Hospital Regulations

On September 1, 1994, we published regulations governing hospitals-within-hospitals (HwHs) to address inappropriate Medicare payments to LTCHs that were effectively units of other hospitals (59 FR 45330). There was concern that the LTCH HwH model was being used by some acute care hospitals paid under the IPPS as a way of inappropriately receiving higher payments for a subset of their cases. Moreover, we stated that the IPPS-exclusion of long-term care ''units'' may be inconsistent with the statutory scheme, which does not provide for the

exclusion from the IPPS of long-term care units.

Therefore, we codified the HwH regulations at 42 CFR 412.23 (currently at § 412.22(e)) for an LTCH HwH that is co-located with another hospital. A co-located hospital is a hospital that occupies space in a building also used by another hospital or in one or more separate buildings located on the same campus as buildings used by another hospital. The regulations at § 412.22(e) required that, to be excluded from the IPPS, long-term care HwHs must have a separate governing body, a chief medical officer, medical staff, and a chief executive officer, from that of the hospital with which it is co-located. In addition, the long-term care HwH must have met either of the following two criteria: The HwH must perform certain specified basic hospital functions on its own and not receive them from the host hospital or a third entity that controls both hospitals; or the HwH must receive at least 75 percent of its inpatients from sources other than the co-located hospital. A third option was added to the regulations on September 1, 1995 (60 FR 45778) that allowed long-term care HwHs to demonstrate their separateness by showing that the cost of the services that the hospital obtains under contracts or other agreements with the co-located hospital or a third entity that controls both hospitals is no more than 15 percent of the hospital's total inpatient operating cost. In 1997, we extended application of the HwH regulations at § 412.22 to all classifications of IPPS-excluded hospitals. Therefore, effective for cost reporting periods beginning on or after October 1, 1997, psychiatric, rehabilitation, cancer, and children's hospitals that are co-located with another hospital also are generally required to meet the ''separateness'' criteria at § 412.22(e). In addition, a ''grandfathering'' provision (that is, hospitals that were IPPS-excluded HwHs before October 1, 1995 are not required to comply with the separateness and control regulations so long as they continue to operate under the same terms and conditions) was added to the regulations at § 412.22(f). We later modified the grandfathering provision to allow for a grandfathered hospital to make specified changes (for example increasing the number of beds) during particular timeframes, which vary depending on the change the hospital had made. Below we discuss our FY 2018 proposed and finalized changes to our HwH regulations.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20004), we proposed to revise our HwH regulations so that the separateness and control requirements would only apply to IPPS-excluded HwHs that are co-located with IPPS hospitals. Under this proposal, any hospital that occupies a building also used by another hospital, or in one or more separate buildings located on the same campus as buildings used by another hospital would remain, by definition, an HwH. However, the separateness and control requirements for IPPS-excluded HwHs would apply only when the IPPS-excluded hospital is co-located with an IPPS hospital. The proposal was premised on the belief that the policy concerns that underlie our existing HwH regulations (that is, inappropriate patient shifting and hospitals acting as illegal de facto units) are sufficiently moderated in situations where IPPS-excluded hospitals are co-located with each other but not IPPS hospitals, in large part due to the payment system changes that have occurred over the intervening years for IPPS-excluded hospitals. For example, LTCHs, inpatient rehabilitation facilities (IRFs) and inpatient psychiatric facilities (IPFs) are no longer paid on a reasonable cost-basis as was the case when HwH regulations were adopted. Currently, LTCHs, IRFs, and IPFs are each paid under their own respective PPS, and those payment systems include policies based on the types of patients they admit for treatment. For example, to be classified for payment under Medicare's IRF PPS, at least 60 percent of a facility's total inpatient population must require inpatient hospital-level treatment for one or more of 13 conditions listed in 42 CFR 412.29(b)(2), and recent statutory changes require that specified patient-level criteria be met for LTCH discharges to be paid based on the standard Federal payment rate under the LTCH PPS. For these reasons, we proposed to revise our HwH regulations so that the separateness and control requirements would only apply to IPPS-excluded HwHs that are co-located with IPPS hospitals; we proposed to revise the introductory language of § 412.22(e) to reflect the proposed change. That is, the introductory language of § 412.22(e) would state that, beginning on or after October 1, 2017, an HwH that is excluded from the IPPS that occupies space in a building also used by an IPPS hospital, or in one or more separate buildings located on the same campus as buildings used by an IPPS hospital, must meet the criteria specified in §§ 412.22(e)(1) through (e)(3) in order to be excluded from the IPPS. While we did not propose to make changes to our HwH regulations for co-located IPPS and IPPS-excluded hospitals, we invited public comments on the issue of whether the separateness and control requirements are still necessary for IPPS-excluded HwHs that are co-located with IPPS hospitals, which we would consider for potential future rulemaking.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20004), we also proposed to revise the requirements at § 412.22(e)(1)(v), which outlines performance of basic hospital functions, to make them effective for fiscal years prior to FY 2018. We believe that the requirements in paragraph (e)(1)(v)(A) are generally duplicative of CMS' interpretative guidance that relate to a number of hospital conditions of participation (CoPs) that are in the regulations (for example, 42 CFR 482.21 through 482.27, 482.30, 482.42, 482.43, and 482.45). As such, we proposed to remove the overlap between the HwH regulations and the CoP Interpretative Guidance from the regulations by sunsetting the requirements in paragraph (e)(1)(v)(A) of § 412.22. (The COP Interpretive Guidance for hospitals can be found in Appendix A of the State Operations Manual (CMS Pub. 100–07).) In addition, we proposed to remove the requirements in paragraph (e)(1)(v)(B) of § 412.22 because we believe these payment requirements could be interpreted to conflict with the requirements under the hospital CoPs, which do not provide for a minimum cost threshold regarding the services the HwH obtains from the hospital with which it is occupying space. We stated that we did not believe that this proposed revision would result in a practical change to how HwHs are currently operated because the performance of basic hospital functions requirements at § 412.22(e)(1)(v) are currently addressed under CMS' Interpretative Guidance for the hospital CoPs. In addition, we stated that we did not believe, at that time, that there are payment policy concerns that would justify imposition of regulatory requirements on the performance of basic hospital functions for HwHs that are more stringent than what is addressed under the Interpretative Guidance for the hospital CoPs.

We invited public comment on these proposals.

Comment: Several commenters supported CMS' proposal to apply the separateness and control requirements only to IPPS-excluded HwHs that are co-located with IPPS hospitals. Some commenters requested clarification that § 412.22(e)(1)(v)(C) would also not apply to a HwH after October 1, 2017 because the retention of that

requirement, taken together with the removal of § 412.22(e)(1)(v)(A) and (B), would have the result of eliminating HwH status for many IPPS-excluded HwHs. Some commenters also stated that the proposed revision to § 412.22(e)(1)(v) should not be interpreted to mean that a HwH must have complied with § 412.22(e)(1)(v) prior to October 1, 2017 in order to maintain its IPPS-excluded status after October 1, 2017.

Response: We thank the commenters for their support and confirm that our intent was to eliminate the requirement that HwHs comply with § 412.22(e)(1)(v) in its entirety starting in FY 2018. Eliminating § 412.22(e)(1)(v)(A) and (B), but not (C), would have the unintended effect of requiring HwHs to ensure that they met the 75 percent inpatient population requirement during the 6-month period immediately preceding the first cost reporting period for which they sought an exclusion in order to maintain that excluded status. As that was not our intent, we are finalizing that, beginning with FY 2018, HwHs will no longer be required to satisfy any of the criteria in § 412.22(e)(1)(v) in order to maintain their HwH status. This change will not affect requirements applicable to HwHs prior to October 1, 2017. We also note that none of the changes to the HwH regulations that we are finalizing in this final rule constitute changes to the conditions of participation (CoPs) at 42 CFR part 482 and applicable interpretative guidance; and that every hospital, regardless of co-location, must independently comply with all applicable CoPs.

Comment: Some commenters believed that the proposed revisions to the HwH rules apply to all forms of co-located hospitals. Other commenters requested that CMS make analogous changes to the satellite facility rules in addition to the HwH rules.

Response: We believe that some commenters have misunderstood the scope of our proposals. Co-located hospital locations can be either HwHs (entire hospitals that are co-located with another hospital) or satellite facilities (parts of hospitals that are co-located with another hospital). The HwH rules do not apply to satellite facilities. Regulations governing payment to satellite facilities can be found at § 412.22(h). We appreciate the request by some commenters to consider making analogous changes to the regulations governing satellite facilities, and we will take that request under advisement for future rulemaking.

Comment: Several commenters responded to CMS' solicitation of comments on whether it remains necessary to maintain the separateness and control requirements for IPPS-excluded HwHs that are co-located with IPPS hospitals.

Response: We appreciate the comments we received on this topic and will take them under advisement for future rulemaking.

After consideration of the public comments we received, we are finalizing our proposals as proposed, with one modification. Under our final policies, HwHs will no longer be required to satisfy any of the criteria at § 412.22(e)(1)(v), including paragraph (e)(1)(v)(C), in order to maintain their HwH status.

C. Report on Adjustment (Exceptions) Payments

Section 4419(b) of Public Law 105–33 requires the Secretary to publish annually in the **Federal Register** a report describing the total amount of adjustment payments made to excluded hospitals and hospital units by reason of section 1886(b)(4) of the Act during the previous fiscal year.

The process of requesting, adjusting, and awarding an adjustment payment is likely to occur over a 2-year period or longer. First, generally, an excluded hospital must file its cost report for the fiscal year in accordance with § 413.24(f)(2) of the regulations. The MAC reviews the cost report and issues a notice of provider reimbursement (NPR). Once the hospital receives the NPR, if its operating costs are in excess of the ceiling, the hospital may file a request for an adjustment payment. After the MAC receives the hospital's request in accordance with applicable regulations, the MAC or CMS, depending on the type of adjustment requested, reviews the request and determines if an adjustment payment is warranted. This determination is sometimes not made until more than 180 days after the date the request is filed because there are times when the request applications are incomplete and additional information must be requested in order to have a completed request application. However, in an attempt to provide interested parties with data on the most recent adjustment payments for which we have data, we are publishing data on adjustment payments that were processed by the MAC or CMS during FY 2016.

The table below includes the most recent data available from the MACs and CMS on adjustment payments that were adjudicated during FY 2016. As indicated above, the adjustments made during FY 2016 only pertain to cost reporting periods ending in years prior to FY 2016. Total adjustment payments given to excluded hospitals during FY 2016 are $13,123,870. The table depicts for each class of hospitals, in the aggregate, the number of adjustment requests adjudicated, the excess operating costs over the ceiling, and the amount of the adjustment payments.

Class of hospital	Number	Excess cost over ceiling	Adjustment payments
Hospitals in Territories	1	$3,007,636	$2,112,404
Cancer	1	21,255,065	10,236,366
Religious Nonmedical Health Care Institution (RNHCI)	4	420,960	420,960
Psychiatric Unit	1	2,116,384	354,140
Total			13,123,870

D. Critical Access Hospitals (CAHs)

1. Background

Section 1820 of the Act provides for the establishment of Medicare Rural Hospital Flexibility Programs (MRHFPs), under which individual States may designate certain facilities as critical access hospitals (CAHs). Facilities that are so designated and meet the CAH conditions of participation under 42 CFR part 485, subpart F, will be certified as CAHs by CMS. Regulations governing payments to CAHs for services to Medicare beneficiaries are located in 42 CFR part 413.

2. Frontier Community Health Integration Project (FCHIP) Demonstration

Section 123 of the Medicare Improvements for Patients and

Providers Act of 2008 (Pub. L. 110–275), as amended by section 3126 of the Affordable Care Act, authorizes a demonstration project to allow eligible entities to develop and test new models for the delivery of health care services in eligible counties in order to improve access to and better integrate the delivery of acute care, extended care and other health care services to Medicare beneficiaries. The demonstration is titled ''Demonstration Project on Community Health Integration Models in Certain Rural Counties,'' and is commonly known as the Frontier Community Health Integration Project (FCHIP) demonstration.

The authorizing statute states the eligibility criteria for entities to be able to participate in the demonstration. An eligible entity, as defined in section 123(d)(1)(B) of Public Law 110–275, as amended, is an MRHFP grantee under section 1820(g) of the Act (that is, a CAH); and is located in a State in which at least 65 percent of the counties in the State are counties that have 6 or less residents per square mile.

The authorizing statute stipulates several other requirements for the demonstration. Section 123(d)(2)(B) of Public Law 110–275, as amended, limits participation in the demonstration to eligible entities in not more than 4 States. Section 123(f)(1) of Public Law 110–275 requires the demonstration project to be conducted for a 3-year period. In addition, section 123(g)(1)(B) of Public Law 110–275 requires that the demonstration be budget neutral. Specifically, this provision states that in conducting the demonstration project, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project under the section were not implemented. Furthermore, section 123(i) of Public Law 110–275 states that the Secretary may waive such requirements of titles XVIII and XIX of the Act as may be necessary and appropriate for the purpose of carrying out the demonstration project, thus allowing the waiver of Medicare payment rules encompassed in the demonstration.

In January 2014, CMS released a request for applications (RFA) for the FCHIP demonstration. Using 2013 data from the U.S. Census Bureau, CMS identified Alaska, Montana, Nevada, North Dakota, and Wyoming as meeting the statutory eligibility requirement for participation in the demonstration. The RFA solicited CAHs in these five States to participate in the demonstration, stating that participation would be limited to CAHs in four of the States. To apply, CAHs were required to meet the eligibility requirements in the authorizing legislation, and, in addition, to describe a proposal to enhance health-related services that would complement those currently provided by the CAH and better serve the community's needs. In addition, in the RFA, CMS interpreted the eligible entity definition in the statute as meaning a CAH that receives funding through the MHRFP. The RFA identified four interventions, under which specific waivers of Medicare payment rules would allow for enhanced payment for telehealth, skilled nursing facility/nursing facility beds, ambulance services, and home health services, respectively. These waivers were formulated with the goal of increasing access to care with no net increase in costs.

Ten CAHs were selected for participation in the demonstration, which started on August 1, 2016. These CAHs are located in Montana, Nevada and North Dakota, and they are participating in three of the four interventions identified in the FY 2017 IPPS/LTCH PPS final rule. Eight CAHs are participating in the telehealth intervention, three CAHs are participating in the skilled nursing facility/nursing facility bed intervention, and two CAHs are participating in the ambulance services intervention. Each CAH is allowed to participate in more than one of the interventions. None of the selected CAHs are participants in the home health intervention, which was the fourth intervention proposed in the RFA.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57064 through 57065), we finalized a policy to address the budget neutrality requirement for the demonstration. As explained in the FY 2017 IPPS/LTCH PPS final rule, we based our selection of CAHs for participation with the goal of maintaining the budget neutrality of the demonstration on its own terms (that is, the demonstration will produce savings from reduced transfers and admissions to other health care providers, thus offsetting any increase in payments resulting from the demonstration). However, because of the small size of this demonstration and uncertainty associated with projected Medicare utilization and costs, we adopted a contingency plan to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met. If analysis of claims data for Medicare beneficiaries receiving services at each of the participating CAHs, as well as from other data sources, including cost reports for these CAHs, shows that increases in Medicare payments under the demonstration during the 3-year period are not sufficiently offset by reductions elsewhere, we will recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide. Because of the small scale of the demonstration, we indicated that we did not believe it would be feasible to implement budget neutrality by reducing payments to only the participating CAHs. Therefore, in the event that this demonstration is found to result in aggregate payments in excess of the amount that would have been paid if this demonstration were not implemented, we will comply with the budget neutrality requirement by reducing payments to all CAHs, not just those participating in the demonstration. We stated that we believe it is appropriate to make any payment reductions across all CAHs because the FCHIP demonstration is specifically designed to test innovations that affect delivery of services by the CAH provider category. We explained our belief that the language of the statutory budget neutrality requirement at section 123(g)(1)(B) of Public Law 110–275 permits the agency to implement the budget neutrality provision in this manner. The statutory language merely refers to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not implemented, and does not identify the range across which aggregate payments must be held equal.

Based on actuarial analysis using cost report settlements for FYs 2013 and 2014, the demonstration is projected to satisfy the budget neutrality requirement and likely yield a total net savings. For the FY 2017 IPPS/LTCH PPS final rule, we estimated that the total impact of the payment recoupment would be no greater than 0.03 percent of CAHs' total Medicare payments within one fiscal year (that is, Medicare Part A and Part B). The final budget neutrality estimates for the FCHIP demonstration will be based on the demonstration period, which is August 1, 2016 through July 31, 2019.

The demonstration is projected to impact payments to participating CAHs under both Medicare Part A and Part B. As stated in the FY 2017 IPPS/LTCH PPS final rule, in the event the demonstration is found not to have been budget neutral, any excess costs will be recouped over a period of 3 cost

reporting years, beginning in CY 2020. The 3-year period for recoupment will allow for a reasonable timeframe for the payment reduction and to minimize any impact on CAHs' operations. Therefore, because any reduction to CAH payments in order to recoup excess costs under the demonstration will not begin until CY 2020, this policy will have no impact for any national payment system for FY 2018.

We did not receive any public comments on our discussion of this demonstration in the proposed rule.

3. Physician Certification Requirement for Payment of Inpatient CAH Services Under Medicare Part A

a. Background

For inpatient CAH services to be payable under Medicare Part A, section 1814(a)(8) of the Act requires that a physician certify that the individual may reasonably be expected to be discharged or transferred to a hospital within 96 hours after admission to the CAH. The regulations implementing this statutory requirement are located at 42 CFR 424.15.

We most recently addressed the 96-hour certification requirement in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50163 through 50165). In that rule, we finalized a policy regarding the timing of this physician certification requirement. We revised the regulations such that all physician certification requirements must be completed, signed, and documented in the medical record no later than 1 day before the date on which the claim for payment for the inpatient CAH service is submitted. This policy change was effective October 1, 2014. Prior to that revision, our policy, which was in effect during FY 2014, had been that the certification began with the order for inpatient admission and was required to be completed, signed, and documented in the medical record prior to discharge.

In addition to this change regarding the timing of the 96-hour certification requirement, we also provided a general review of this certification requirement in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50165). We stated that because the statutory requirement at section 1814(a)(8) of the Act is based on an expectation, if a physician certifies, in good faith, that an individual may reasonably be expected to be discharged or transferred to a hospital within 96 hours after admission to the CAH and then something unforeseen occurs that causes the individual to stay longer at the CAH, Medicare will pay for the costs of treating that patient and there would not be a problem with regard to the CAH designation as long as that individual's stay does not cause the CAH to exceed its 96-hour annual average condition of participation (CoP) requirement under 42 CFR 485.620(b) (which we note is separate and distinct from the 96-hour physician certification requirement). However, if a physician cannot in good faith certify that an individual may reasonably be expected to be discharged or transferred within 96 hours after admission to the CAH, the CAH will not receive Medicare Part A payment for any portion of that individual's inpatient stay (79 FR 50165). We further noted that time as an outpatient at the CAH is not included in applying the 96-hour requirement, nor does time in a CAH swing bed, which is being used to provide skilled nursing services, count towards the 96-hour requirement. The clock for the 96 hours only begins once the individual is admitted to the CAH as an inpatient.

b. Notice Regarding Changes to Instructions for the Review of the CAH 96-Hour Certification Requirement

As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20007), based on feedback from stakeholders, we reviewed the CAH 96-hour certification requirement to determine if there were ways to minimize providers' concerns regarding this requirement. We noted that the requirement is statutory and cannot be modified through regulation. However, we do have discretion to determine how CMS will prioritize monitoring and enforcement of the requirement. In order to minimize the concerns of CAHs with respect to the 96-hour certification requirement, in the FY 2018 IPPS/LTCH PPS proposed rule, we provided notice that CMS will direct Quality Improvement Organizations (QIOs), Medicare Administrative Contractors (MACs), the Supplemental Medical Review Contractor (SMRC), and Recovery Audit Contractors (RACs) to make the CAH 96-hour certification requirement a low priority for medical record reviews conducted on or after October 1, 2017. We stated that this means that, absent concerns of probable fraud, waste, or abuse, these contractors will not conduct medical record reviews with respect to the 96-hour certification requirement. Reviews by other entities, including, but not limited to, Zone Program Integrity Contractors (ZPICs), the Office of Inspector General, and the Department of Justice will continue as appropriate. Quality reviews and automated reviews (for example, those reviews that do not involve medical records) will also continue as appropriate.

We stated that, in the past, RACs have never performed medical record reviews for CAH claims, and we will not approve medical record review of CAHs for only the 96-hour certification requirement. We provided notice that, beginning October 1, 2017, CMS will direct the QIOs, MACs, and the SMRC to make medical record review of CAHs for only the 96-hour certification requirement a low priority. We stated that QIOs and MACs may continue to conduct medical record review of CAH claims for the purposes of verifying compliance with other requirements, such as beneficiary complaints, quality of care reviews, higher weighted DRG reviews, readmission reviews, and the requirement that procedures be medically necessary.

In the FY 2018 IPPS/LTCH PPS proposed rule, we stated that, under the revised instructions to contractors, CAHs will not receive any medical record requests from MACs, RACs, QIOs, or the SMRC related to the 96-hour certification requirement unless CMS or its contractors find evidence of gaming or a failure to comply with CMS' provider screening and revalidation requirements, or if medical review is needed for other issues. If this occurs, the MACs, RACs, QIOs, or the SMRC could also review the 96-hour certification requirement. In addition, if data analysis or other information indicates that possible fraud exists, CAHs may also receive medical record requests for the 96-hour certification requirement.

Comment: Commenters supported CMS' notice in the FY 2018 IPPS/LTCH PPS proposed rule that, with respect to the 96-hour certification requirement, CMS is directing QIOs, MACs, the SMRC, and RACs to make the CAH 96-hour certification requirement a low priority for medical record reviews conducted on or after October 1, 2017.

Commenters requested permanent removal of the 96-hour certification requirement, and many noted they are continuing to advocate for a legislative solution.

Commenters stated they appreciated CMS recognizing that the 96-hour certification requirement could hinder the promotion of essential and life-saving health care services to rural America. Commenters also noted they appreciated CMS recognizing the conflict between the 96-hour certification requirement and the 96-hour annual average CoP requirement, as well as the administrative complexity associated with the certification requirement. Some commenters urged CMS to finalize the proposed notice so that CAHs can be assured that the 96-

hour certification requirement will not be the subject of future audits. Other commenters stated that providing notice that the CAH 96-hour certification requirement is a low priority for medical record reviews is a positive first step. One commenter stated that the notice demonstrates that CMS is aware of the problems inherent in the 96-hour certification requirement, and asked CMS to provide a solution for these problems in future rulemaking that goes beyond instructing contractors to forego reviews of medical records associated with the 96-hour certification requirement apart from instances where there are specific concerns related to program integrity.

Other commenters stated they appreciated CMS' notice but were concerned that the notice, as included in the proposed rule, is too ambiguous because it does not remove the 96-hour certification requirement from the statute, and, therefore, CAHs are still at risk for penalties. The commenters believed there would be varying levels of enforcement of the 96-hour certification because of both broad definitions and concerns of fraud, waste and abuse. They encouraged CMS to finalize permanent removal of the 96-hour certification requirement to give CAHs certainty that CMS will not engage in future audits related to the 96-hour certification requirement.

One commenter appreciated the recognition that the 96-hour certification requirement is burdensome and unnecessary. However, the commenter indicated that the notice regarding the 96-hour certification requirement included in the proposed rule is not a permanent moratorium. The commenter stated that CAHs must still comply with the requirement and, therefore, can still be audited for noncompliance. The commenter expressed concern regarding the impact on large health systems where failures of one hospital in the system can result in consequences for the entire system. The commenter stated that the notice included in the proposed rule ''muddies the waters'' and urged CMS to eliminate the 96-hour certification requirement.

Commenters stated that, while the notice provides some relief, it does not remove the 96-hour certification requirement from statute, and, therefore, there are concerns that CAHs may still be at risk for penalties, including liability under the False Claims Act, as well as outside auditors using the 96-hour certification requirement to target and penalize CAHs.

Response: We appreciate commenters' support of the notice included in the proposed rule regarding the 96-hour certification requirement. In this final rule, we are reiterating that CMS will direct QIOs, MACs, the SMRC, and RACs to make the CAH 96-hour certification requirement a low priority for medical record reviews conducted on or after October 1, 2017. CAHs should not expect to receive any medical record requests from QIOs, MACs, RACs, or the SMRC related to the 96-hour certification requirement unless CMS or its contractors find evidence of gaming or a failure to comply with CMS' provider screening and revalidation requirements, or if medical review is needed for other issues. As commenters have noted, the 96-hour certification requirement is statutory; therefore, removal of this requirement requires legislative action.

Comment: Commenters expressed their concerns with respect to the 96-hour certification requirement in general. Commenters stated that while CAHs may meet the 96-hour annual average length of stay CoP requirement, they also provide medical services that require inpatient stays of more than 96 hours. In these situations, CAHs cannot adhere to the 96-hour certification requirement because a physician cannot, in good faith, certify that the beneficiary's stay will be 96 hours or less. In this scenario, if the 96-hour certification requirement were to be enforced, a CAH would not receive payment for the specific inpatient service and, as a result, patients would no longer have access to critical services that require an inpatient length of stay of more than 96 hours. Commenters further noted that because Medicare payments comprise approximately 47 percent of CAHs' revenues, any change in these payments is difficult to absorb and affects CAHs' ability to provide care to those living in rural areas.

One commenter stated that from the inception of the CAH program through late 2013, the 96-hour annual average CoP requirement provided CAHs with greater flexibility within the CAH designation process. The commenter stated that strict enforcement of the 96-hour certification requirement leads to unnecessary red tape and barriers for CAHs as well as eliminates the flexibility to allow general surgical services to be provided by high quality local providers. The commenter stated that the 96-hour certification requirement is not consistent with congressional intent to provide CAHs with greater flexibility. The commenter referenced the change made as part of the Balanced Budget Refinement Act of 1999 (Pub. L. 106–113), which amended the CAH CoP length of stay requirement such that it became based on an annual average number of hours. The commenter stated that the 96-hour certification requirement limits access to rural health care because it does not permit providers to focus on patient care. The commenter further stated that the 96-hour certification requirement interferes with practitioner judgment because high quality and qualified local providers are placed in a situation where they cannot care for their patients, and therefore patients have to travel further from home to receive care. The commenter believed these transfers result in additional Medicare expenditures because it is 2.5 percent less expensive to provide the same Medicare services in a rural setting versus an urban or suburban setting. The commenter referred to a study published in the *Journal of the American Medical Association* (JAMA), which stated that Medicare expenditures for minor general surgical procedures, when adjusted for patient factors and procedure type, are lower in CAHs, and that such procedures are associated with lower rates of serious complications when performed in CAHs. The commenter noted that these are the types of procedures generally called into question under the 96-hour certification requirement. Another comment raised concerns regarding ''judgmental pressure'' placed on admitting physicians and inconveniences placed on patients and their families with respect to meeting the 96-hour certification requirement.

One commenter stated that the 96-hour certification requirement has imposed significant burdens on the surgical community, whose members extend essential surgical care to Medicare's rural beneficiaries. The commenter also expressed concerns regarding compliance with the 96-hour certification requirement and its intersection with the Emergency Medical Treatment and Labor Act (EMTALA) and the CoPs. Another commenter communicated concern that the 96-hour certification requirement is a quality and safety CoP requirement and is, therefore, for enforcement purposes, required to be included in accrediting body manuals. The commenter requested that CMS remove the 96-hour certification requirement from the quality and safety CoPs and instead rely on MACs such that accrediting organizations are not required to enforce the requirement but rather it is a part of CMS' fiscal oversight.

Response: We appreciate commenters sharing their concerns regarding the 96-hour certification requirement. As noted throughout this section of the preamble,

the 96-hour certification requirement is statutory and cannot be amended through notice-and-comment rulemaking without a change in legislation. We also clarify that the 96-hour certification requirement (section 1814(a)(8) of the Act) is separate and distinct from the 96-hour annual average length of inpatient stay CoP (meaning condition of participation) requirement (section 1820(c)(2)(B)(iii) of the Act). The 96-hour certification requirement is not directly relevant to determining whether a facility remains eligible for designation as a CAH, but rather is applicable to determining whether a CAH may receive Medicare payment under Part A for inpatient CAH services. Therefore, primary enforcement of the 96-hour certification requirement should not be conducted by accrediting bodies.

In summary, as stated earlier, we are reiterating that CMS will direct QIOs, MACs, the SMRC, and RACs to make the CAH 96-hour certification requirement a low priority for medical record reviews conducted on or after October 1, 2017. CAHs should not expect to receive any medical record requests from QIOs, MACs, RACs, or the SMRC related to the 96-hour certification requirement unless CMS or its contractors find evidence of gaming or a failure to comply with CMS' provider screening and revalidation requirements or if medical review is needed for other issues.

VIII. Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2018

A. Background of the LTCH PPS

1. Legislative and Regulatory Authority

Section 123 of the Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) as amended by section 307(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) provides for payment for both the operating and capital-related costs of hospital inpatient stays in long-term care hospitals (LTCHs) under Medicare Part A based on prospectively set rates. The Medicare prospective payment system (PPS) for LTCHs applies to hospitals that are described in section 1886(d)(1)(B)(iv) of the Act, effective for cost reporting periods beginning on or after October 1, 2002.

Section 1886(d)(1)(B)(iv)(I) of the Act originally defined an LTCH as a hospital which has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days. Section 1886(d)(1)(B)(iv)(II) of the Act also provided an alternative definition of LTCHs: Specifically, a hospital that first received payment under section 1886(d) of the Act in 1986 and had an average inpatient length of stay (as determined by the Secretary of Health and Human Services (the Secretary)) of greater than 20 days and had 80 percent or more of its annual Medicare inpatient discharges with a principal diagnosis that reflected a finding of neoplastic disease in the 12-month cost reporting period ending in FY 1997. However, as discussed below, section 15008 of the 21st Century Cures Act (Pub. L. 114–255) amended section 1886 of the Act to exclude former ''subclause II'' LTCHs from payment under the LTCH PPS and created a new category of IPPS-excluded hospitals (named in the proposed rule ''long-term care neoplastic disease hospitals'' but renamed in this final rule ''extended neoplastic disease care hospitals'') for hospitals that were formally classified as ''subclause (II)'' LTCHs.

Section 123 of the BBRA requires the PPS for LTCHs to be a ''per discharge'' system with a diagnosis-related group (DRG) based patient classification system that reflects the differences in patient resources and costs in LTCHs.

Section 307(b)(1) of the BIPA, among other things, mandates that the Secretary shall examine, and may provide for, adjustments to payments under the LTCH PPS, including adjustments to DRG weights, area wage adjustments, geographic reclassification, outliers, updates, and a disproportionate share adjustment.

In the August 30, 2002 **Federal Register**, we issued a final rule that implemented the LTCH PPS authorized under the BBRA and BIPA (67 FR 55954). For the initial implementation of the LTCH PPS (FYs 2003 through FY 2007), the system used information from LTCH patient records to classify patients into distinct long-term care diagnosis-related groups (LTC–DRGs) based on clinical characteristics and expected resource needs. Beginning in FY 2008, we adopted the Medicare severity long-term care diagnosis-related groups (MS–LTC–DRGs) as the patient classification system used under the LTCH PPS. Payments are calculated for each MS–LTC–DRG and provisions are made for appropriate payment adjustments. Payment rates under the LTCH PPS are updated annually and published in the **Federal Register**.

The LTCH PPS replaced the reasonable cost-based payment system under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97–248) for payments for inpatient services provided by an LTCH with a cost reporting period beginning on or after October 1, 2002. (The regulations implementing the TEFRA reasonable cost-based payment provisions are located at 42 CFR part 413.) With the implementation of the PPS for acute care hospitals authorized by the Social Security Amendments of 1983 (Pub. L. 98–21), which added section 1886(d) to the Act, certain hospitals, including LTCHs, were excluded from the PPS for acute care hospitals and were paid their reasonable costs for inpatient services subject to a per discharge limitation or target amount under the TEFRA system. For each cost reporting period, a hospital-specific ceiling on payments was determined by multiplying the hospital's updated target amount by the number of total current year Medicare discharges. (Generally, in this section of the preamble of this final rule, when we refer to discharges, we describe Medicare discharges.) The August 30, 2002 final rule further details the payment policy under the TEFRA system (67 FR 55954).

In the August 30, 2002 final rule, we provided for a 5-year transition period from payments under the TEFRA system to payments under the LTCH PPS. During this 5-year transition period, an LTCH's total payment under the PPS was based on an increasing percentage of the Federal rate with a corresponding decrease in the percentage of the LTCH PPS payment that is based on reasonable cost concepts, unless an LTCH made a one-time election to be paid based on 100 percent of the Federal rate. Beginning with LTCHs' cost reporting periods beginning on or after October 1, 2006, total LTCH PPS payments are based on 100 percent of the Federal rate.

In addition, in the August 30, 2002 final rule, we presented an in-depth discussion of the LTCH PPS, including the patient classification system, relative weights, payment rates, additional payments, and the budget neutrality requirements mandated by section 123 of the BBRA. The same final rule that established regulations for the LTCH PPS under 42 CFR part 412, subpart O, also contained LTCH provisions related to covered inpatient services, limitation on charges to beneficiaries, medical review requirements, furnishing of inpatient hospital services directly or under arrangement, and reporting and recordkeeping requirements. We refer readers to the August 30, 2002 final rule for a comprehensive discussion of the research and data that supported the

establishment of the LTCH PPS (67 FR 55954).

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623), we implemented the provisions of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67), which mandated the application of the ''site neutral'' payment rate under the LTCH PPS for discharges that do not meet the statutory criteria for exclusion beginning in FY 2016. For cost reporting periods beginning on or after October 1, 2015, discharges that do not meet certain statutory criteria for exclusion are paid based on the site neutral payment rate. Discharges that do meet the statutory criteria continue to receive payment based on the LTCH PPS standard Federal payment rate. For more information on the statutory requirements of the Pathway for SGR Reform Act of 2013, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623).

Section 231 of Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(m)(6) of the Act by revising subparagraph (A)(i) and adding new subparagraph (E), which established a temporary exception to the site neutral payment rate for certain severe wound care discharges occurring prior to January 1, 2017 from LTCHs identified by the amendment made by section 4417(a) of the Balanced Budget Act of 1997 that are located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or treated as being so located in accordance with section 1886(d)(8)(E) of the Act.

We implemented the provisions of section 231 of Public Law 114–113, and amended our regulations at 42 CFR 412.522 to reflect those policies, in an interim final rule with comment period (IFC) that appeared in the **Federal Register** on April 21, 2016 (81 FR 23428 through 23438). In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57068), we finalized the provisions of the April 21, 2016 IFC and made limited modifications of those policies set forth in the April 21, 2016 IFC by revising the definitions of a ''wound with morbid obesity'' and an ''infected wound,'' and adding additional ICD–10 diagnosis codes to our list of such codes to identify cases that meet the established definition of a ''severe wound'' for the six severe wound categories other than the categories of a ''wound with morbid obesity'' and an ''infected wound.'' The provisions implementing section 231 of Public Law 114–113 were effective for LTCH discharges from qualifying LTCHs for discharges on or after April 21, 2016, through December 31, 2016. For a full discussion of these provisions, we refer readers to the April 21, 2016 IFC (81 FR 23428) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57068 through 57075).

The 21st Century Cures Act (''the Cures Act'') (Pub. L. 114–255) contains several provisions that affect the LTCH PPS. Section 15004 of Public Law 114–255 contains provisions that change the moratorium on increasing the number of beds in existing LTCHs and LTCH satellite facilities. We discuss our implementation of the provisions of section 15004 in section VIII.H. of the preamble of this final rule. The provisions of section 15004 also included a change to the payment methodology for high-cost outlier payments made to LTCHs. We discuss our proposals and final policies related to high-cost outlier payments in section V.D. of the Addendum of this final rule. The provisions of section 15006 of Public Law 114–255 extended various moratoria on the implementation of the 25-percent threshold policy. We discuss our proposals and final policy related to the provisions of section 15006 in section VIII.G. of the preamble of this final rule. The provisions of section 15007 of Public Law 114–255 revised the requirements of the average length-of-stay criterion for LTCH classification. We discuss our proposals and final policy related to the provisions of section 15007 in section VIII.I. of the preamble of this final rule. The provisions of section 15008 of Public Law 114–255 changed the classification of certain hospitals. We discuss our proposals and final policy related to the provisions of section 15008 in section VIII.J. of the preamble of this final rule. The provisions of section 15009 of Public Law 114–255 contain a temporary exception to the site neutral payment rate for certain spinal cord specialty hospitals. We discuss our proposals and final policy related to the provisions of section 15009 in section VIII.E. of the preamble of this final rule. The provisions of section 15010 of Public Law 114–255 contain a temporary exception to the site neural payment rate for certain severe wound care discharges from certain LTCHs. We discuss our proposals and final policy related to the provisions of section 15010 in section VIII.F. of the preamble of this final rule. In addition, as we proposed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20009), in this final rule we are amending 42 CFR 412.500 to include Public Law 114–255 as one of the bases and scope of subpart O of part 412.

We received several public comments that addressed issues that were outside the scope of the FY 2018 proposed rule. We will keep these comments in mind and may consider them for future rulemaking.

2. Criteria for Classification as an LTCH

a. Classification as an LTCH

Under the regulations at § 412.23(e)(1), to qualify to be paid under the LTCH PPS, a hospital must have a provider agreement with Medicare. Furthermore, § 412.23(e)(2)(i), which implements section 1886(d)(1)(B)(iv) of the Act, requires that a hospital have an average Medicare inpatient length of stay of greater than 25 days to be paid under the LTCH PPS. Alternatively, existing § 412.23(e)(2)(ii) states that, for cost reporting periods beginning on or after August 5, 1997, a hospital that was first excluded from the PPS in 1986 and can demonstrate that at least 80 percent of its annual Medicare inpatient discharges in the 12-month cost reporting period ending in FY 1997 have a principal diagnosis that reflects a finding of neoplastic disease must have an average inpatient length of stay for all patients, including both Medicare and non-Medicare inpatients, of greater than 20 days (referred to as ''subclause (II)'' LTCHs). In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20029), under our proposed changes to § 412.23(e)(2)(ii) of the regulations to implement the provisions of section 15008 of Public Law 114–255, we proposed to add a sunset date to subclause (II) LTCHs (which have become a new category of IPPS-excluded hospitals named in the proposed rule ''long-term care neoplastic disease hospitals'' but renamed ''extended neoplastic disease care hospitals'' in this final rule). Extended neoplastic disease care hospitals are discussed in greater detail in section VIII.J. of the preamble of this final rule. In addition, in section VIII.I. of the preamble of the proposed rule and this final rule, we discuss the proposed and finalized changes to the calculation of the greater than 25-day average length-of-stay requirement provided by the provisions of section 15007 of Public Law 114–255.

b. Hospitals Excluded From the LTCH PPS

The following hospitals are paid under special payment provisions, as described in § 412.22(c) and, therefore, are not subject to the LTCH PPS rules:

- Veterans Administration hospitals.
- Hospitals that are reimbursed under State cost control systems approved under 42 CFR part 403.
- Hospitals that are reimbursed in accordance with demonstration projects authorized under section 402(a) of the

Social Security Amendments of 1967 (Pub. L. 90–248) (42 U.S.C. 1395b–1), section 222(a) of the Social Security Amendments of 1972 (Pub. L. 92–603) (42 U.S.C. 1395b–1 (note)) (Statewide all-payer systems, subject to the rate-of-increase test at section 1814(b) of the Act), or section 3201 of the Patient Protection and Affordable Care Act (Pub. L. 111–148 (42 U.S.C. 1315a)).

- Nonparticipating hospitals furnishing emergency services to Medicare beneficiaries.

3. Limitation on Charges to Beneficiaries

In the August 30, 2002 final rule, we presented an in-depth discussion of beneficiary liability under the LTCH PPS (67 FR 55974 through 55975). This discussion was further clarified in the RY 2005 LTCH PPS final rule (69 FR 25676). In keeping with those discussions, if the Medicare payment to the LTCH is the full LTC–DRG payment amount, consistent with other established hospital prospective payment systems, § 412.507 currently provides that an LTCH may not bill a Medicare beneficiary for more than the deductible and coinsurance amounts as specified under §§ 409.82, 409.83, and 409.87 and for items and services specified under § 489.30(a). However, under the LTCH PPS, Medicare will only pay for days for which the beneficiary has coverage until the short-stay outlier (SSO) threshold is exceeded. If the Medicare payment was for a SSO case (§ 412.529), and that payment was less than the full LTC–DRG payment amount because the beneficiary had insufficient remaining Medicare days, the LTCH is currently also permitted to charge the beneficiary for services delivered on those uncovered days (§ 412.507). In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49623), we amended our regulations to expressly limit the charges that may be imposed on beneficiaries whose discharges are paid at the site neutral payment rate under the LTCH PPS.

In section VII.G. of the preamble of the FY 2017 IPPS/LTCH PPS final rule (81 FR 57102), we also amended the existing regulations relating to the limitation on charges to expressly address beneficiary charges for LTCH services provided by subclause (II) LTCHs as part of our refinement of the payment adjustment for subclause (II) LTCHs under § 412.526. We also amended the regulations under § 412.507 to clarify our existing policy that blended payments made to an LTCH during its transitional period (that is, payment for discharges occurring in cost reporting periods beginning in FY 2016 or 2017) are considered to be site neutral payment rate payments.

4. Administrative Simplification Compliance Act (ASCA) and Health Insurance Portability and Accountability Act (HIPAA) Compliance

Claims submitted to Medicare must comply with both the Administrative Simplification Compliance Act (ASCA) (Pub. L. 107–105), and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191). Section 3 of the ASCA generally requires that the Medicare Program deny payment under Part A or Part B for any expenses incurred for items or services for which a claim is submitted other than in an electronic form specified by the Secretary. Section 1862(h) of the Act (as added by section 3(a) of the ASCA) provides that the Secretary shall waive such denial in two specific types of cases, and may also waive such denial in such unusual cases as the Secretary finds appropriate (68 FR 48805). Section 3 of the ASCA operates in the context of the HIPAA regulations, which include, among other provisions, the transactions and code sets standards requirements codified under 45 CFR parts 160 and 162 (generally known as the Transactions Rule). The Transactions Rule requires covered entities, including covered health care providers, to conduct certain electronic health care transactions according to the applicable transactions and code sets standards.

The Department of Health and Human Services (HHS) has a number of initiatives designed to encourage and support the adoption of health information technology (health IT) and promote nationwide health information exchange to improve health care. The Office of the National Coordinator for Health Information Technology (ONC) leads these efforts in collaboration with other agencies, including CMS and the Office of the Assistant Secretary for Planning and Evaluation (ASPE). Through a number of activities, including several open government initiatives, HHS is promoting the adoption of health IT products, including electronic health record (EHR) technology certified under the ONC Health IT Certification Program (*https://www.healthit.gov/policy-researchers-implementers/about-onc-health-it-certification-program*) developed to support secure, interoperable, health information exchange. We believe that the use of certified EHRs by LTCHs (and other types of providers that are ineligible for the Medicare and Medicaid EHR Incentive Programs) can effectively and efficiently help providers improve internal care delivery practices, support the exchange of important information across care partners and during transitions of care, and enable the reporting of electronically specified clinical quality measures (eCQMs) (as described elsewhere in this final rule). In 2015, ONC released a document entitled ''Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap'' (available at: *https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf*). In the near term, the Roadmap focuses on actions that will enable individuals and providers across the care continuum to send, receive, find, and use a common set of electronic clinical information at the nationwide level by the end of 2017. The Roadmap's goals also align with the Improving Medicare Post-Acute Care Transformation Act of 2014 (Pub. L. 113–185) (IMPACT Act), which requires assessment data to be standardized and interoperable to allow for exchange of the data. Moreover, the vision described in the Roadmap significantly expands the types of electronic health information, information sources, and information users well beyond clinical information derived from EHRs. The Roadmap identifies four critical pathways that health IT stakeholders should focus on now in order to create a foundation for long-term success: (1) Improve technical standards and implementation guidance for priority data domains and associated elements; (2) rapidly shift and align Federal, State, and commercial payment policies from fee-for-service to value-based models to stimulate the demand for interoperability; (3) clarify and align Federal and State privacy and security requirements that enable interoperability; and (4) align and promote the use of consistent policies and business practices that support interoperability and address those that impede interoperability, in coordination with stakeholders.

In support of the goals of the Roadmap, ONC released the 2017 Interoperability Standards Advisory (ISA) (available at: *https://www.healthit.gov/standards-advisory*), a coordinated catalog of standards and implementation specifications developed and used to meet specific interoperability needs. The ISA is intended to serve as an industry resource to further the use of

interoperable electronic health information exchange.

B. Medicare Severity Long-Term Care Diagnosis-Related Group (MS–LTC–DRG) Classifications and Relative Weights for FY 2018

1. Background

Section 123 of the BBRA required that the Secretary implement a PPS for LTCHs to replace the cost-based payment system under TEFRA. Section 307(b)(1) of the BIPA modified the requirements of section 123 of the BBRA by requiring that the Secretary examine the feasibility and the impact of basing payment under the LTCH PPS on the use of existing (or refined) hospital DRGs that have been modified to account for different resource use of LTCH patients.

When the LTCH PPS was implemented for cost reporting periods beginning on or after October 1, 2002, we adopted the same DRG patient classification system utilized at that time under the IPPS. As a component of the LTCH PPS, we refer to this patient classification system as the ''long-term care diagnosis-related groups (LTC–DRGs).'' Although the patient classification system used under both the LTCH PPS and the IPPS are the same, the relative weights are different. The established relative weight methodology and data used under the LTCH PPS result in relative weights under the LTCH PPS that reflect the differences in patient resource use of LTCH patients, consistent with section 123(a)(1) of the BBRA (Pub. L. 106–113).

As part of our efforts to better recognize severity of illness among patients, in the FY 2008 IPPS final rule with comment period (72 FR 47130), the MS–DRGs and the Medicare severity long-term care diagnosis-related groups (MS–LTC–DRGs) were adopted under the IPPS and the LTCH PPS, respectively, effective beginning October 1, 2007 (FY 2008). For a full description of the development, implementation, and rationale for the use of the MS–DRGs and MS–LTC–DRGs, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47141 through 47175 and 47277 through 47299). (We note that, in that same final rule, we revised the regulations at § 412.503 to specify that for LTCH discharges occurring on or after October 1, 2007, when applying the provisions of 42 CFR part 412, subpart O applicable to LTCHs for policy descriptions and payment calculations, all references to LTC–DRGs would be considered a reference to MS–LTC–DRGs. For the remainder of this section, we present the discussion in terms of the current MS–LTC–DRG patient classification system unless specifically referring to the previous LTC–DRG patient classification system that was in effect before October 1, 2007.)

The MS–DRGs adopted in FY 2008 represent an increase in the number of DRGs by 207 (that is, from 538 to 745) (72 FR 47171). The MS–DRG classifications are updated annually. There are currently 757 MS–DRG groupings. For FY 2018, there will be 754 MS–DRG groupings based on the changes discussed in section II.F. of the preamble of this FY 2018 IPPS/LTCH PPS final rule. Consistent with section 123 of the BBRA, as amended by section 307(b)(1) of the BIPA, and § 412.515 of the regulations, we use information derived from LTCH PPS patient records to classify LTCH discharges into distinct MS–LTC–DRGs based on clinical characteristics and estimated resource needs. We then assign an appropriate weight to the MS–LTC–DRGs to account for the difference in resource use by patients exhibiting the case complexity and multiple medical problems characteristic of LTCHs.

In this section of the final rule, we provide a general summary of our existing methodology for determining the FY 2018 MS–LTC–DRG relative weights under the LTCH PPS.

As we proposed, in this final rule, in general, for FY 2018, we are continuing to use our existing methodology to determine the proposed MS–LTC–DRG relative weights (as discussed in greater detail in section VIII.B.3. of the preamble of this final rule). As we established when we implemented the dual rate LTCH PPS payment structure codified under § 412.522, which began in FY 2016, the annual recalibration of the MS–LTC–DRG relative weights are determined: (1) Using only data from available LTCH PPS claims that would have qualified for payment under the new LTCH PPS standard Federal payment rate if that rate had been in effect at the time of discharge when claims data from time periods before the dual rate LTCH PPS payment structure applies are used to calculate the relative weights; and (2) using only data from available LTCH PPS claims that qualify for payment under the new LTCH PPS standard Federal payment rate when claims data from time periods after the dual rate LTCH PPS payment structure applies are used to calculate the relative weights (80 FR 49624). That is, under our current methodology, our MS–LTC–DRG relative weight calculations do not use data from cases paid at the site neutral payment rate under § 412.522(c)(1) or data from cases that would have been paid at the site neutral payment rate if the dual rate LTCH PPS payment structure had been in effect at the time of that discharge. For the remainder of this discussion, we use the phrase ''applicable LTCH cases'' or ''applicable LTCH data'' when referring to the resulting claims data set used to calculate the relative weights (as described later in greater detail in section VIII.B.3.c. of the preamble of this final rule). In addition, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20011), for FY 2018, we proposed to continue to exclude the data from all-inclusive rate providers and LTCHs paid in accordance with demonstration projects, as well as any Medicare Advantage claims from the MS–LTC–DRG relative weight calculations for the reasons discussed in section VIII.B.3.c. of the preamble of the proposed rule.

Furthermore, for FY 2018, in using data from applicable LTCH cases to establish MS–LTC–DRG relative weights, we proposed to continue to establish low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs with less than 25 cases) using our quintile methodology in determining the MS–LTC–DRG relative weights because LTCHs do not typically treat the full range of diagnoses as do acute care hospitals. Therefore, for purposes of determining the relative weights for the large number of low-volume MS–LTC–DRGs, we group all of the low-volume MS–LTC–DRGs into five quintiles based on average charges per discharge. Then, under our existing methodology, we account for adjustments made to LTCH PPS standard Federal payments for short-stay outlier (SSO) cases (that is, cases where the covered length of stay at the LTCH is less than or equal to five-sixths of the geometric average length of stay for the MS–LTC–DRG), and we make adjustments to account for nonmonotonically increasing weights, when necessary. The methodology is premised on more severe cases under the MS–LTC–DRG system requiring greater expenditure of medical care resources and higher average charges such that, in the severity levels within a base MS–LTC–DRG, the relative weights should increase monotonically with severity from the lowest to highest severity level. (We discuss each of these components of our MS–LTC–DRG relative weight methodology in greater detail in section VIII.B.3.g. of the preamble of this final rule.)

We did not receive any public comments on these proposals. Therefore, we are finalizing our proposals for calculating the MS–LTC–

DRG relative weights for FY 2018 without modification.

2. Patient Classifications Into MS–LTC–DRGs

a. Background

The MS–DRGs (used under the IPPS) and the MS–LTC–DRGs (used under the LTCH PPS) are based on the CMS DRG structure. As noted previously in this section, we refer to the DRGs under the LTCH PPS as MS–LTC–DRGs although they are structurally identical to the MS–DRGs used under the IPPS.

The MS–DRGs are organized into 25 major diagnostic categories (MDCs), most of which are based on a particular organ system of the body; the remainder involve multiple organ systems (such as MDC 22, Burns). Within most MDCs, cases are then divided into surgical DRGs and medical DRGs. Surgical DRGs are assigned based on a surgical hierarchy that orders operating room (O.R.) procedures or groups of O.R. procedures by resource intensity. The GROUPER software program does not recognize all ICD–10–PCS procedure codes as procedures affecting DRG assignment. That is, procedures that are not surgical (for example, EKGs), or minor surgical procedures (for example, a biopsy of skin and subcutaneous tissue (procedure code 0JBH3ZX)) do not affect the MS–LTC–DRG assignment based on their presence on the claim.

Generally, under the LTCH PPS, a Medicare payment is made at a predetermined specific rate for each discharge that varies based on the MS–LTC–DRG to which a beneficiary's discharge is assigned. Cases are classified into MS–LTC–DRGs for payment based on the following six data elements:

- Principal diagnosis;
- Additional or secondary diagnoses;
- Surgical procedures;
- Age;
- Sex; and
- Discharge status of the patient.

Currently, for claims submitted using version ASC X12 5010 format, up to 25 diagnosis codes and 25 procedure codes are considered for an MS–DRG assignment. This includes one principal diagnosis and up to 24 secondary diagnoses for severity of illness determinations. (For additional information on the processing of up to 25 diagnosis codes and 25 procedure codes on hospital inpatient claims, we refer readers to section II.G.11.c. of the preamble of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50127).)

Under the HIPAA transactions and code sets regulations at 45 CFR parts 160 and 162, covered entities must comply with the adopted transaction standards and operating rules specified in Subparts I through S of Part 162. Among other requirements, by January 1, 2012, covered entities were required to use the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12N/005010X223, and Type 1 Errata to Health Care Claim: Institutional (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X233A1 for the health care claims or equivalent encounter information transaction (45 CFR 162.1102(c)).

HIPAA requires covered entities to use the applicable medical data code set requirements when conducting HIPAA transactions (45 CFR 162.1000). Currently, upon the discharge of the patient, the LTCH must assign appropriate diagnosis and procedure codes from the most current version of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, both of which were required to be implemented October 1, 2015 (45 CFR 162.1002(c)(2) and (3)). For additional information on the implementation of the ICD–10 coding system, we refer readers to section II.F.1. of the FY 2017 IPPS/LTCH PPS final rule (81 FR 56787 through 56790) and section II.F.1. of the preamble of this final rule. Additional coding instructions and examples are published in the AHA's *Coding Clinic for ICD-10-CM/PCS.*

To create the MS–DRGs (and by extension, the MS–LTC–DRGs), base DRGs were subdivided according to the presence of specific secondary diagnoses designated as complications or comorbidities (CCs) into one, two, or three levels of severity, depending on the impact of the CCs on resources used for those cases. Specifically, there are sets of MS–DRGs that are split into 2 or 3 subgroups based on the presence or absence of a CC or a major complication or comorbidity (MCC). We refer readers to section II.D. of the FY 2008 IPPS final rule with comment period for a detailed discussion about the creation of MS–DRGs based on severity of illness levels (72 FR 47141 through 47175).

MACs enter the clinical and demographic information submitted by LTCHs into their claims processing systems and subject this information to a series of automated screening processes called the Medicare Code Editor (MCE). These screens are designed to identify cases that require further review before assignment into a MS–LTC–DRG can be made. During this process, certain cases are selected for further explanation (74 FR 43949).

After screening through the MCE, each claim is classified into the appropriate MS–LTC–DRG by the Medicare LTCH GROUPER software on the basis of diagnosis and procedure codes and other demographic information (age, sex, and discharge status). The GROUPER software used under the LTCH PPS is the same GROUPER software program used under the IPPS. Following the MS–LTC–DRG assignment, the MAC determines the prospective payment amount by using the Medicare PRICER program, which accounts for hospital-specific adjustments. Under the LTCH PPS, we provide an opportunity for LTCHs to review the MS–LTC–DRG assignments made by the MAC and to submit additional information within a specified timeframe as provided in § 412.513(c).

The GROUPER software is used both to classify past cases to measure relative hospital resource consumption to establish the MS–LTC–DRG relative weights and to classify current cases for purposes of determining payment. The records for all Medicare hospital inpatient discharges are maintained in the MedPAR file. The data in this file are used to evaluate possible MS–DRG and MS–LTC–DRG classification changes and to recalibrate the MS–DRG and MS–LTC–DRG relative weights during our annual update under both the IPPS (§ 412.60(e)) and the LTCH PPS (§ 412.517), respectively.

b. Changes to the MS–LTC–DRGs for FY 2018

As specified by our regulations at § 412.517(a), which require that the MS–LTC–DRG classifications and relative weights be updated annually, and consistent with our historical practice of using the same patient classification system under the LTCH PPS as is used under the IPPS, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20012), we proposed to update the MS–LTC–DRG classifications effective October 1, 2017, through September 30, 2018 (FY 2018), consistent with the proposed changes to specific MS–DRG classifications presented in section II.F. of the preamble of the proposed rule. Accordingly, the MS–LTC–DRGs for FY 2018 presented in the proposed rule and this final rule are the same as the MS–DRGs that will be used under the IPPS for FY 2018. In addition, because the

MS–LTC–DRGs for FY 2018 are the same as the MS–DRGs for FY 2018, the other changes that affect MS–DRG (and by extension MS–LTC–DRG) assignments under GROUPER Version 35 as discussed in section II.F. of the preamble of this final rule, including the changes to the MCE software and the ICD–10–CM/PCS coding system, also will be applicable under the LTCH PPS for FY 2018.

3. Development of the FY 2018 MS–LTC–DRG Relative Weights

a. General Overview of the Development of the MS–LTC–DRG Relative Weights

One of the primary goals for the implementation of the LTCH PPS is to pay each LTCH an appropriate amount for the efficient delivery of medical care to Medicare patients. The system must be able to account adequately for each LTCH's case-mix in order to ensure both fair distribution of Medicare payments and access to adequate care for those Medicare patients whose care is more costly (67 FR 55984). To accomplish these goals, we have annually adjusted the LTCH PPS standard Federal prospective payment rate by the applicable relative weight in determining payment to LTCHs for each case. In order to make these annual adjustments under the dual rate LTCH PPS payment structure, beginning with FY 2016, we recalibrate the MS–LTC–DRG relative weighting factors annually using data from applicable LTCH cases (80 FR 49614 through 49617). Under this policy, the resulting MS–LTC–DRG relative weights would continue to be used to adjust the LTCH PPS standard Federal payment rate when calculating the payment for LTCH PPS standard Federal payment rate cases.

The established methodology to develop the MS–LTC–DRG relative weights is generally consistent with the methodology established when the LTCH PPS was implemented in the August 30, 2002 LTCH PPS final rule (67 FR 55989 through 55991). However, there have been some modifications of our historical procedures for assigning relative weights in cases of zero volume and/or nonmonotonicity resulting from the adoption of the MS–LTC–DRGs, along with the change made in conjunction with the implementation of the dual rate LTCH PPS payment structure beginning in FY 2016 to use LTCH claims data from only LTCH PPS standard Federal payment rate cases (or LTCH PPS cases that would have qualified for payment under the LTCH PPS standard Federal payment rate if the dual rate LTCH PPS payment structure had been in effect at the time of the discharge). (For details on the modifications to our historical procedures for assigning relative weights in cases of zero volume and/or nonmonotonicity, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47289 through 47295) and the FY 2009 IPPS final rule (73 FR 48542 through 48550).) For details on the change in our historical methodology to use LTCH claims data only from LTCH PPS standard Federal payment rate cases (or cases that would have qualified for such payment had the LTCH PPS dual payment rate structure been in effect at the time) to determine the MS–LTC–DRG relative weights, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49614 through 49617). Under the LTCH PPS, relative weights for each MS–LTC–DRG are a primary element used to account for the variations in cost per discharge and resource utilization among the payment groups (§ 412.515). To ensure that Medicare patients classified to each MS–LTC–DRG have access to an appropriate level of services and to encourage efficiency, we calculate a relative weight for each MS–LTC–DRG that represents the resources needed by an average inpatient LTCH case in that MS–LTC–DRG. For example, cases in an MS–LTC–DRG with a relative weight of 2 would, on average, cost twice as much to treat as cases in an MS–LTC–DRG with a relative weight of 1.

b. Development of the MS–LTC–DRG Relative Weights for FY 2018

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57078 through 57079), we presented our policies for the development of the MS–LTC–DRG relative weights for FY 2017.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20013), we proposed to continue to use our current methodology to determine the MS–LTC–DRG relative weights for FY 2018, including the continued application of established policies related to: The hospital-specific relative value methodology, the treatment of severity levels in the MS–LTC–DRGs, low-volume and no-volume MS–LTC–DRGs, adjustments for nonmonotonicity, the steps for calculating the MS–LTC–DRG relative weights with a budget neutrality factor, and only using data from applicable LTCH cases (which includes our policy of only using cases that would meet the criteria for exclusion from the site neutral payment rate (or, for discharges occurring prior to the implementation of the dual rate LTCH PPS payment structure, would have met the criteria for exclusion had those criteria been in effect at the time of the discharge)).

In this section, we present our application of our existing methodology for determining the MS–LTC–DRG relative weights for FY 2018, and we discuss the effects of our policies concerning the data used to determine the FY 2018 MS–LTC–DRG relative weights on the various components of our existing methodology in the discussion that follows.

c. Data

For this final rule, consistent with our policies regarding the calculation of the MS–LTC–DRG relative weights for FY 2018, we obtained total charges from FY 2016 Medicare LTCH claims data from the March 2017 update of the FY 2016 MedPAR file, which are the best available data at this time, and we are using Version 35 of the GROUPER to classify LTCH cases. Consistent with our historical practice, we used those data and the finalized Version 35 of the GROUPER in establishing the FY 2018 MS–LTC–DRG relative weights in this final rule. To calculate the FY 2018 MS–LTC–DRG relative weights under the dual rate LTCH PPS payment structure, we are continuing to use applicable LTCH data, which includes our policy of only using cases that meet the criteria for exclusion from the site neutral payment rate (or would have met the criteria had they been in effect at the time of the discharge) (80 FR 49624). Specifically, we began by first evaluating the LTCH claims data in the March 2017 update of the FY 2016 MedPAR file to determine which LTCH cases would meet the criteria for exclusion from the site neutral payment rate under § 412.522(b) had the dual rate LTCH PPS payment structure been in effect at the time of discharge. (We note that while the dual rate LTCH PPS payment structure began to be phased in during FY 2016, due to the statutory requirement that individual LTCHs begin to receive payment under the dual rate LTCH PPS payment structure based on their individual cost reporting periods, there are LTCH discharges that occurred in FY 2016 that would not have been paid under that structure.) We identified the FY 2016 LTCH cases that were not assigned to MS–LTC–DRGs 876, 880, 881, 882, 883, 884, 885, 886, 887, 894, 895, 896, 897, 945 and 946, which identify LTCH cases that do not have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation; and that either—

- The admission to the LTCH was ''immediately preceded'' by discharge from a subsection (d) hospital and the immediately preceding stay in that

subsection (d) hospital included at least 3 days in an ICU, as we define under the ICU criterion; or

• The admission to the LTCH was ''immediately preceded'' by discharge from a subsection (d) hospital and the claim for the LTCH discharge includes the applicable procedure code that indicates at least 96 hours of ventilator services were provided during the LTCH stay, as we define under the ventilator criterion. Claims data from the FY 2016 MedPAR file that reported ICD–10–PCS procedure code 5A1955Z were used to identify cases involving at least 96 hours of ventilator services in accordance with the ventilator criterion.

We note that, for purposes of developing the FY 2018 MS–LTC–DRG relative weights using our current methodology, we did not make any proposals regarding the identification of cases that would have been excluded from the site neutral payment rate under the statutory provisions that provided for temporary exception from the site neutral payment rate under the LTCH PPS for certain severe wound care discharges from certain LTCHs or for certain spinal cord specialty hospitals provided by sections 15009 and 15010 of Public Law 114–255, respectively, had our implementation of that law and the dual rate LTCH PPS payment structure been in effect at the time of the discharge. At this time, it is uncertain how many LTCHs and how many cases in the claims data we are using for this final rule would have met the criteria to be excluded from the site neutral payment rate under those exceptions (had the dual rate LTCH PPS payment structure been in effect at the time of the discharge). Therefore, for the remainder of this section, when we refer to LTCH claims only from cases that meet the criteria for exclusion from the site neutral payment rate (or would have met the criteria had the applicable statutes been in effect at the time of the discharge), such data do not include any discharges that would have been paid based on the LTCH PPS standard Federal payment rate under the provisions of sections 15009 and 15010 of Public Law 114–255, had the exception been in effect at the time of the discharge.

Furthermore, consistent with our historical methodology, as we proposed, we are excluding any claims in the resulting data set that were submitted by LTCHs that are all-inclusive rate providers and LTCHs that are paid in accordance with demonstration projects authorized under section 402(a) of Public Law 90–248 or section 222(a) of Public Law 92–603. In addition, consistent with our historical practice and our policies, we are excluding any Medicare Advantage (Part C) claims in the resulting data. Such claims were identified based on the presence of a GHO Paid indicator value of ''1'' in the MedPAR files. The claims that remained after these three trims (that is, the applicable LTCH data) were then used to calculate the MS–LTC–DRG relative weights for FY 2018. In summary, in general, we identified the claims data used in the development of the FY 2018 MS–LTC–DRG relative weights in this final rule, as we proposed, by trimming claims data that would have been paid the site neutral rate had the dual payment rate structure been in effect (except for discharges which would have been excluded from the site neutral payment under the temporary exception for certain severe wound care discharges from certain LTCHs and under the temporary exception for certain spinal cord specialty hospitals), as well as the claims data of 9 all-inclusive rate providers reported in the March 2017 update of the FY 2016 MedPAR file and any Medicare Advantage claims data. (We note that there were no data from any LTCHs that are paid in accordance with a demonstration project reported in the March 2017 update of the FY 2016 MedPAR file. However, had there been we would trim the claims data from those LTCHs as well, in accordance with our established policy.) We used the remaining data (that is, the applicable LTCH data) to calculate the relative weights for FY 2018.

d. Hospital-Specific Relative Value (HSRV) Methodology

By nature, LTCHs often specialize in certain areas, such as ventilator-dependent patients. Some case types (MS–LTC–DRGs) may be treated, to a large extent, in hospitals that have, from a perspective of charges, relatively high (or low) charges. This nonrandom distribution of cases with relatively high (or low) charges in specific MS–LTC–DRGs has the potential to inappropriately distort the measure of average charges. To account for the fact that cases may not be randomly distributed across LTCHs, consistent with the methodology we have used since the implementation of the LTCH PPS, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20014), we proposed to continue to use a hospital-specific relative value (HSRV) methodology to calculate the MS–LTC–DRG relative weights for FY 2018. We believe that this method removes this hospital-specific source of bias in measuring LTCH average charges (67 FR 55985). Specifically, under this methodology, we proposed to reduce the impact of the variation in charges across providers on any particular MS–LTC–DRG relative weight by converting each LTCH's charge for an applicable LTCH case to a relative value based on that LTCH's average charge for such cases.

Under the HSRV methodology, we standardize charges for each LTCH by converting its charges for each applicable LTCH case to hospital-specific relative charge values and then adjusting those values for the LTCH's case-mix. The adjustment for case-mix is needed to rescale the hospital-specific relative charge values (which, by definition, average 1.0 for each LTCH). The average relative weight for an LTCH is its case-mix; therefore, it is reasonable to scale each LTCH's average relative charge value by its case-mix. In this way, each LTCH's relative charge value is adjusted by its case-mix to an average that reflects the complexity of the applicable LTCH cases it treats relative to the complexity of the applicable LTCH cases treated by all other LTCHs (the average LTCH PPS case-mix of all applicable LTCH cases across all LTCHs).

In accordance with our established methodology, for FY 2018, as we proposed, we are continuing to standardize charges for each applicable LTCH case by first dividing the adjusted charge for the case (adjusted for SSOs under § 412.529 as described in section VIII.B.3.g. (Step 3) of the preamble of this final rule) by the average adjusted charge for all applicable LTCH cases at the LTCH in which the case was treated. SSO cases are cases with a length of stay that is less than or equal to five-sixths the average length of stay of the MS–LTC–DRG (§ 412.529 and § 412.503). The average adjusted charge reflects the average intensity of the health care services delivered by a particular LTCH and the average cost level of that LTCH. The resulting ratio is multiplied by that LTCH's case-mix index to determine the standardized charge for the case.

Multiplying the resulting ratio by the LTCH's case-mix index accounts for the fact that the same relative charges are given greater weight at an LTCH with higher average costs than they would at a LTCH with low average costs, which is needed to adjust each LTCH's relative charge value to reflect its case-mix relative to the average case-mix for all LTCHs. By standardizing charges in this manner, we count charges for a Medicare patient at an LTCH with high average charges as less resource intensive than they would be at an LTCH with low average charges. For example, a $10,000 charge for a case at

an LTCH with an average adjusted charge of $17,500 reflects a higher level of relative resource use than a $10,000 charge for a case at an LTCH with the same case-mix, but an average adjusted charge of $35,000. We believe that the adjusted charge of an individual case more accurately reflects actual resource use for an individual LTCH because the variation in charges due to systematic differences in the markup of charges among LTCHs is taken into account.

e. Treatment of Severity Levels in Developing the MS–LTC–DRG Relative Weights

For purposes of determining the MS–LTC–DRG relative weights, under our historical methodology, there are three different categories of MS–DRGs based on volume of cases within specific MS–LTC–DRGs: (1) MS–LTC–DRGs with at least 25 applicable LTCH cases in the data used to calculate the relative weight, which are each assigned a unique relative weight; (2) low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases that are grouped into quintiles (as described later in this section of the final rule) and assigned the relative weight of the quintile); and (3) no-volume MS–LTC–DRGs that are cross-walked to other MS–LTC–DRGs based on the clinical similarities and assigned the relative weight of the cross-walked MS–LTC–DRG (as described in greater detail below). For FY 2018, we proposed to continue to use applicable LTCH cases to establish the same volume-based categories to calculate the FY 2018 MS–LTC–DRG relative weights.

In determining the FY 2018 MS–LTC–DRG relative weights, when necessary, as is our longstanding practice, as we proposed, we make adjustments to account for nonmonotonicity, as discussed in greater detail later in Step 6 of section VIII.B.3.g. of the preamble of this final rule. We refer readers to the discussion in the FY 2010 IPPS/RY 2010 LTCH PPS final rule for our rationale for including an adjustment for nonmonotonicity (74 FR 43953 through 43954).

f. Low-Volume MS–LTC–DRGs

In order to account for MS–LTC–DRGs with low-volume (that is, with fewer than 25 applicable LTCH cases), consistent with our existing methodology, we proposed to continue to employ the quintile methodology for low-volume MS–LTC–DRGs, such that we group the ''low-volume MS–LTC–DRGs'' (that is, MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases into one of five categories (quintiles) based on average charges (67 FR 55984 through 55995; 72 FR 47283 through 47288; and 81 FR 25148)). In cases where the initial assignment of a low-volume MS–LTC–DRG to a quintile results in nonmonotonicity within a base-DRG, as we proposed, we make adjustments to the resulting low-volume MS–LTC–DRGs to preserve monotonicity, as discussed in detail in section VIII.B.3.g. (Step 6) of the preamble of this final rule.

In this final rule, based on the best available data (that is, the March 2017 update of the FY 2016 MedPAR files), we identified 262 MS–LTC–DRGs that contained between 1 and 24 applicable LTCH cases. This list of MS–LTC–DRGs was then divided into one of the 5 low-volume quintiles, each containing at least 52 MS–LTC–DRGs (262/5 = 52 with a remainder of 2). We assigned the low-volume MS–LTC–DRGs to specific low-volume quintiles by sorting the low-volume MS–LTC–DRGs in ascending order by average charge in accordance with our established methodology. Based on the data available for the proposed rule, the number of MS–LTC–DRGs with less than 25 applicable LTCH cases was not evenly divisible by 5 and, therefore, we employed our historical methodology for determining which of the proposed low-volume quintiles contain the additional proposed low-volume MS–LTC–DRG. However, based on the data available for this final rule, the number of MS–LTC–DRGs with less than 25 applicable LTCH cases was not evenly divisible by 5 and, therefore, we employed our historical methodology for determining which of the low-volume quintiles contain the additional proposed low-volume MS–LTC–DRG. Specifically for this final rule, after organizing the MS–LTC–DRGs by ascending order by average charge, we assigned the first 52 (1st through 52nd) of low-volume MS–LTC–DRGs (with the lowest average charge) into Quintile 1. The 52 MS–LTC–DRGs with the highest average charge cases were assigned into Quintile 5. Because the average charge of the 105th low-volume MS–LTC–DRG in the sorted list was closer to the average charge of the 104th low-volume MS–LTC–DRG (assigned to Quintile 2) than to the average charge of the 106th low-volume MS–LTC–DRG (assigned to Quintile 3), we assigned it to Quintile 2 (such that Quintile 2 contains 53 low-volume MS–LTC–DRGs before any adjustments for nonmonotonicity, as discussed below). Because the average charge of the 158th low-volume MS–LTC–DRG in the sorted list was closer to the 157th low-volume MS–LTC–DRG (assigned to Quintile 3) than to the average charge of the 159th low-volume MS–LTC–DRG (assigned to Quintile 4), we assigned it to Quintile 3 (such that Quintile 3 contains 53 low-volume MS–LTC–DRGs before any adjustments for nonmonotonicity, as discussed below. This results in 3 of the 5 low-volume quintiles containing 52 MS–LTC–DRGs (Quintiles 1, 4, and 5) and 2 low-volume quintile containing 53 MS–LTC–DRGs (Quintiles 2 and 3). Table 13A, listed in section VI. of the Addendum to this final rule and available via the Internet, lists the composition of the low-volume quintiles for MS–LTC–DRGs for FY 2018.

In order to determine the FY 2018 relative weights for the low-volume MS–LTC–DRGs, consistent with our historical practice, we used the five low-volume quintiles described previously. We determined a relative weight and (geometric) average length of stay for each of the five low-volume quintiles using the methodology described in section VIII.B.3.g. of the preamble of this final rule. We assigned the same relative weight and average length of stay to each of the low-volume MS–LTC–DRGs that make up an individual low-volume quintile. We note that, as this system is dynamic, it is possible that the number and specific type of MS–LTC–DRGs with a low-volume of applicable LTCH cases will vary in the future. Furthermore, we note that we continue to monitor the volume (that is, the number of applicable LTCH cases) in the low-volume quintiles to ensure that our quintile assignments used in determining the MS–LTC–DRG relative weights result in appropriate payment for LTCH cases grouped to low-volume MS–LTC–DRGs and do not result in an unintended financial incentive for LTCHs to inappropriately admit these types of cases.

g. Steps for Determining the FY 2018 MS–LTC–DRG Relative Weights

In this final rule, as we proposed, we are continuing to use our current methodology to determine the FY 2018 MS–LTC–DRG relative weights.

In summary, to determine the FY 2018 MS–LTC–DRG relative weights, we grouped applicable LTCH cases to the appropriate MS–LTC–DRG, while taking into account the low-volume quintiles (as described above) and cross-walked no-volume MS–LTC–DRGs (as described later in this section). After establishing the appropriate MS–LTC–DRG (or low-volume quintile), as we proposed, we calculated the FY 2018 relative weights by first removing cases with a length of stay of 7 days or less and statistical outliers (Steps 1 and 2 below). Next, we adjusted the number of applicable LTCH

cases in each MS–LTC–DRG (or low-volume quintile) for the effect of SSO cases (Step 3 below). After removing applicable LTCH cases with a length of stay of 7 days or less (Step 1 below) and statistical outliers (Step 2 below), which are the SSO-adjusted applicable LTCH cases and corresponding charges (step 3 below), we calculated ''relative adjusted weights'' for each MS–LTC–DRG (or proposed low-volume quintile) using the HSRV method.

Step 1—Remove cases with a length of stay of 7 days or less.

The first step in our calculation of the FY 2018 MS–LTC–DRG relative weights is to remove cases with a length of stay of 7 days or less. The MS–LTC–DRG relative weights reflect the average of resources used on representative cases of a specific type.

Generally, cases with a length of stay of 7 days or less do not belong in an LTCH because these stays do not fully receive or benefit from treatment that is typical in an LTCH stay, and full resources are often not used in the earlier stages of admission to an LTCH. If we were to include stays of 7 days or less in the computation of the FY 2018 MS–LTC–DRG relative weights, the value of many relative weights would decrease and, therefore, payments would decrease to a level that may no longer be appropriate. We do not believe that it would be appropriate to compromise the integrity of the payment determination for those LTCH cases that actually benefit from and receive a full course of treatment at an LTCH by including data from these very short stays. Therefore, consistent with our existing relative weight methodology and as proposed, in determining the FY 2018 MS–LTC–DRG relative weights, we removed LTCH cases with a length of stay of 7 days or less from applicable LTCH cases. (For additional information on what is removed in this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 2—Remove statistical outliers.

The next step in our calculation of the FY 2018 MS–LTC–DRG relative weights is to remove statistical outlier cases from the LTCH cases with a length of stay of at least 8 days. Consistent with our existing relative weight methodology, as we proposed, we continued to define statistical outliers as cases that are outside of 3.0 standard deviations from the mean of the log distribution of both charges per case and the charges per day for each MS–LTC–DRG. These statistical outliers are removed prior to calculating the relative weights because we believe that they may represent aberrations in the data that distort the measure of average resource use. Including those LTCH cases in the calculation of the relative weights could result in an inaccurate relative weight that does not truly reflect relative resource use among those MS–LTC–DRGs. (For additional information on what is removed in this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.) After removing cases with a length of stay of 7 days or less and statistical outliers, we are left with applicable LTCH cases that have a length of stay greater than or equal to 8 days. In this final rule, we refer to these cases as ''trimmed applicable LTCH cases.''

Step 3—Adjust charges for the effects of SSOs.

As the next step in the calculation of the FY 2018 MS–LTC–DRG relative weights, consistent with our historical approach and as we proposed, we adjusted each LTCH's charges per discharge for those remaining cases (that is, trimmed applicable LTCH cases) for the effects of SSOs (as defined in § 412.529(a) in conjunction with § 412.503). Specifically, we made this adjustment by counting an SSO case as a fraction of a discharge based on the ratio of the length of stay of the case to the average length of stay for the MS–LTC–DRG for non-SSO cases. This has the effect of proportionately reducing the impact of the lower charges for the SSO cases in calculating the average charge for the MS–LTC–DRG. This process produces the same result as if the actual charges per discharge of an SSO case were adjusted to what they would have been had the patient's length of stay been equal to the average length of stay of the MS–LTC–DRG.

Counting SSO cases as full LTCH cases with no adjustment in determining the FY 2018 MS–LTC–DRG relative weights would lower the FY 2018 MS–LTC–DRG relative weight for affected MS–LTC–DRGs because the relatively lower charges of the SSO cases would bring down the average charge for all cases within a MS–LTC–DRG. This would result in an ''underpayment'' for non-SSO cases and an ''overpayment'' for SSO cases. Therefore, as we proposed, we are continuing to adjust for SSO cases under § 412.529 in this manner because it would result in more appropriate payments for all LTCH PPS standard Federal payment rate cases. (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 4—Calculate the FY 2018 MS–LTC–DRG relative weights on an iterative basis.

Consistent with our historical relative weight methodology and as we proposed, we calculated the FY 2018 MS–LTC–DRG relative weights using the HSRV methodology, which is an iterative process. First, for each SSO-adjusted trimmed applicable LTCH case, we calculate a hospital-specific relative charge value by dividing the charge per discharge after adjusting for SSOs of the LTCH case (from Step 3) by the average charge per SSO-adjusted discharge for the LTCH in which the case occurred. The resulting ratio is then multiplied by the LTCH's case-mix index to produce an adjusted hospital-specific relative charge value for the case. We used an initial case-mix index value of 1.0 for each LTCH.

For each MS–LTC–DRG, we calculated the FY 2018 relative weight by dividing the SSO-adjusted average of the hospital-specific relative charge values for applicable LTCH cases for the MS–LTC–DRG (that is, the sum of the hospital-specific relative charge value from above divided by the sum of equivalent cases from Step 3 for each MS–LTC–DRG) by the overall SSO-adjusted average hospital-specific relative charge value across all applicable LTCH cases for all LTCHs (that is, the sum of the hospital-specific relative charge value from above divided by the sum of equivalent applicable LTCH cases from Step 3 for each MS–LTC–DRG). Using these recalculated MS–LTC–DRG relative weights, each LTCH's average relative weight for all of its SSO-adjusted trimmed applicable LTCH cases (that is, its case-mix) was calculated by dividing the sum of all the LTCH's MS–LTC–DRG relative weights by its total number of SSO-adjusted trimmed applicable LTCH cases. The LTCHs' hospital-specific relative charge values (from previous) are then multiplied by the hospital-specific case-mix indexes. The hospital-specific case-mix adjusted relative charge values are then used to calculate a new set of MS–LTC–DRG relative weights across all LTCHs. This iterative process continued until there was convergence between the relative weights produced at adjacent steps, for example, when the maximum difference was less than 0.0001.

Step 5—Determine a FY 2018 relative weight for MS–LTC–DRGs with no applicable LTCH cases.

Using the trimmed applicable LTCH cases, consistent with our historical methodology and as we proposed, we identified the MS–LTC–DRGs for which there were no claims in the March 2017

update of the FY 2016 MedPAR file and, therefore, for which no charge data was available for these MS–LTC–DRGs. Because patients with a number of the diagnoses under these MS–LTC–DRGs may be treated at LTCHs, consistent with our historical methodology, we generally assign a relative weight to each of the no-volume MS–LTC–DRGs based on clinical similarity and relative costliness (with the exception of ''transplant'' MS–LTC–DRGs, ''error'' MS–LTC–DRGs, and MS–LTC–DRGs that indicate a principal diagnosis related to a psychiatric diagnosis or rehabilitation (referred to as the ''psychiatric or rehabilitation'' MS–LTC–DRGs), as discussed later in this section of this final rule). (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55991 and 74 FR 43959 through 43960.)

We cross-walked each no-volume MS–LTC–DRG to another MS–LTC–DRG for which we calculated a relative weight (determined in accordance with the methodology described above). Then, the ''no-volume'' MS–LTC–DRG was assigned the same relative weight (and average length of stay) of the MS–LTC–DRG to which it was cross-walked (as described in greater detail in this section of this final rule).

Of the 754 MS–LTC–DRGs for FY 2018, we identified 348 MS–LTC–DRGs for which there are no trimmed applicable LTCH cases (the number identified includes the 8 ''transplant'' MS–LTC–DRGs, the 2 ''error'' MS–LTC–DRGs, and the 15 ''psychiatric or rehabilitation'' MS–LTC–DRGs, which are discussed below). We assigned relative weights to each of the 348 no-volume MS–LTC–DRGs that contained trimmed applicable LTCH cases based on clinical similarity and relative costliness to 1 of the remaining 406 (754 − 348 = 406) MS–LTC–DRGs for which we calculated relative weights based on the trimmed applicable LTCH cases in the FY 2016 MedPAR file data using the steps described previously. (For the remainder of this discussion, we refer to the ''cross-walked'' MS–LTC–DRGs as the MS–LTC–DRGs to which we cross-walked 1 of the 348 ''no volume'' MS–LTC–DRGs.) Then, we generally assigned the 348 no-volume MS–LTC–DRGs the relative weight of the cross-walked MS–LTC–DRG. (As explained below in Step 6, when necessary, we made adjustments to account for nonmonotonicity.)

We cross-walked the no-volume MS–LTC–DRG to a MS–LTC–DRG for which we calculated relative weights based on the March 2017 update of the FY 2016 MedPAR file, and to which it is similar clinically in intensity of use of resources and relative costliness as determined by criteria such as care provided during the period of time surrounding surgery, surgical approach (if applicable), length of time of surgical procedure, postoperative care, and length of stay. (For more details on our process for evaluating relative costliness, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (73 FR 48543).) We believe in the rare event that there would be a few LTCH cases grouped to one of the no-volume MS–LTC–DRGs in FY 2017, the relative weights assigned based on the cross-walked MS–LTC–DRGs would result in an appropriate LTCH PPS payment because the crosswalks, which are based on clinical similarity and relative costliness, would be expected to generally require equivalent relative resource use.

We then assigned the relative weight of the cross-walked MS–LTC–DRG as the relative weight for the no-volume MS–LTC–DRG such that both of these MS–LTC–DRGs (that is, the no-volume MS–LTC–DRG and the cross-walked MS–LTC–DRG) have the same relative weight (and average length of stay) for FY 2018. We note that, if the cross-walked MS–LTC–DRG had 25 applicable LTCH cases or more, its relative weight (calculated using the methodology described in Steps 1 through 4 above) is assigned to the no-volume MS–LTC–DRG as well. Similarly, if the MS–LTC–DRG to which the no-volume MS–LTC–DRG was cross-walked had 24 or less cases and, therefore, is designated to 1 of the low-volume quintiles for purposes of determining the relative weights, we assigned the relative weight of the applicable low-volume quintile to the no-volume MS–LTC–DRG such that both of these MS–LTC–DRGs (that is, the no-volume MS–LTC–DRG and the cross-walked MS–LTC–DRG) have the same relative weight for FY 2018. (As we noted previously, in the infrequent case where nonmonotonicity involving a no-volume MS–LTC–DRG resulted, additional adjustments as described in Step 6 are required in order to maintain monotonically increasing relative weights.)

For this final rule, a list of the no-volume MS–LTC–DRGs and the MS–LTC–DRGs to which each was cross-walked (that is, the cross-walked MS–LTC–DRGs) for FY 2018 is shown in Table 13B, which is listed in section VI. of the Addendum to this final rule and is available via the Internet on the CMS Web site.

To illustrate this methodology for determining the relative weights for the proposed FY 2018 MS–LTC–DRGs with no applicable LTCH cases, we are providing the following example, which refers to the no-volume proposed MS–LTC–DRGs crosswalk information for FY 2018 provided in Table 13B.

Example: There were no trimmed applicable LTCH cases in the FY 2016 MedPAR file that we are using for this final rule for MS–LTC–DRG 061 (Acute Ischemic Stroke with Use of Thrombolytic Agent with MCC). We determined that MS–LTC–DRG 070 (Nonspecific Cerebrovascular Disorders with MCC) is similar clinically and based on resource use to MS–LTC–DRG 061. Therefore, we assigned the same relative weight (and average length of stay) of MS–LTC–DRG 70 of 0.8833 for FY 2018 to MS–LTC–DRG 061 (we refer readers to Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the Internet on the CMS Web site). Again, we note that, as this system is dynamic, it is entirely possible that the number of MS–LTC–DRGs with no volume will vary in the future. Consistent with our historical practice, we used the most recent available claims data to identify the trimmed applicable LTCH cases from which we determined the relative weights in this rule.

For FY 2018, consistent with our historical relative weight methodology and as we proposed, we are establishing a relative weight of 0.0000 for the following transplant MS–LTC–DRGs: Heart Transplant or Implant of Heart Assist System with MCC (MS–LTC–DRG 001); Heart Transplant or Implant of Heart Assist System without MCC (MS–LTC–DRG 002); Liver Transplant with MCC or Intestinal Transplant (MS–LTC–DRG 005); Liver Transplant without MCC (MS–LTC–DRG 006); Lung Transplant (MS–LTC–DRG 007); Simultaneous Pancreas/Kidney Transplant (MS–LTC–DRG 008); Pancreas Transplant (MS–LTC–DRG 010); and Kidney Transplant (MS–LTC–DRG 652). This is because Medicare only covers these procedures if they are performed at a hospital that has been certified for the specific procedures by Medicare and presently no LTCH has been so certified. At the present time, we include these eight transplant MS–LTC–DRGs in the GROUPER program for administrative purposes only. Because we use the same GROUPER program for LTCHs as is used under the IPPS, removing these MS–LTC–DRGs would be administratively burdensome. (For additional information regarding our treatment of transplant MS–LTC–DRGs, we refer readers to the RY 2010 LTCH PPS final rule (74 FR 43964).) In addition, consistent with our historical policy and as we proposed, we are

establishing a relative weight of 0.0000 for the 2 ''error'' MS–LTC–DRGs (that is, MS–LTC–DRG 998 (Principal Diagnosis Invalid as Discharge Diagnosis) and MS–LTC–DRG 999 (Ungroupable)) because applicable LTCH cases grouped to these MS–LTC–DRGs cannot be properly assigned to an MS–LTC–DRG according to the grouping logic.

In this final rule, consistent with our practice in FYs 2016 and 2017 and as we proposed, we are establishing a relative weight for FY 2018 equal to the respective FY 2015 relative weight of the MS–LTC–DRGs for the following ''psychiatric or rehabilitation'' MS–LTC–DRGs: MS–LTC–DRG 876 (O.R. Procedure with Principal Diagnoses of Mental Illness); MS–LTC–DRG 880 (Acute Adjustment Reaction & Psychosocial Dysfunction); MS–LTC–DRG 881 (Depressive Neuroses); MS–LTC–DRG 882 (Neuroses Except Depressive); MS–LTC–DRG 883 (Disorders of Personality & Impulse Control); MS–LTC–DRG 884 (Organic Disturbances & Mental Retardation); MS–LTC–DRG 885 (Psychoses); MS–LTC–DRG 886 (Behavioral & Developmental Disorders); MS–LTC–DRG 887 (Other Mental Disorder Diagnoses); MS–LTC–DRG 894 (Alcohol/Drug Abuse or Dependence, Left Ama); MS–LTC–DRG 895 (Alcohol/Drug Abuse or Dependence, with Rehabilitation Therapy); MS–LTC–DRG 896 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy with MCC); MS–LTC–DRG 897 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy without MCC); MS–LTC–DRG 945 (Rehabilitation with CC/MCC); and MS–LTC–DRG 946 (Rehabilitation without CC/MCC). As we discussed when we implemented the dual rate LTCH PPS payment structure, LTCH discharges that are grouped to these 15 ''psychiatric and rehabilitation'' MS–LTC–DRGs do not meet the criteria for exclusion from the site neutral payment rate.

As such, under the criterion for a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation, there are no applicable LTCH cases to use in calculating a relative weight for the ''psychiatric and rehabilitation'' MS–LTC–DRGs. In other words, any LTCH PPS discharges grouped to any of the 15 ''psychiatric and rehabilitation'' MS–LTC–DRGs would always be paid at the site neutral payment rate, and, therefore, those MS–LTC–DRGs would never include any LTCH cases that meet the criteria for exclusion from the site neutral payment rate. However, section 1886(m)(6)(B) of the Act establishes a transitional payment method for cases that would be paid at the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 or FY 2017. Under the transitional payment method for site neutral payment rate cases, for LTCH discharges occurring in cost reporting periods beginning on or after October 1, 2016, and on or before September 30, 2017, site neutral payment rate cases are paid a blended payment rate, calculated as 50 percent of the applicable site neutral payment rate amount for the discharge and 50 percent of the applicable LTCH PPS standard Federal payment rate. Because the LTCH PPS standard Federal payment rate is based on the relative weight of the MS–LTC–DRG, in order to determine the transitional blended payment for site neutral payment rate cases grouped to one of the ''psychiatric or rehabilitation'' MS–LTC–DRGs in FY 2018, we assigned a relative weight to these MS–LTC–DRGs for FY 2018 that is the same as the FY 2015 relative weight (which is also the same as the FY 2016 relative weight). We believe that using the respective FY 2015 relative weight for each of the ''psychiatric or rehabilitation'' MS–LTC–DRGs results in appropriate payments for LTCH cases that are paid at the site neutral payment rate under the transition policy provided by the statute because there are no clinically similar MS–LTC–DRGs for which we were able to determine relative weights based on applicable LTCH cases in the March 2017 update of the FY 2016 MedPAR file data using the steps described above. Furthermore, we believe that it would be administratively burdensome and introduce unnecessary complexity to the MS–LTC–DRG relative weight calculation to use the LTCH discharges in the MedPAR file data to calculate a relative weight for those 15 ''psychiatric and rehabilitation'' MS–LTC–DRGs to be used for the sole purpose of determining half of the transitional blended payment for site neutral payment rate cases during the transition period (80 FR 49631 through 49632).

In summary, for FY 2018, we are establishing a relative weight (and average length of stay thresholds) equal to the respective FY 2015 relative weight of the MS–LTC–DRGs for the 15 ''psychiatric or rehabilitation'' MS–LTC–DRGs listed previously (that is, MS–LTC–DRGs 876, 880, 881, 882, 883, 884, 885, 886, 887, 894, 895, 896, 897, 945, and 946). Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the Internet on the CMS Web site, reflects this policy.

Step 6—Adjust the FY 2018 MS–LTC–DRG relative weights to account for nonmonotonically increasing relative weights.

The MS–DRGs contain base DRGs that have been subdivided into one, two, or three severity of illness levels. Where there are three severity levels, the most severe level has at least one secondary diagnosis code that is referred to as an MCC (that is, major complication or comorbidity). The next lower severity level contains cases with at least one secondary diagnosis code that is a CC (that is, complication or comorbidity). Those cases without an MCC or a CC are referred to as ''without CC/MCC.'' When data do not support the creation of three severity levels, the base MS–DRG is subdivided into either two levels or the base MS–DRG is not subdivided. The two-level subdivisions may consist of the MS–DRG with CC/MCC and the MS–DRG without CC/MCC. Alternatively, the other type of two-level subdivision may consist of the MS–DRG with MCC and the MS–DRG without MCC.

In those base MS–LTC–DRGs that are split into either two or three severity levels, cases classified into the ''without CC/MCC'' MS–LTC–DRG are expected to have a lower resource use (and lower costs) than the ''with CC/MCC'' MS–LTC–DRG (in the case of a two-level split) or both the ''with CC'' and the ''with MCC'' MS–LTC–DRGs (in the case of a three-level split). That is, theoretically, cases that are more severe typically require greater expenditure of medical care resources and would result in higher average charges. Therefore, in the three severity levels, relative weights should increase by severity, from lowest to highest. If the relative weights decrease as severity increases (that is, if within a base MS–LTC–DRG, an MS–LTC–DRG with CC has a higher relative weight than one with MCC, or the MS–LTC–DRG ''without CC/MCC'' has a higher relative weight than either of the others), they are nonmonotonic. We continue to believe that utilizing nonmonotonic relative weights to adjust Medicare payments would result in inappropriate payments because the payment for the cases in the higher severity level in a base MS–LTC–DRG (which are generally expected to have higher resource use and costs) would be lower than the payment for cases in a lower severity level within the same base MS–LTC–DRG (which are generally expected to have lower resource use and costs). Therefore, in determining the FY 2018 MS–LTC–DRG relative weights, consistent with our historical methodology, we are continuing to combine MS–LTC–DRG severity levels within a base MS–LTC–DRG for the purpose of computing a relative weight

when necessary to ensure that monotonicity is maintained. For a comprehensive description of our existing methodology to adjust for nonmonotonicity, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43964 through 43966). Any adjustments for nonmonotonicity that were made in determining the FY 2018 MS–LTC–DRG relative weights in this final rule by applying this methodology are denoted in Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the Internet on the CMS Web site.

Step 7—Calculate the FY 2018 MS–LTC–DRG reclassification and recalibration budget neutrality factor.

In accordance with the regulations at § 412.517(b) (in conjunction with § 412.503), the annual update to the MS–LTC–DRG classifications and relative weights is done in a budget neutral manner such that estimated aggregate LTCH PPS payments would be unaffected, that is, would be neither greater than nor less than the estimated aggregate LTCH PPS payments that would have been made without the MS–LTC–DRG classification and relative weight changes. (For a detailed discussion on the establishment of the budget neutrality requirement for the annual update of the MS–LTC–DRG classifications and relative weights, we refer readers to the RY 2008 LTCH PPS final rule (72 FR 26881 and 26882).)

The MS–LTC–DRG classifications and relative weights are updated annually based on the most recent available LTCH claims data to reflect changes in relative LTCH resource use (§ 412.517(a) in conjunction with § 412.503). To achieve the budget neutrality requirement at § 412.517(b), under our established methodology, for each annual update, the MS–LTC–DRG relative weights are uniformly adjusted to ensure that estimated aggregate payments under the LTCH PPS would not be affected (that is, decreased or increased). Consistent with that provision and as we proposed, we are update the MS–LTC–DRG classifications and relative weights for FY 2018 based on the most recent available LTCH data for applicable LTCH cases, and continue to apply a budget neutrality adjustment in determining the FY 2018 MS–LTC–DRG relative weights. In this FY 2018 IPPS/LTCH PPS final rule, as we proposed, to ensure budget neutrality in the update to the MS–LTC–DRG classifications and relative weights under § 412.517(b), we are continuing to use our established two-step budget neutrality methodology.

To calculate the normalization factor for FY 2018, we grouped applicable LTCH cases using the FY 2018 Version 35 GROUPER, and the recalibrated FY 2018 MS–LTC–DRG relative weights to calculate the average case-mix index (CMI); we grouped the same applicable LTCH cases using the FY 2017 GROUPER Version 34 and MS–LTC–DRG relative weights and calculated the average CMI; and computed the ratio by dividing the average CMI for FY 2017 by the average CMI for FY 2018. That ratio is the normalization factor. Because the calculation of the normalization factor involves the relative weights for the MS–LTC–DRGs that contained applicable LTCH cases to calculate the average CMIs, any low-volume MS–LTC–DRGs are included in the calculation (and the MS–LTC–DRGs with no applicable LTCH cases are not included in the calculation).

To calculate the budget neutrality adjustment factor, we simulated estimated total FY 2018 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the FY 2018 normalized relative weights and GROUPER Version 35; simulated estimated total FY 2017 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the FY 2017 MS–LTC–DRG relative weights and the FY 2017 GROUPER Version 34; and calculated the ratio of these estimated total payments by dividing the simulated estimated total LTCH PPS standard Federal payment rate payments for FY 2017 by the simulated estimated total LTCH PPS standard Federal payment rate payments for FY 2018. The resulting ratio is budget neutrality adjustment factor. The calculation of the budget neutrality factor involves the relative weights for the LTCH cases used in the payment simulation, which includes any cases grouped to low-volume MS–LTC–DRGs or to MS–LTC–DRGs with no applicable LTCH cases, and generally does not include payments for cases grouped to a MS–LTC–DRG with no applicable LTCH cases. (Occasionally, a few LTCH cases (that is, those with a covered length of stay of 7 days or less, which are removed from the relative weight calculation in step 2) that are grouped to a MS–LTC–DRG with no applicable LTCH cases are included in the payment simulations used to calculate the budget neutrality factor. However, the number and payment amount of such cases have a negligible impact on the budget neutrality factor calculation).

In this final rule, to ensure budget neutrality in the update to the MS–LTC–DRG classifications and relative weights under § 412.517(b), as we proposed, we are continuing to use our established two-step budget neutrality methodology. Therefore, in this final rule, in the first step of our MS–LTC–DRG budget neutrality methodology, for FY 2018, we calculate and apply a normalization factor to the recalibrated relative weights (the result of Steps 1 through 6 discussed previously) to ensure that estimated payments are not affected by changes in the composition of case types or the changes to the classification system. That is, the normalization adjustment is intended to ensure that the recalibration of the MS–LTC–DRG relative weights (that is, the process itself) neither increases nor decreases the average case-mix index.

To calculate the normalization factor for FY 2018 (the first step of our budget neutrality methodology), we used the following three steps: (1.a.) Used the most recent available applicable LTCH cases from the most recent available data (that is, LTCH discharges from the FY 2016 MedPAR file) and grouped them using the FY 2018 GROUPER (that is, Version 35 for FY 2018) and the recalibrated FY 2018 MS–LTC–DRG relative weights (determined in Steps 1 through 6 above) to calculate the average case-mix index; (1.b.) grouped the same applicable LTCH cases (as are used in Step 1.a.) using the FY 2017 GROUPER (Version 34) and FY 2017 MS–LTC–DRG relative weights and calculated the average case-mix index; and (1.c.) computed the ratio of these average case-mix indexes by dividing the average CMI for FY 2017 (determined in Step 1.b.) by the average case-mix index for FY 2018 (determined in Step 1.a.). As a result, in determining the MS–LTC–DRG relative weights for FY 2018, each recalibrated MS–LTC–DRG relative weight is multiplied by the normalization factor of 1.28590 (determined in Step 1.c.) in the first step of the budget neutrality methodology, which produced ''normalized relative weights.''

In the second step of our MS–LTC–DRG budget neutrality methodology, we calculate a second budget neutrality factor consisting of the ratio of estimated aggregate FY 2018 LTCH PPS standard Federal payment rate payments for applicable LTCH cases (the sum of all calculations under Step 1.a. mentioned previously) after reclassification and recalibration to estimated aggregate payments for FY 2018 LTCH PPS standard Federal payment rate payments for applicable LTCH cases before reclassification and recalibration (that is, the sum of all calculations under Step 1.b. mentioned previously).

That is, for this final rule, for FY 2018, under the second step of the budget neutrality methodology, as we proposed, we determine the budget neutrality adjustment factor using the following three steps: (2.a.) Simulated estimated total FY 2018 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the normalized relative weights for FY 2018 and GROUPER Version 35 (as described above); (2.b.) simulated estimated total FY 2017 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the FY 2017 GROUPER (Version 34) and the FY 2017 MS–LTC–DRG relative weights in Table 11 of the FY 2017 IPPS/LTCH PPS final rule available on the Internet, as described in section VI. of the Addendum of that final rule; and (2.c.) calculated the ratio of these estimated total payments by dividing the value determined in Step 2.b. by the value determined in Step 2.a. In determining the FY 2018 MS–LTC–DRG relative weights, each normalized relative weight is then multiplied by a budget neutrality factor of 0.9907845 (the value determined in Step 2.c.) in the second step of the budget neutrality methodology to achieve the budget neutrality requirement at § 412.517(b).

Accordingly, in determining the FY 2018 MS–LTC–DRG relative weights in this final rule, consistent with our existing methodology, we applied a normalization factor of 1.28590 and a budget neutrality factor of 0.9907845. Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the Internet on the CMS Web site, lists the MS–LTC–DRGs and their respective relative weights, geometric mean length of stay, and five-sixths of the geometric mean length of stay (used to identify SSO cases under § 412.529(a)) for FY 2018.

C. Changes to the LTCH PPS Payment Rates and Other Changes to the LTCH PPS for FY 2018

1. Overview of Development of the LTCH PPS Standard Federal Payment Rates

The basic methodology for determining LTCH PPS standard Federal payment rates is currently set forth at 42 CFR 412.515 through 412.538. In this section, we discuss the factors that we used to update the LTCH PPS standard Federal payment rate for FY 2018, that is, effective for LTCH discharges occurring on or after October 1, 2017 through September 30, 2018. Under the dual rate LTCH PPS payment structure required by statute, beginning with discharges in cost reporting periods beginning in FY 2016, only LTCH discharges that meet the criteria for exclusion from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate specified at § 412.523. (For additional details on our finalized policies related to the dual rate LTCH PPS payment structure required by statute, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623).)

Prior to the implementation of the dual payment rate system in FY 2016, all LTCHs were paid similarly to those now exempt from the site neutral payment rate. That legacy payment rate was called the standard Federal rate. For details on the development of the initial standard Federal rate for FY 2003, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56027 through 56037). For subsequent updates to the standard Federal rate (FYs 2003 through 2015)/LTCH PPS standard Federal payment rate (FY 2016 through present) as implemented under § 412.523(c)(3), we refer readers to the following final rules: RY 2004 LTCH PPS final rule (68 FR 34134 through 34140); RY 2005 LTCH PPS final rule (68 FR 25682 through 25684); RY 2006 LTCH PPS final rule (70 FR 24179 through 24180); RY 2007 LTCH PPS final rule (71 FR 27819 through 27827); RY 2008 LTCH PPS final rule (72 FR 26870 through 27029); RY 2009 LTCH PPS final rule (73 FR 26800 through 26804); FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 44021 through 44030); FY 2011 IPPS/LTCH PPS final rule (75 FR 50443 through 50444); FY 2012 IPPS/LTCH PPS final rule (76 FR 51769 through 51773); FY 2013 IPPS/LTCH PPS final rule (77 FR 53479 through 53481); FY 2014 IPPS/LTCH PPS final rule (78 FR 50760 through 50765); FY 2015 IPPS/LTCH PPS final rule (79 FR 50176 through 50180); FY 2016 IPPS/LTCH PPS final rule (80 FR 49634 through 49637); and FY 2017 IPPS/LTCH PPS final rule (81 FR 57296 through 57310).

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20021 through 20022), we presented our proposals related to the proposed annual update to the LTCH PPS standard Federal payment rate for FY 2018, which include certain statutory requirements as discussed below.

The application of the update to the LTCH PPS standard Federal payment rate for FY 2018 is presented in section V.A. of the Addendum to this final rule. The components of the annual update to the LTCH PPS standard Federal payment rate for FY 2018 are discussed below, including the reduction to the annual update for LTCHs that fail to submit quality reporting data for FY 2018 as required by the statute (as discussed in section VIII.C.2.c. of the preamble of this final rule). In addition, we are making an adjustment to the LTCH PPS standard Federal payment rate to account for the estimated effect of the changes to the area wage level adjustment for FY 2018 on estimated aggregate LTCH PPS payments, in accordance with § 412.523(d)(4) (as discussed in section V.B. of the Addendum to this final rule), and a budget neutrality adjustment stemming from our change to the SSO payment methodology (as discussed in VIII.D. of the preamble of this final rule).

2. FY 2018 LTCH PPS Standard Federal Payment Rate Annual Market Basket Update

a. Overview

Historically, the Medicare program has used a market basket to account for input price increases in the services furnished by providers. The market basket used for the LTCH PPS includes both operating and capital related costs of LTCHs because the LTCH PPS uses a single payment rate for both operating and capital-related costs. We adopted the 2013-based LTCH-specific market basket for use under the LTCH PPS beginning in FY 2017 (81 FR 57101 through 57102). For additional details on the historical development of the market basket used under the LTCH PPS, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53467 through 53476), and for a complete discussion of the LTCH market basket and a description of the methodologies used to determine the operating and capital-related portions of the 2013-based LTCH market basket, we refer readers to section VII.D. of the preamble of the FY 2017 IPPS/LTCH PPS proposed and final rules.

Section 3401(c) of the Affordable Care Act provides for certain adjustments to any annual update to the LTCH PPS standard Federal payment rate and refers to the timeframes associated with such adjustments as a ''rate year'' (which are discussed in more detail in section VIII.C.2.b. of the preamble of this final rule.) We note that because the annual update to the LTCH PPS policies, rates, and factors now occurs on October 1, we adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010, to conform with the standard definition of the Federal fiscal year (October 1 through September 30) used by other PPSs, such as the IPPS (75 FR 50396 through

50397). Although the language of sections 3004(a), 3401(c), 10319, and 1105(b) of the Affordable Care Act refers to years 2010 and thereafter under the LTCH PPS as ''rate year,'' consistent with our change in the terminology used under the LTCH PPS from ''rate year'' to ''fiscal year,'' for purposes of clarity, when discussing the annual update for the LTCH PPS standard Federal payment rate, including the provisions of the Affordable Care Act, we use ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.

b. Annual Update to the LTCH PPS Standard Federal Payment Rate for FY 2018

Section 1886(m)(3)(A) of the Act provides that, beginning in FY 2010, any annual update to the LTCH PPS standard Federal payment rate is reduced by the adjustments specified in clauses (i) and (ii) of subparagraph (A). Clause (i) of section 1886(m)(3)(A) of the Act provides for a reduction, for FY 2012 and each subsequent rate year, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (that is, ''the multifactor productivity (MFP) adjustment''). Clause (ii) of section 1886(m)(3)(A) of the Act provides for a reduction, for each of FYs 2010 through 2019, by the ''other adjustment'' described in section 1886(m)(4)(F) of the Act.

Section 411(e) of the Medicare Access and CHIP Reauthorization Act (MACRA) (Pub. L. 114–10), enacted on April 16, 2015, amended section 1886(m)(3) of the Act by amending subparagraph (A) to be ''subject to subparagraph (C)'' and by adding new subparagraph (C), which specifies an additional special rule for FY 2018. Specifically, section 1886(m)(3)(C) of the Act states for FY 2018, the annual update under subparagraph (A) for the fiscal year, after application of clauses (i) and (ii) of subparagraph (A), shall be 1 percent. That is, the annual update for FY 2018, after applications of the reductions for the MFP adjustment (under clause (i) of section 1886(m)(3)(A)) and the ''other adjustment'' (under clause (ii) of section 1886(m)(3)(A)) is 1 percent.

Historically, CMS has used an estimated market basket increase to update the LTCH PPS. Under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we adopted a newly created 2013-based LTCH-specific market basket for use under the LTCH PPS beginning in FY 2017. The 2013-based LTCH-specific market basket is based solely on the Medicare cost report data submitted by LTCHs and, therefore, specifically reflects the cost structures of only LTCHs. For additional details on the development of the 2013-based LTCH-specific market basket, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57101 through 57102). For FYs 2010 through 2017, the estimated market basket update under the LTCH PPS was reduced by the MFP adjustment and ''other adjustment'' as applicable. However, as described above, section 411(e) of the MACRA subsequently amended section 1886(m)(3)(A) of the Act so that, after the adjustments above, the FY 2018 annual update is set at 1 percent.

c. Adjustment to the LTCH PPS Standard Federal Payment Rate Under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In accordance with section 1886(m)(5) of the Act, as added by section 3004(a) of the Affordable Care Act, the Secretary established the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). Failure to report quality data under the LTCH QRP for FY 2014 and subsequent fiscal years results in a 2.0 percentage point reduction in the annual update as codified under § 412.523(c)(4) of the regulations. (As previously noted, although the language of section 3004(a) of the Affordable Care Act refers to years 2011 and thereafter under the LTCH PPS as ''rate year,'' consistent with our change in the terminology used under the LTCH PPS from ''rate year'' to ''fiscal year,'' for purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the Affordable Care Act, we use ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.) The LTCH QRP, as required for FY 2014 and subsequent fiscal years by section 1886(m)(5)(A)(i) of the Act, applies a 2.0 percentage point reduction to any update under § 412.523(c)(3) for an LTCH that does not submit quality reporting data to the Secretary in accordance with section 1886(m)(5)(C) of the Act with respect to such a year (that is, in the form and manner and at the time specified by the Secretary under the LTCH QRP) (§ 412.523(c)(4)(i)). Section 1886(m)(5)(A)(ii) of the Act provides that the application of the 2.0 percentage points reduction may result in an annual update that is less than 0.0 for a year, and may result in LTCH PPS payment rates for a year being less than such LTCH PPS payment rates for the preceding year (§ 412.523(c)(4)(iii)). Furthermore, section 1886(m)(5)(B) of the Act specifies that the 2.0 percentage points reduction is applied in a noncumulative manner, such that any reduction made under section 1886(m)(5)(A) of the Act shall apply only with respect to the year involved, and shall not be taken into account in computing the LTCH PPS payment amount for a subsequent year (§ 412.523(c)(4)(ii)).

d. Annual Update Under the LTCH PPS for FY 2018

Consistent with the amendments to section 1886(m)(3)(C) of the Act provided by section 411 of the MACRA, as we proposed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20021), we are making an update to the LTCH PPS standard Federal payment rate of 1 percent for FY 2018.

For FY 2018, section 1886(m)(5) of the Act requires that, for LTCHs that do not submit quality reporting data as required under the LTCH QRP, any annual update to an LTCH PPS standard Federal payment rate, after application of the adjustments required by section 1886(m)(3) of the Act, shall be further reduced by 2.0 percentage points. For LTCHs that fail to submit quality reporting data under the LTCH QRP, under § 412.523(c)(3)(xiv) in conjunction with § 412.523(c)(4), as we proposed, we are further reducing the annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points in accordance with section 1886(m)(5) of the Act. As such, the update to the LTCH PPS standard Federal payment rate for FY 2018 for LTCHs that fail to submit quality reporting data under the LTCH QRP is the 1-percent annual rate increase for FY 2018 reduced by 2.0 percentage points. For this final rule, we are establishing an annual update to the LTCH PPS standard Federal payment rate of −1 percent (that is, 1 percent minus 2.0 percentage points) for FY 2018 for LTCHs that fail to submit quality reporting data as required under the LTCH QRP. As provided in § 412.523(c)(4)(iii) and as noted above, the application of the 2.0 percentage points reduction may result in an annual update that is less than 0.0 for a year, and may result in LTCH PPS payment rates for a year being less than such LTCH PPS payment rates for the preceding year. (We note that, consistent with historical practice, in determining the FY 2018 LTCH PPS standard Federal payment rate, we are also applying an area wage level budget neutrality factor in accordance with § 412.523(d)(4) (as discussed in section V.B. of the Addendum to this final rule) and a budget neutrality adjustment stemming from our change to the SSO payment methodology (as discussed in VIII.D. of the preamble of this final rule).

Absent the special provisions for FY 2018 required by section 1886(m)(3)(C) of the Act, we note the annual market basket update would have been based on the FY 2018 full market basket increase of 2.7 percent (based on IGI's second quarter 2017 forecast of the 2013-based LTCH market basket) reduced by the FY 2018 MFP adjustment of 0.6 percentage point (also based on IGI's second quarter 2017 forecast). Following application of the productivity adjustment, the adjusted market basket update of 2.1 percent (2.7 percent minus 0.6 percentage point) would have then been further reduced by 0.75 percentage point, as required by sections 1886(m)(3)(A)(ii) and 1886(m)(4)(F) of the Act. This would have resulted in an annual market basket update under to the LTCH PPS standard Federal payment rate for FY 2018 of 1.35 percent (that is, 2.7 percent, less the MFP adjustment of 0.6 percentage point, and less the 0.75 percentage point required under section 1886(m)(4)(F) of the Act). (For additional information on the application of the MFP adjustment and ''other adjustment'' in developing the annual market based update under our historical approach, refer to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57296 through 57310).)

D. Changes to the Short-Stay Outlier Adjustment Policy (§ 412.529)

In the FY 2003 LTCH PPS final rule (67 FR 55954) that implemented the LTCH PPS, under § 412.529, we established a special payment policy for short-stay outlier (SSO) cases; that is, cases with a covered length of stay that is less than or equal to five-sixths of the geometric average length of stay for each LTC–DRG. When we established the SSO policy, we explained that a short-stay outlier case may occur when a beneficiary receives less than the full course of treatment at the LTCH before being discharged (67 FR 55995). Also, in the FY 2003 LTCH PPS final rule, we stated that when we first described the policy in the proposed rule, we based the proposed policy on the belief that many of these patients could have been treated more appropriately in an acute hospital subject to the acute care hospital inpatient prospective payment system (67 FR 55995).

Therefore, under the LTCH PPS, we implemented a special payment adjustment for SSO cases. Under the original SSO policy, for LTCH PPS discharges with a covered length of stay of up to and including five-sixths of the geometric average length of stay for the LTC–DRG, we adjusted the per discharge payment amount under the LTCH PPS as the least of 120 percent of the estimated cost of the case, 120 percent of the LTC–DRG specific per diem amount multiplied by the covered length of stay of that discharge, or the full LTC–DRG payment amount (67 FR 55995 through 56000).

As noted previously, generally LTCHs are defined by statute as having an average length of stay of greater than 25 days. In the FY 2003 LTCH PPS final rule, we stated that we believed that the SSO payment adjustment results in more appropriate payments because these SSO cases most likely did not receive a full course of treatment at a LTCH level in such a short period of time, and the full LTC–DRG payment would generally not be appropriate. Payment-to-cost ratio analyses at that time indicated that if LTCHs received a full LTC–DRG payment for those cases, they would have been significantly ''overpaid'' for the resources they actually expended in treating those patients (67 FR 55995 through 56000). Furthermore, in establishing the SSO policy, we stated that we believed that providing a reduced payment for SSO cases would discourage hospitals from admitting these patients. We also believed that the policy did not severely penalize providers that, in good faith, had admitted a patient and provided some services before realizing that the beneficiary could receive more appropriate treatment at another site of care. As we further explained in the FY 2003 LTCH PPS final rule, establishing a SSO payment adjustment for these types of cases addresses the incentives inherent in a discharge-based PPS for LTCHs for treating patients with a short length of stay (67 FR 55995 through 56000). We have made several changes to our SSO policy since it was first introduced.

For a full discussion of those historic changes, we refer readers to the RY 2008 LTCH PPS final rule (72 FR 26904 through 26919).

During our FY 2016 and FY 2017 IPPS/LTCH PPS rulemaking cycles, we received public comments that we determined were outside the scope of the FY 2016 and FY 2017 proposed rules that expressed concern with our existing SSO policy. Commenters stated that our SSO payment adjustment appears to result in an incentive to improperly hold patients beyond the SSO threshold (five-sixths the geometric average length of stay for the MS–LTC–DRG). Specifically, as SSO cases are paid the ''lesser of'' various payment options, while non-SSO cases are paid the full MS–LTC–DRG payment, there is an economic incentive to hold a patient beyond the SSO threshold in order to increase (and in some cases dramatically increase) the LTCH PPS payment for that case. In its comment in response to the FY 2016 IPPS/LTCH PPS proposed rule, MedPAC stated that its analysis of LTCH discharge patterns have shown that LTCHs respond to that incentive. Analyses of lengths-of-stay by MS–LTC–DRG have consistently shown that the frequency of discharges rises sharply immediately after the SSO threshold is met.

This pattern holds true across MS–LTC–DRGs and for every category of LTCHs. We believe that these analyses strongly suggest that LTCHs' discharge decisions are influenced at least as much by this financial incentive as by clinical considerations. Our own analysis of LTCH claims data showed similar findings.

In light of these concerns, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20023), we proposed to address this financial incentive and discourage such delay in the discharge of LTCH patients by proposing to revise our SSO policy. We note that, under the dual rate LTCH PPS payment structure, our existing SSO policy only applies to the LTCH PPS standard Federal payment rate. Accordingly, as explained in the proposed rule, the proposed changes to our SSO policy would only apply to LTCH PPS standard Federal payment rate cases (or, for cost reporting periods beginning before October 1, 2017, the LTCH PPS standard Federal payment rate portion of the blended rate payment under § 412.522(c)(3)(ii)).

Under our proposed policy, the SSO definition remained unchanged, but the current payment adjustment options would be replaced with a single graduated per diem payment adjustment calculated using a blended payment rate that, as the length of stay increases, consists of a decreasing portion of the payment amount paid at the IPPS per diem amount (referred to as the ''IPPS comparable amount'') and an increasing portion paid at 120 percent of the MS–LTC–DRG per diem payment amount (referred to as the ''LTCH PPS per diem amount''), with a maximum payment amount set at the full LTCH PPS standard Federal payment rate. Specifically, beginning with discharges occurring on or after October 1, 2017, we proposed to pay SSO cases solely on the ''blended'' option in the current SSO payment adjustment formula described at § 412.529(c)(2)(iv); that is, a SSO case would be paid based on a blend of the IPPS comparable amount (determined under § 412.529(d)(4)(i)) and the MS–LTC–DRG per diem amount (determined under § 412.529(d)(1) in conjunction with § 412.503).

Under this blended payment method at existing § 412.529(c)(2)(iv), as the length of stay of a SSO case increases, the percentage of the per diem payment amounts based on the full MS–LTC–DRG standard Federal payment rate would increase, and the percentage of the payment based on the IPPS comparable amount would decrease. This blended per diem payment rate adjustment would result in paying LTCH cases with a very short length of stay more like an IPPS case, and LTCH cases with relatively longer lengths-of-stay more like a non-short-stay LTCH PPS standard Federal payment rate case.

Therefore, as the length of stay of as SSO case increases, the treatment resources and costs associated with the stay are more comparable with typical LTCH PPS standard Federal payment rate payments and less comparable to payments for the same stay at an acute care hospital under the IPPS.

We stated in the proposed rule that, if adopted, this policy would result in payment amounts becoming more commensurate with the LTCH PPS standard Federal payment rate as the case begins to resemble a more characteristic LTCH PPS standard Federal payment rate case. We stated that we believe that, by paying SSO cases on this basis, we would reduce, if not eliminate, the payment ''cliffs'' (or payment differentials) inherent in our current payment methodology, as well as the financial incentives that appear to have resulted in potentially improper delays in patient discharges other than solely for medical reasons. In addition, we stated that we believe that the per diem ''blended'' approach would provide an appropriate balance between the 1-day marginal payment and the 1-day marginal incurred cost.

Under this proposal, we proposed to codify the change to the SSO policy described above by revising § 412.529 of the regulation. Specifically, we proposed to add paragraph (c)(4) to provide that, for discharges occurring on or after October 1, 2017, SSO cases will be paid according to the blended payment option at existing § 412.529(c)(2)(iv) and corresponding changes to § 412.529(c)(3) by sunsetting the previous SSO payment formula as of October 1, 2017.

Comment: Commenters supported the proposal to revise the SSO policy. Many commenters requested clarification on the interaction between the proposal and the so-called ''very short stay outlier'' policy at § 412.529(c)(3)(ii).

Response: We appreciate the commenters' support. In response to those seeking clarification, we note that our proposed changes to the SSO policy would apply to all short-stay cases, including those cases currently paid under § 412.529(c)(3)(ii) (that is, the ''very short stay outlier'' policy). Because the proposed blended payment method pays cases with relatively short stays more like IPPS cases, we believe this single payment option provides appropriate payments for those SSO cases that most likely did not receive a full course of treatment at an LTCH. Moreover, as stated above, in the proposed rule, we proposed to sunset the existing SSO payment formula at § 412.529(c)(3), effective October 1, 2017. Because the ''very short stay outlier'' payment is paragraph (ii) of § 412.529(c)(3), our proposal would eliminate that payment option, while our proposed addition of § 412.529(c)(4) provides for an adjustment to all SSO cases under a single payment formula.

After consideration of the public comments we received, we are adopting our proposed changes to § 412.529 as final without modification. Specifically, we are finalizing our proposal to add paragraph (c)(4) to provide that, for discharges occurring on or after October 1, 2017, SSO cases will be paid according to the blended payment option at existing § 412.529(c)(2)(iv) and finalizing our proposal to make corresponding changes to § 412.529(c)(3) by sunsetting the previous SSO payment formula as of October 1, 2017.

The goal of revising the SSO policy is to remove the incentive to delay patient discharges for payment reasons. As explained in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20023), in assessing the potential impact of this proposed policy change, we found two different impacts on Medicare LTCH spending: One would increase spending while the other would decrease spending.

First, as we stated in the proposed rule, we expect this SSO payment adjustment methodology would result in increased payments to SSO cases. Based on data and FY 2018 payment estimates used for the proposed rule, we estimate that, under this SSO payment adjustment, Medicare payments to SSO cases will increase approximately 30 percent, or approximately $145 million (without taking into account any assumptions on changes to LTCHs' discharge practices). These increased payments for SSO cases will produce a somewhat substantial increase in aggregate Medicare spending for LTCH PPS standard Federal payment rate cases (that is, an approximate 4.6-percent increase to current projected LTCH PPS standard Federal payment rate case payments).

At the same time, without the economic incentive to delay discharge until the SSO threshold is met, under our proposal, we stated that we expect LTCHs would discharge some patients sooner, even while the length of stay of the patient is still within the SSO period. Therefore, in the absence of this policy, these cases would not have previously been SSO cases. We stated our belief that this policy would result in some reduction in Medicare spending due to an expected decrease in Medicare payments for LTCH PPS standard Federal payment rate cases that, under the current SSO policy, were not receiving the SSO payment adjustment (because discharges were delayed until the SSO threshold was met).

However, as also discussed in the proposed rule, while we expect this behavior change by LTCHs will reduce Medicare expenditures, we do not believe that the decrease in expenditures from fewer delayed discharge cases will offset the estimated increase in expenditures under the proposed SSO payment adjustment methodology. As such, we projected that the proposed change to the payment formula for SSOs would result in a net increase in aggregate Medicare LTCH payments compared to aggregate Medicare payments under the current methodology.

As we stated in the proposed rule, the goal of the proposed policy is to remove the incentive to delay patient discharges for payment reasons, not to increase aggregate Medicare LTCH PPS payments. Therefore, we believed the appropriate policy approach was to propose to implement this change to the SSO payment methodology on a budget neutral basis; that is, to implement the SSO payment adjustment methodology by adjusting the LTCH PPS standard Federal payment rate so that our projection of aggregate FY 2018 payments for LTCH PPS standard Federal payment rate cases made under this SSO payment adjustment methodology would be equal to our projection of aggregate FY 2018 payments paid for LTCH PPS standard Federal payment rate cases under our existing SSO payment adjustment methodology.

We further note that, based on most recent claims data, we believe the effects of a budget neutral approach would primarily occur within each LTCH and, therefore, result in minimal redistribution between different LTCHs. Specifically, FY 2015 claims data show that nearly all LTCHs treated at least one SSO case, and those that did not treat any SSO cases, on average, had very few LTCH PPS standard Federal

payment rate cases. In addition, for over 90 percent of all LTCHs, at least 20 percent of their LTCH PPS standard Federal payment rate cases were SSO cases. Therefore, in the proposed rule, we stated that we expect that, for most LTCHs, the increase in payments for their SSO cases under this proposed change to the SSO payment methodology would generally offset any SSO budget neutrality-related decrease in payment to their non-SSO LTCH PPS standard Federal payment rate cases.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20023), we proposed to implement the proposed change to the SSO payment methodology by using a budget neutrality adjustment to offset the projected net increase in Medicare spending while accounting for both the estimated decrease in Medicare payments resulting from LTCHs no longer holding patients until the SSO threshold is met and the larger estimated increase in spending to SSO cases described earlier. We stated that we believe our proposal to incorporate a projection of the expected decrease in spending resulting from a behavior change to not hold patients beyond the SSO threshold appropriately reflects the net impact of the proposed change. Further, this lessens the impact of any budget neutrality adjustment estimated without accounting for these expected behavioral changes—in other words, if the budget neutrality adjustment only adjusted for the increased payments to SSO cases.

To do so, we proposed to amend § 412.523(d) by adding a new paragraph (5), which would specify that the LTCH PPS standard Federal payment rate will be adjusted by a one-time, permanent factor that accounts for the projected change in estimated aggregate payments to LTCH PPS standard Federal payment rate cases in FY 2018 due to the change in the payment methodology for SSO cases described at § 412.529(c)(4). (As noted earlier, this budget neutrality adjustment would only affect the LTCH PPS standard Federal payment rate.) This factor would ensure that the proposed change to the SSO payment methodology in FY 2018 does not affect aggregate LTCH PPS payments; that is, this proposed policy change is budget neutral. Specifically, in the proposed rule, we set out a proposed methodology to determine the budget neutrality factor that would be applied to the FY 2018 LTCH PPS standard Federal payment rate using the 2016 LTCH standard Federal payment rate payment cases used for the proposed rule. These estimates were based upon the most recently available data (the December 2016 update of the FY 2016 MedPAR file), and consistent with historical practice, if more recent data become available, we proposed to use such data for the final rule.

Comment: A few commenters, including MedPAC, supported the proposal to implement changes to the SSO payment adjustment by including a budget neutrality factor to the FY 2018 LTCH PPS standard Federal payment rate. Several other commenters urged CMS to implement these changes without a budget neutrality adjustment in light of various other changes to Medicare payment policies relating to LTCHs, such as the decrease in payments to site neutral payment rate cases resulting from the end of the blended payment rate provided under the statute. Many commenters objected to making the proposed changes to the SSO payment methodology (which, if finalized, would increase payments) budget neutral on the grounds that previous revisions to the SSO payment adjustment resulted in a net decrease in aggregate LTCH PPS payments and were not made budget neutral. Other commenters urged CMS to apply this factor in FY 2018 but not make it permanent. Commenters generally supported the proposal to include behavioral impact estimates in determining the budget neutral factor.

However, some commenters addressed the actuarial assumptions used in the proposal, which we discuss in greater detail below.

Response: We thank MedPAC and other commenters for their support of our proposal. In regard to those comments urging us to implement these changes without the budget neutral adjustment or only a temporary budget neutral adjustment, as we stated earlier and in the proposed rule, the goal of the proposed policy is to remove the incentive to delay patient discharges for payment reasons, not to increase aggregate Medicare LTCH PPS payments. While commenters are correct that previous changes to the SSO policy were not budget neutral, the proposed change to the SSO policy is being made for considerably different policy reasons than previous ones. In the past, we made changes to the SSO policy to ensure that LTCHs were paid appropriately for cases that were notably shorter than average. The proposed change in the SSO policy in the FY 2018 proposed rule was developed in response to LTCHs' apparent inappropriate behavior in delaying discharge in order to maximize Medicare payment. We see no reason why addressing the financial incentive for such behavior should result in increased payments to LTCHs. Therefore, we believe that it is wholly appropriate to make this change in a budget neutral manner. We further note that, under our proposed budget neutrality adjustment, the redistributional effects occur largely within individual LTCHs. As such, while individual hospitals will experience a difference in payment for individual discharges, they will not typically experience an overall reduction in aggregate payments for all of the LTCH's discharges due to this budget neutral change to the SSO policy. A temporary budget neutral adjustment would only maintain the level of aggregate payments for the period the budget neutrality adjustment is applied, thereby merely delaying the increase aggregate Medicare LTCH PPS payments until that adjustment is removed. Lastly, the purpose of the budget neutrality adjustment is not related to the statutory change in payments under the application of the site neutral payment rate and, therefore, does not provide sufficient explanation for implementing the proposed changes to the SSO policy without a budget neutrality adjustment.

After consideration of the public comments we received, we are finalizing our proposal, without modifications, to amend § 412.523(d) by adding a new paragraph (5), which will specify that the LTCH PPS standard Federal payment rate will be adjusted by a one-time, permanent factor that accounts for the projected change in estimated aggregate payments to LTCH PPS standard Federal payment rate cases in FY 2018 due to the change in the payment methodology for SSO cases described at § 412.529(c)(4). Moreover, we are finalizing our proposal to include behavioral impact estimates in determining the budget neutral factor.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20023 through 20026), we proposed to use a 3-step methodology (which contained substeps) to determine the budget neutrality factor that would be applied to the FY 2018 LTCH PPS standard Federal payment rate. The steps in our proposed methodology are summarized below.

Step 1—Simulate estimated aggregate FY 2018 LTCH PPS standard Federal payment rate payments using the existing SSO payment methodology at § 412.529(c)(3).

Step 2—Simulate estimated aggregate FY 2018 LTCH PPS standard Federal payment rate payments using the proposed SSO payment methodology at proposed § 412.529(c)(4), after accounting for expected changes in

LTCHs' discharge behavior, which is determined as follows in Step 2a through Step 2d.

Step 2a—Simulate estimated aggregate FY 2018 LTCH PPS standard Federal payment rate payments under the proposed SSO payment methodology without accounting for expected changes in LTCHs' discharge behavior.

Step 2b—Determine the estimated amount of aggregate FY 2018 LTCH PPS standard Federal payment rate payments that would reflect the projected decrease in non-SSO cases under the changes to the SSO policy.

Step 2c—Determine the estimated amount of aggregate FY 2018 LTCH PPS standard Federal payment rate payments that reflect the projected increase in SSO cases under the proposed changes to the SSO policy.

Step 2d—Adjust the original estimated unadjusted FY 2018 payments under the proposed SSO payment methodology (from Step 2a) to account for the projected decrease in non-SSO cases under the proposed changes to the SSO policy (by subtracting the amount determined in Step 2b) and for the projected increase in SSO cases under the proposed changes to the SSO policy (by adding the amount estimated in Step 2c).

Step 3—Calculate the ratio of the estimated aggregate FY 2018 LTCH PPS standard Federal payment rate payments under the existing and proposed SSO policies to determine the adjustment factor that would need to be applied to the proposed FY 2018 LTCH PPS standard Federal payment rate to achieve budget neutrality (that is, where the estimated aggregate payments calculated in Step 2 are estimated to be equal to the estimated aggregate payments calculated in Step 1). A discussion and supporting details for the assumptions for expected changes in LTCHs' discharge behavior used in Step 2 are provided below. (A complete discussion of our proposed budget neutrality methodology, which we are finalizing without modification as discussed more fully below, can be found in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20023 through 20026).)

Specifically, in the proposed rule (82 FR 20024 through 20025), we discussed the actuarial assumptions for shifts in cases used under Steps 2b and 2c in our proposed methodology for determining the budget neutrality factor or the proposed changes to the SSO payment methodology. As explained in the proposed rule, our actuarial assumptions for LTCHs' discharge behavior under our proposed SSO policy were estimated based on a comparative analysis of distributions of LTCH discharges relative to the SSO thresholds in FY 2003 and FY 2015 using data from FY 2002 (the year before the LTCH PPS was implemented and the final year prior to a SSO payment adjustment) to LTCH discharges in FY 2015 (the most recent complete year of data available at the time the comparative analysis was performed in preparation for the proposed rule). (We note that, for FY 2002, because there was no applicable SSO threshold, we used the SSO thresholds from FY 2003 (LTC–DRG Version 23) based on the billed LTC–DRG (LTC–DRG Version 22) on the FY 2002 claim.)

The FY 2002 distribution shows a nearly continuous distribution of LTCH discharges relative to what would become the SSO threshold in FY 2003, and approximate symmetry before and after the SSO threshold. In other words, for FY 2002, the distribution of discharges just after what would become the FY 2003 threshold looks similar to the distribution of discharges just before that threshold, and there is a corresponding similarity between discharges well after and well before what would become the SSO threshold.

While the FY 2015 distribution of LTCH discharges relative to the SSO threshold shows the same symmetry among discharges well before and well after the threshold, there are significantly fewer discharges just before the SSO threshold and significantly more discharges just after the SSO threshold (instead of a symmetry among discharges just before and just after the SSO threshold). For FY 2015, this lack of symmetry is concentrated in the 3 days leading up to the SSO threshold. (We note that, in our analysis of LTCH discharge patterns relative to the applicable SSO threshold, we found similar patterns for FYs 2003 through 2014 as those observed for FY 2015, as well as for FY 2016 LTCH discharges.)

In particular, the FY 2015 LTCH discharges have, as a proportion of total FY 2015 LTCH discharges, approximately 20 percent more discharges occurring just after the SSO threshold when compared to FY 2002 discharges. However, due to other substantial changes in Medicare payments to LTCHs, including the introduction of the LTCH PPS in FY 2003, we stated that we do not believe the entire 20-percent shift in discharges is attributable to only the introduction and subsequent revisions to the LTCH PPS SSO payment adjustment. Moreover, this shift is not uniform across all SSO discharges because the majority of shifting past the SSO threshold occurs within 3 days of the SSO threshold. Based on this, we stated that our actuaries estimate that the elimination of the payment cliff would result in a 10-percent reduction in non-SSO cases, so that SSO cases increase at the same level as the projected decrease in non-SSO cases. For these non-SSO cases that shift, we stated that our actuaries estimate the discharges to occur within 3 days prior to the SSO threshold based on the analysis of LTCH discharge patterns relative to the applicable SSO threshold described earlier.

Comment: Several commenters advocated for a smaller budget neutrality reduction, with many commenters urging CMS to reconsider the actuarial assumptions used to arrive at the 10 percent behavioral shift as they believed this shift should be higher. A few commenters considered CMS' 10 percent behavioral shift to be arbitrary, and some commenters urged CMS to consider 15 percent to 20 percent or higher. Among those urging CMS to consider 15 percent to 20 percent, a few commenters pointed to a working paper [98] that they believed supports a 15-percent behavioral shift, while other commenters referred to analysis by KNG Health Consulting on behalf of the National Association of Long Term Hospitals (NALTH) that shows LTCHs can shift 20 percent or more of non-SSO cases to below the SSO threshold and still meet the greater than 25-day average length of stay requirement. Other commenters, based on comparisons of historic LTCH discharge rates, suggested that CMS consider LTCH cases discharged within 6 days of the threshold, thereby increasing the expected shift beyond the 10 percent estimated by our actuaries. One commenter stated that its internal modeling suggested the budget neutrality adjustment should be 2.7 percent instead of the approximately 3.3 percent reduction in the proposed rule.

Response: We reviewed all the supporting material and studies submitted or referenced by commenters. We note that we do not have sufficient information to evaluate the individual commenter's claim that the budget neutrality adjustment should be 2.7 percent. However, we note that an adjustment of this magnitude is in line with what we estimate the budget neutrality adjustment would be under our proposed methodology if we were to

[98] Paul J. Eliason, et al. Strategic Patient Discharge: The Case of Long-Term Care Hospitals. National Bureau of Economic Research. NBER Working Paper 22958. Available at: *http://www.nber.org/papers/w22598.pdf.*

use an assumption of a behavioral shift in the 15 to 20 percent range as suggested by other commenters.

As stated in the proposed rule and earlier in this final rule, while we observed a shift of 20 percent in non-SSO cases from FY 2002 to FY 2015, the introduction of various payment policies in the intervening years does not support attributing the full 20 percent to the SSO payment policy alone, and thus, our actuarial assumption of 10 percent is based upon consideration of the impact such changes have had over the years. Similarly, we do not believe it is appropriate to further extend our analysis based on a 3-day window to a 6-day window because we do not have any rationale or evidence to attribute the FY 2002 to FY 2015 change in discharges 6 days past the threshold to the SSO policy. In this case, particularly, we do not believe cases more than 3 days past the threshold represent a response to financial incentives because each day past the threshold a patient remains in the LTCH represents a negative response to these financial incentives: each day a patient is held beyond the threshold increases the provider's costs without the opportunity to increase the full MS–LTC–DRG payment. In other words, there are diminishing returns the longer a discharge is delayed for financial reasons.

After consideration of the public comments and supporting documents we received, we believe the available data and supporting studies are consistent with our actuarial assumption of a 10-percent behavioral shift. As noted by commenters, the KNG Health Consulting study only shows that increasing the shift to 20 percent is feasible in light of the greater than 25 average length of stay requirement for LTCHs. In other words, this finding establishes a ceiling for the behavioral shift, but it does not establish a lower bound nor does it point to an appropriate or expected shift resulting from the proposed changes to the SSO policy. Therefore, this analysis is consistent with a shift of up to 20 percent, which includes our actuarial assumption of a 10-percent shift.

While commenters pointed to the working paper as evidence for increasing our assumption of the shift in LTCH cases to 15 percent, we note the working paper is not addressing the same issue. The study examines the influence of financial incentives on LTCHs' discharges in order to compare the effectiveness various SSO payment policies have on this incentive by building a model incorporating financial incentives of a selected category of LTCH discharges. Specifically, as noted in the paper, the study assesses the impact of various SSO payment policies on nine selected MS–LTC–DRGs (177, 189, 190, 193, 207, 539, 592, 871, and 949) and among these DRGs, only those LTCH patients discharged to home or a nursing facility as ''these are the discharges for which hospitals have the most discretion.'' (Paul J. Eliason, et al., p. 18.) The 15 percent cited by commenters represents the proportion of change in modeled non-SSO discharges, limited to these select cases, from our current SSO payment policy (their baseline) to a per diem SSO payment policy among these selected cases. As noted above, the paper presumes their selected category of cases are the LTCH cases most likely to be held, and thus, much like the average length of stay analysis discussed above, the 15 percent cited by commenters, as with the analysis by KNG Health Consulting, represents a ceiling on the behavioral shift and is not inconsistent with our actuarial assumption of 10 percent, which is representative of all MS–LTC–DRGs and cases.

After consideration of the public comments we received, for the reasons presented above, we are finalizing our proposed methodology for computing the budget neutrality factor, including the 10 percent actuarial assumption in steps 2b and 2c, without modification.

Based on the claims data used for the proposed rule, we estimated that our proposed change to the SSO payment methodology would result in an increase in payments of approximately $102 million (that is, the $3.177 billion as calculated in Step 1 in the proposed rule minus the $3.279 billion as calculated in Step 2 in the proposed rule) which reflected the approximate $43 million decrease that accounts for our actuarial assumptions for expected changes in LTCHs' discharge behavior under the proposed changes to the SSO policy. For the proposed rule, using the steps in the proposed methodology, we then determined a proposed budget neutrality factor for the proposed change to the SSO payment methodology of 0.9672. Accordingly, in section V.A. of the Addendum to the proposed rule, to determine the proposed FY 2018 LTCH PPS standard Federal payment rate, we proposed to apply a one-time, permanent budget neutrality factor of 0.9672 for the proposed change in the SSO payment methodology (82 FR 20025 through 20026).

For this final rule, as we proposed, we are using the most recent available data (that is, FY 2016 LTCH standard Federal payment rate payment cases from the March 2017 update of the FY 2016 MedPAR file) to determine the budget neutrality factor applied to the FY 2018 LTCH PPS standard Federal payment rate to ensure that the change to the SSO payment methodology in FY 2018 does not affect aggregate LTCH PPS payments. Based upon the most recent data, and discussed in greater detail below, we are applying a one-time, permanent budget neutrality factor of 0.9651 under new § 412.523(d)(5) for the change in the SSO payment methodology at new § 412.529(c)(4).

Specifically, the methodology summarized above and outlined in the proposed rule (82 FR 20025 through 20026) applied to the best available data used for this final rule yields the following results. We estimate that our change to the SSO payment methodology results in an increase in payments of approximately $112 million (that is, the $3.204 billion as calculated in Step 1 using data for this final rule minus the $3.316 billion as calculated in Step 2 using data for this final rule) which reflects the approximate $40 million decrease that accounts for our actuarial assumptions for expected changes in LTCHs' discharge behavior under the changes to the SSO policy. Therefore, for this final rule, using the steps in the methodology outlined in the proposed rule and using the most recently updated data, we have determined a budget neutrality factor for the change to the SSO payment methodology of 0.9651. Accordingly, in section V.A. of the Addendum to this final rule, to determine the FY 2018 LTCH PPS standard Federal payment rate, we are finalizing the application of a one-time, permanent budget neutrality factor of 0.9651 for the change in the SSO payment methodology.

E. Temporary Exception to the Site Neutral Payment Rate for Certain Spinal Cord Specialty Hospitals

Section 15009 of Public Law 114–255 added new subparagraph (F) to section 1886(m)(6) of the Act, which provides for a temporary exception to the site neutral payment rate for certain spinal cord specialty hospitals. Under this provision, discharges occurring in cost reporting periods beginning during FY 2018 and FY 2019 for LTCHs that meet the specified statutory criteria are excepted from the site neutral payment rate (that is, all discharges from such LTCHs during this period would be paid at the LTCH PPS standard Federal payment rate). Clauses (i) through (iii) of section 1886(m)(6)(F) of the Act state that, in order for an LTCH to qualify for this temporary exception, the LTCH

must: (1) Have been a not-for-profit LTCH on June 1, 2014, as determined by cost report data; (2) of the discharges in calendar year 2013 from the LTCH for which payment was made under the LTCH PPS, at least 50 percent were classified under MS–LTC–DRGs 28, 29, 52, 57, 551, 573, and 963; and (3) have discharged inpatients (including both individuals entitled to, or enrolled for, Medicare Part A benefits and individuals not so entitled or enrolled) during FY 2014 who had been admitted from at least 20 of the 50 States, determined by the States of residency of such inpatients and based on such data submitted by the hospital to the Secretary as the Secretary may require. The statute further provides authority for the Secretary to implement the third criterion (set forth at section 1886(m)(6)(F)(iii) of the Act and referred to as the ''significant out-of-state admissions criterion'') by program instruction or otherwise, and exempts the policy initiatives from any information collection requirements under the Paperwork Reduction Act (Chapter 35 of Title 44 of the United States Code). Given this express authority, as we stated in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20026), we plan to provide further details regarding the implementation of the significant out-of-state admissions criterion through subregulatory guidance. However, in the proposed rule, we proposed to codify the requirements of the temporary exception to the site neutral payment rate for certain spinal cord specialty hospitals specified under section 1886(m)(6)(F) of the Act, as added by section 15009 of Public Law 114–255. Specifically, we proposed to codify the requirements of this provision at new § 412.522(b)(4), by providing for an exception from the site neutral payment rate for discharges occurring in cost reporting periods beginning during FYs 2018 and 2019 for LTCHs that meet the specified statutory criteria.

We sought public comments on this proposal. Based on information currently available, we believe that two hospitals may qualify for this exception.

Comment: Several commenters supported CMS' proposals to implement section 15009 of the 21st Century Cures Act.

Response: We thank these commenters for their support.

After consideration of the public comments we received, we are finalizing our proposals without modification.

F. Temporary Exception to the Site Neutral Payment Rate for Certain Discharges With Severe Wounds From Certain LTCHs

Section 15010 of Public Law 114–255 added a new subparagraph (G) to section 1886(m)(6) of the Act, which creates a temporary exception to the site neutral payment rate for certain severe wound discharges from certain LTCHs during such LTCHs' cost reporting periods beginning during FY 2018 (that is, for cost reporting period beginning on or after October 1, 2017 and on or before September 30, 2018). Under the provisions of section 15010 of Public Law 114–255, in order for an LTCH's discharge to be excluded from the site neutral payment rate under this exception during its FY 2018 cost reporting period, the discharge must be: (1) From an LTCH ''identified by the last sentence of subsection (d)(1)(B)'' of the Act; (2) classified under MS–LTC–DRG 602, 603, 539, or 540; and (3) with respect to an individual treated by an LTCH, for a severe wound. The statute defines a ''severe wound,'' for the purposes of the exception, as ''a wound which is a stage 3 wound, stage 4 wound, unstageable wound, non-healing surgical wound, or fistula as identified in the claim from the long-term care hospital.'' The statute further defines a ''wound'' as ''an injury involving division of tissue or rupture of the integument or mucous membrane with exposure to the external environment.''

Much of this language is identical or substantially similar to the language for the previous temporary exception for discharges for the treatment of severe wounds provided for under the amendments made by section 231 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113), except for three key differences. First, the previous temporary exception for severe wound discharges applied to LTCHs that are grandfathered hospitals-within-hospitals (HwHs) (that is, hospitals that are described under § 412.23(e)(2)(i) that meet the criteria of § 412.22(f)) and are located in a rural area or treated as rural (§ 412.522(b)(2)(ii)(B)), while the new temporary exception for severe wound discharges only requires that LTCHs are grandfathered HwHs (and does not require the LTCH to also be located in a rural area or treated as rural). Second, under this new temporary exception for severe wound discharges, the definition of a ''severe wound'' includes only five of the eight categories (stage 3 wound, stage 4 wound, unstageable wound, non-healing surgical wound, and fistula) included in the definition of a ''severe wound'' under the original temporary exception for severe wound discharges (and does not include the categories of infected wound, osteomyelitis, and wound with morbid obesity). Finally, this new temporary exception for severe wound discharges is limited to discharges that meet the definition of a severe wound and are grouped to certain specified MS–LTC–DRGs, while the previous temporary exception for severe wound discharges only required the discharge to meet the definition of a severe wound (and did not include the requirement for the discharge to also be grouped to certain specified MS–LTC–DRGs). Additional details of the new temporary exception for payment for severe wound discharges provided by Public Law 114–255, including further discussion of the likenesses to and differences from the original temporary exception for payment for severe wound discharges provided by Public Law 114–113 are discussed below.

We implemented the original temporary exception for payment for discharges for the treatment of severe wounds that was provided by the amendments made by section 231 of Public Law 114–113 in an interim final rule with comment period (IFC) that appeared in the **Federal Register** on April 21, 2016 (81 FR 23428 through 23438) (referred to as the ''April 21, 2016 IFC'') and finalized our FY 2017 proposed rule and that IFC concurrently in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57070). Therefore, to the extent applicable, we are implementing the temporary exception provision in an identical manner to our implementation of the original temporary exception under section 231 of Pub. 114–113, which is codified in the LTCH PPS regulations at § 412.522(b)(2). Specifically, § 412.522(b)(2)(ii)(B)(1) refers to LTCHs ''identified by the last sentence of subsection (d)(1)(B)'' of the Act as LTCHs ''[d]escribed in § 412.23(e)(2)(i) and meets the criteria of § 412.22(f).'' In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20026), we proposed to codify the requirements of this ''new'' temporary exception for severe wounds at new § 412.522(b)(3), by providing for an exception for discharges meeting the statutory criteria that occur in a cost reporting period that begins during FY 2018 for LTCHs described in § 412.23(e)(2)(i) and meet the criteria of § 412.22(f).

Clauses (ii) and (iii) of section 1886(m)(6)(G) of the Act, respectively, as added by section 15010 of Public Law 114–255, includes definitions of ''severe wound'' and ''wound'' for purposes of this ''new'' temporary exception for discharges for the treatment of severe

wounds. We proposed to incorporate the definitions of ''wound'' and ''severe wound'' at § 412.522(b)(3)(i) as they are defined in the statute. We note that the definition of a ''wound'' in section 15010 is nearly identical to CMS' definition of ''wound'' at existing § 412.522(b)(2)(i). We further note that the definition of a ''severe wound'' is nearly identical to the definition used in section 231 of Public Law 114–113 with the exception that three categories included in the latter (that is, infected wound, osteomyelitis, and wound with morbid obesity) are not included in the definition set forth in section 15010 of Public Law 114–255. The five remaining categories of stage 3 wound, stage 4 wound, unstageable wound, non-healing surgical wound, and fistula are identified by the list of ICD–10–CM codes posted to the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/download.html* under the ''Severe Wound Diagnosis Codes by Category for Implementation of Section 231 of Public Law 114–113'' download file. For more information on our interpretation of these terms, we refer readers to the April 21, 2016 IFC (81 FR 23428 through 23438) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57070). Therefore, this information on how CMS interpreted the meanings of these categories of a ''severe wound'' for Public Law 114–113 was available at the time Public Law 114–255 was enacted. As such, we are implementing the ''new'' temporary exception for discharges for the treatment of severe wounds provided for by section 15010 using the same list of ICD–10–CM codes to identify the five categories of severe wounds enumerated in that section of Public Law 114–255. In addition, as provided by section 1886(m)(6)(G)(i)(III) of the Act as added by section 15010 of Public Law 114–255, we proposed at new § 412.522(b)(3)(ii) that the patient must be treated for a severe wound that meets the statutory definition of a ''severe wound'' at proposed § 412.522(b)(3)(i) in order for the LTCH discharge to meet this ''new'' temporary exception for discharges for the treatment of severe wounds.

As we stated in the proposed rule, we believe that the requirement under the ''new'' temporary exception for discharges for the treatment of severe wounds set forth under section 1886(m)(6)(G)(i)(II) of the Act as added by section 15010 of Public Law 114–255 for an LTCH discharge be classified under MS–LTC–DRG 602, 603, 539, or 540 is self-implementing. Accordingly, we proposed to codify this requirement at new § 412.522(b)(3)(ii)(C) by listing the applicable MS–LTC–DRGs.

Section 1886(m)(6)(G)(i)(I) of the Act, as added by section 15010 of Public Law 114–255, specifies that, for purposes of this ''new'' temporary exception for discharges for the treatment of severe wounds, the LTCH discharge must be from an LTCH ''identified by the last sentence of subsection (d)(1)(B)''. The phrase ''identified by the last sentence of subsection (d)(1)(B) [of the Act]'' is equivalent to the phrase ''identified by the amendment made by section 4417(a) of the Balanced Budget Act of 1997'' used in section 231 of Public Law 114–113, because the amendment made by section 4417(a) of the Balanced Budget Act of 1997 added the last sentence of subsection (d)(1)(B) to the Act. As discussed in the April 21, 2016 IFC (81 FR 23428), the phrase ''identified by the amendment made by section 4417(a) of the Balanced Budget Act of 1997'' (which as previously discussed is equivalent to ''identified by the last sentence of subsection (d)(1)(B) of the Act'') has been interpreted by CMS to mean hospitals-within-hospitals (HwHs) that were participating in Medicare, but excluded from the hospital IPPS on or before September 30, 1995 (that is, hospitals which are described under § 412.23(e)(2)(i)) that meet the criteria of § 412.22(f) (81 FR 23430 through 23432). As further discussed in the April 21, 2016 IFC, § 412.22(f) generally requires that, in order to have grandfathered status, an HwH must continue to operate under the same terms and conditions, including, but not limited to, the number of beds. A limited exception to this general policy allowed eligible hospitals to increase the number of beds between October 1, 1995, and September 30, 2003, without loss of their grandfathered status. A second exception allows grandfathered HwHs to increase square footage or decrease the number of beds for cost reporting periods beginning on or after October 1, 2006, while still retaining grandfathered status. Because this phrase had already been interpreted in this manner, the April 21, 2016 IFC adopted the same meaning of the phrase for purposes of implementing section 231 of Public Law 114–113. For additional information on hospitals ''identified by the amendment made by section 4417(a) of the Balanced Budget Act of 1997,'' we refer readers to the April 21, 2016 IFC (81 FR 23431 through 23432). Therefore, for the purposes of the new temporary exception for LTCH discharges for the treatment of severe wounds, ''identified by the last sentence of subsection (d)(1)(B) of the Act'' means HwHs that were participating in Medicare, but excluded from the hospital IPPS on or before September 30, 1995 (that is, hospitals which are described under § 412.23(e)(2)(i)) that meet the criteria of § 412.22(f). We finalized this policy without modification in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57069). Because we have already finalized our interpretation of this phrase, we believe that the requirement at section 1886(m)(6)(G)(i)(I) of the Act is self-implementing. Accordingly, we proposed to codify this requirement at new § 412.522(b)(3)(ii)(B). LTCHs that believe they meet the requirements to be a grandfathered HwH should contact their MACs. MACs will verify that the LTCH meets these requirements.

Comment: Several commenters supported CMS' proposals to implement section 15010 of the 21st Century Cures Act.

Response: We thank the commenters for their support.

Comment: Some commenters requested that CMS expand the scope of the exception to allow additional LTCHs to benefit from the provision. Other commenters requested that CMS exclude severe wound discharges from the site neutral payment rate all together or to otherwise broaden the scope of cases excepted from the site neutral payment rate.

Response: As we have stated in response to substantially similar comments in the past (80 FR 49602), under the LTCH PPS we do not have the authority to pay anything other than the site neutral payment rate for any LTCH discharge that does not meet the exclusion criteria. The statute explicitly established the dual payment rate structure, which expressly provides that payment for all LTCH discharges will be calculated based on the site neutral payment rate, unless the LTCH discharge meets the statutorily defined exclusion criteria to be paid based on the LTCH PPS standard Federal payment rate.

After consideration of the public comments we received, we are finalizing our proposals without modification.

G. Moratorium and Regulatory Delay of the Full Implementation of the ''25-Percent Threshold Policy'' Adjustment (§ 412.538)

The ''25-percent threshold policy'' is a per discharge payment adjustment in the LTCH PPS that is applied to payments for Medicare patient discharges from an LTCH when the number of such patients originating from any single referring hospital is in

excess of the applicable threshold for a given cost reporting period (such threshold is generally set at 25 percent, with exceptions for rural and urban single or MSA-dominant hospitals). If an LTCH exceeds the applicable threshold during a cost reporting period, payment for the discharge that puts the LTCH over its threshold and all discharges subsequent to that discharge in the cost reporting period from the referring hospital are adjusted at cost report settlement (discharges not in excess of the threshold are unaffected by the 25-percent threshold policy). The 25-percent threshold policy was originally established in the FY 2005 IPPS final rule for LTCH HwHs and satellites (69 FR 49191 through 49214). We later expanded the 25-percent threshold policy in the RY 2008 LTCH PPS final rule to include all LTCHs and LTCH satellite facilities (72 FR 26919 through 26944). Several laws have mandated delayed implementation of the policy, including, most recently, section 1206 of the Pathway for Sustainable Growth Rate (SGR) Reform Act (Pub. L. 113–67). Section 1206(b)(1)(B) provides a permanent exemption from the application of the 25-percent threshold policy for LTCHs identified by the amendment made by section 4417(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33). As explained more fully in section VIII.H. of the preamble of this final rule, LTCHs ''identified by the amendment made by section 4417(a) of the Balanced Budget Act of 1997'' are HwHs that were participating in Medicare, but excluded from the hospital IPPS on or before September 30, 1995 (that is, hospitals which are described under § 412.23(e)(2)(i)) that meet the criteria of § 412.22(f). LTCHs that believe they meet the requirements to be a grandfathered HwH should contact their MACs. MACs will verify that the LTCH meets these requirements. Section 1206(b)(1)(A) of Public Law 113–67 extended prior moratoria on the full implementation of the 25-percent threshold policy until cost reporting periods beginning on or after either July 1, 2016 (for LTCHs subject to 42 CFR 412.534) or October 1, 2016 (for LTCHs subject to 42 CFR 412.536). For more details on the various laws that delayed the full implementation of the 25-percent threshold policy, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50356 through 50357). In the FY 2017 IPPS/LTCH PPS final rule, we consolidated the 25-percent threshold policy by sunsetting §§ 412.534 and 412.536 and establishing provisions under new § 412.538.

Section 15006 of Public Law 114–255 further amended section 114(c)(1)(A) of the MMSEA (as amended) by striking ''for a 9-year period'' and inserting ''through June 30, 2016, and for discharges occurring on or after October 1, 2016 and before October 1, 2017'', which provides for an extension of the moratorium on the full implementation of the 25-percent threshold policy. In addition, section 15006(b) of Public Law 114–255 further amended section 114(c)(2) of the MMSEA (as amended) by inserting ''or any similar provision,'' after ''Regulations,'' in subparagraphs (A) and (B). (We note that the functional result of the extension of the moratorium under section 15006(a) of Public Law 114–255 only extends to discharges on or after October 1, 2016 and before October 1, 2017.)

To implement the provisions of section 15006 of Public Law 114–255, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20028), we proposed to make conforming amendments to the regulations that currently govern the application of the 25-percent threshold policy. Section 114(c)(1) of the MMSEA, from its inception, precluded CMS from implementing either §§ 412.534 or 412.536 (as applicable), as well as any similar provision to hospitals described in the provision of the MMSEA. Section 15006 of Public Law 114–255 amended section 114(c)(2) of the MMSEA by adding the words ''or any similar provisions'' to both (A) and (B). Section 412.538 of the regulations is a similar provision to the provisions of both §§ 412.534 and 412.536 (we adopted the payment policy under § 412.538 to create a consolidated and streamlined 25-percent threshold policy to replace the policies under §§ 412.534 and 412.536, which were sunset).

Therefore, in order to implement the moratorium on the implementation of the 25-percent threshold policy provided under section 15006 of Public Law 114–255, we proposed to amend § 412.538 to account for these statutory changes. We note that, similar to the July 1, 2012 through September 30, 2012 ''gap'' period discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53484 through 53486), this extension of the moratorium on the full application of the 25-percent threshold policy results in a ''gap'' period where LTCHs are required to comply with the fully-implemented 25-percent threshold policy for their cost reporting periods beginning on or after July 1, 2016, and before October 1, 2016, for any discharges occurring on or before September 30, 2016. For the same reasons discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53485 through 53486), although those LTCHs with cost reporting periods beginning on or after July 1 and before October 1 2016 are ''technically'' subject to the 25-percent threshold policy until October 1, 2016, we believe that very few, if any, LTCHs will actually receive a payment adjustment because these LTCHs would rarely, if ever, admit more than 25 percent of their discharges from any one referring hospital during the limited period of 1 to 3 months (depending on the LTCH's cost reporting beginning date) that the 25-percent threshold policy was technically in effect.)

Comment: Several commenters supported CMS' proposals to implement section 15006 of the 21st Century Cures Act.

Response: We thank these commenters for their support.

After consideration of the public comments we received, we are finalizing our proposals without modification.

In addition, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20028), we proposed to adopt a 1-year regulatory moratorium on the implementation of the 25-percent threshold policy; that is, we proposed to impose a regulatory moratorium on our implementation of § 412.538 until October 1, 2018. This proposal was made in response to the further statutory delays and our continued consideration of public comments received in response to our proposal to consolidate and streamline the 25-percent threshold policy in the FY 2017 IPPS/LTCH PPS proposed rule. In response to that proposed rule, several commenters stated that the new site neutral payment rate would alleviate the policy concerns underlying the 25-percent threshold policy. As we stated in more detail in our response to those comments in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57106), we are not convinced that this is the case.

However, given this additional statutory moratorium, we believe that it was appropriate at that time to propose to establish a regulatory moratorium on the implementation of the 25-percent threshold policy until we can examine data under the application of the site neutral payment rate to further evaluate, when more data are available, whether the policy is in fact still necessary. We stated in the proposed rule that while we are not convinced that the application of the site neutral payment rate removes the need for the 25-percent threshold policy, we believe that evaluating the impact of the application of the site neutral payment rate on LTCH admission practices would be premature at that time. The statute

provides that the site neutral payment rate be phased in, effective with LTCH cost reporting periods beginning on or after October 1, 2015 and before October 1, 2017 (that is, LTCH cost reporting periods beginning in FYs 2016 and 2017). LTCH claims data for discharges that occurred in FY 2016 is currently the best available data, and given that phase-in of the site neutral payment rate is based on LTCHs' cost reporting period start dates, many LTCH discharges that occurred during FY 2016 were not yet subject to the site neutral payment rate because they occurred in a LTCH cost reporting period that had begun prior to October 1, 2016. Consequently, at the time of the proposed rule, we only had a partial year of LTCH claims data under the period where the site neural payment rate was in effect, which may not be fully reflective of any changes in LTCH admission practices under the new dual rate LTCH PPS. We stated in the proposed rule that proposing an additional regulatory moratorium on the 25-percent threshold policy through FY 2018 would allow CMS the opportunity to do an analysis of LTCH admission practices under the new dual payment rate LTCH PPS based on more complete data and would avoid creating any additional confusion by having the 25-percent threshold policy become effective for a period of time when future analysis of LTCH claims data may indicate the policy concerns underlying the 25-percent threshold policy have been moderated.

Therefore, in the proposed rule, we proposed to revise the effective date of § 412.538 so that the 25-percent threshold policy would apply to discharges occurring on or after October 1, 2018. Further, we proposed that if, in response to public comments, we did not finalize this proposed additional 1-year regulatory moratorium, we would revise § 412.538 so that the 25-percent threshold policy would apply to discharges occurring on or after October 1, 2017, consistent with the provisions of section 15006 of Public Law 114–255. We sought public comments on our proposals.

Comment: Several commenters supported CMS' proposal for an additional 1-year regulatory delay in the full application of the 25-percent threshold policy. In addition, several commenters requested that, in lieu of or in addition to the additional 1-year regulatory delay in the full application of the 25-percent threshold policy, CMS rescind the policy. Some of these commenters also requested that CMS make public its analysis about whether the policy continues to be necessary. MedPAC opposed the proposed additional 1-year delay in the full application of the 25-percent threshold policy.

Response: We thank commenters for their support of the proposed additional 1-year regulatory delay of the 25-percent threshold policy for FY 2018. As we explained in both the FY 2016 and FY 2017 rulemaking cycles, and reiterated in the proposed rule, we are not convinced that recent revisions to the LTCH PPS (for example the introduction of the site-neutral payment rate) have addressed the policy concerns which caused us to adopt the policy. We believe that the 1-year delay will allow both CMS and providers to gain additional experience with the site neutral payment rate and allow us to determine whether the policy is still necessary. For this reason, although we understand MedPAC's concerns, we believe that we should have additional experience under the revised LTCH PPS prior to the policy becoming effective in order to ensure it is still necessary and appropriate. We note that if we undertake further rulemaking on this topic, we will, in accordance with the APA, publically note our reasons for any potential proposed changes.

After consideration of the public comments we received, we are finalizing the proposal for an additional 1-year regulatory delay of the 25-percent threshold policy for FY 2018 without modification.

Comment: Some commenters requested confirmation that the regulations at §§ 412.534 and 412.536 would not apply until October 1, 2018 and that the 25-percent threshold policy would not apply during the ''gap'' period between July 1, 2016 and October 1, 2016 for certain locations of certain hospitals.

Response: In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57102), we sunsetted both §§ 412.534 and 536 and replaced them with the unified 25-percent threshold policy at § 412.538. Under the unified policy, regardless of any statutory or regulatory moratorium on § 412.538, by the terms of § 412.534 and 536 themselves, hospitals are no longer subject to them. As discussed above, we are finalizing our proposal of an additional 1-year regulatory delay of the 25-percent threshold policy for FY 2018. As such, we confirm that, under our finalized changes to the regulations, no hospital will be subject to § 412.538 until discharges occurring on or after October 1, 2018. The commenters are incorrect that we proposed not to apply the 25-percent threshold policy during the ''gap'' period. However, as we stated in the proposed rule, we do not believe that there will be any practical effect of the application of the policy. The 25-percent threshold policy (under §§ 412.434, 412.536, and 412.538) is calculated based on a hospital's entire cost reporting period, which is generally a full calendar year (12 months). In order for a hospital to have any payment reduction during the ''gap'' period (which would only apply to discharges occurring before October 1, 2016 in cost reporting periods beginning on or after July 1, 2016) the hospital must exceed the 25-percent threshold with respect to a referring hospital within (at most) a 3-month period.

H. Revision To Moratorium on Increasing Beds in Existing LTCH or LTCH Satellite Locations Under the 21st Century Cures Act (Pub. L. 114–255) (§ 412.23)

Section 1206(b)(2) of Public Law 113–67, as amended by section 112(b) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93), established ''new'' statutory moratoria on the establishment of new LTCHs and LTCH satellite facilities and on the increase in the number of hospital beds in existing LTCHs and LTCH satellite facilities, effective April 1, 2014 through September 30, 2017, by amending section 114(d)(1) of the MMSEA (as amended). In addition, the statute also provided an exception under the ''new'' moratorium under section 114(d)(7) of the MMSEA (as amended) to establish a new LTCH or LTCH satellite facility during the period between April 1, 2014, and September 30, 2017, if a hospital or entity meets criteria, which mirror the expired provisions of section 114(d)(2)(A). For a discussion on our implementation of these moratoria, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50189 through 50193).

Section 15004(a) of Public Law 114–255 further amended section 114(d)(7) of the MMSEA (as amended) by striking ''The moratorium under paragraph (1)(A)'' and inserting ''[a]ny moratorium under paragraph (1)'' and specified that such amendment shall take effect as if included in the enactment of section 112 of the PAMA. Under this amendment, all existing LTCHs or LTCH satellite locations are no longer subject to a moratorium on an increase in LTCH beds set forth in paragraph (1)(B) if they meet certain criteria. In order to implement this statutory change, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20029), we proposed to amend § 412.23(e)(7) by revising paragraph (e)(7)(iii) to specify that the moratorium on increasing the number of beds in existing LTCHs and

existing LTCH satellites does not apply if one or more or the exceptions described in § 412.23(e)(6)(ii) is met in accordance with the provisions of section 15004(a) of Public Law 114–255. (We note that section 15004(b) of Public Law 114–255 provides for a modification to LTCH high-cost outlier payments. Our proposals to implement this provision were discussed in section V.D. of the Addendum to the proposed rule.) We sought public comments on this proposal.

Comment: Several commenters supported CMS' proposal to implement section 15004(a) of the 21st Century Cures Act.

Response: We thank these commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to amend § 412.23(e)(7) by revising paragraph (e)(7)(iii) to specify that the moratorium on increasing the number of beds in existing LTCHs and existing LTCH satellites does not apply if one or more or the exceptions described in § 412.23(e)(6)(ii) is met in accordance with the provisions of section 15004(a) of Public Law 114–255.

I. Change To the Average Length of Stay Criterion Under the 21st Century Cures Act (Pub. L. 114–255)

Under the requirements at sections 1886(d)(1)(B)(iv)(I) and 1861(ccc) of the Act, in order for a hospital to be classified as an LTCH, the hospital has to maintain an average length of stay of greater than 25 days as calculated by the Secretary. Section 1206(a)(3) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) excluded Medicare Advantage plans' and site neutral payment rate discharges from this calculation for hospitals that were classified as LTCHs as of December 10, 2013. We implemented this provision in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49638). Section 15007 of Public Law 114–255 amended section 1206(a)(3) of the Pathway for SGR Reform Act by extending the exclusion of Medicare Advantage plans' and site neutral payment rate discharges from the calculation of the average length of stay to all LTCHs, for discharges occurring in cost reporting periods beginning on or after October 1, 2015. In order to implement this provision, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20029), we proposed to remove the final sentence of our regulations at 42 CFR 412.23(e)(2)(vi), which included site neutral payment rate and Medicare Advantage discharges in the calculation of the average length of stay for LTCHs which were classified as such after December 10, 2013. We sought public comments on our proposal.

Comment: Several commenters supported CMS' proposal to implement section 15007 of the 21st Century Cures Act.

Response: We thank these commenters for their support.

Comment: Several commenters requested that CMS remove the requirement for LTCHs to maintain a greater than 25 day average length of stay entirely, lower the requisite average length of stay, and/or make changes to the method of calculating the average length of stay.

Response: While we consider these comments outside the scope of this proposed rule, we note that the requirement that LTCHs maintain an average length of stay of greater than 25 days is required under section 1886(d)(1)(B)(iv) of the Act, and therefore we have no authority to either remove or reduce this requirement. We may consider the possibility of refining the method of calculating whether an LTCH has maintained the requisite average length of stay in future rulemaking.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to remove the final sentence of our regulations at 42 CFR 412.23(e)(2)(vi), which included site neutral payment rate and Medicare Advantage discharges in the calculation of the average length of stay for LTCHs which were classified as such after December 10, 2013.

J. Change in Medicare Classification for Certain Hospitals (§ 412.22)

When enacted, section 1886(d)(1)(B)(iv) of the Act established a category of hospitals that experience extended average inpatient length of stays, which are known as LTCHs under the Medicare program. Clause (iv) of section 1886(d)(1)(B) consisted of two subclauses (I) and (II) (that is, section 1886(d)(1)(B)(iv)(I) and section 1886(d)(1)(B)(iv)(II) of the Act) which corresponded to two categories of hospitals that were generally referred to as ''subclause (I)'' and ''subclause (II)'' LTCHs. ''Subclause (I)'' LTCHs were required to have an average inpatient length of stay that is greater than 25 days. ''Subclause (II)'' LTCHs were only required to have an average inpatient length of stay of greater than 20 days. The ''subclause (II)'' LTCH definition further limited the classification of a ''subclause (II)'' LTCH by including the requirement that the LTCH must have been first excluded from the IPPS in CY 1986, and treated a Medicare inpatient population in which 80 percent of the discharges in the 12-month reporting period ending in Federal FY 1997 had a principal diagnosis that reflected a finding of neoplastic disease as defined in subsection (f)(1)(iv) section 1886 of the Act. This statutory requirement was implemented under 42 CFR 412.23(e)(2)(ii).

As part of our FY 2015 IPPS/LTCH PPS rulemaking cycle, under the authority provided by section 1206(d)(2) of the Pathway to SGR Reform Act (Pub. L. 113–67), we adopted an adjustment to the LTCH PPS payment for LTCHs classified under section 1886(d)(1)(B)(iv)(II) of the Act (''subclause (II)'' LTCHs). Under this payment adjustment, ''subclause (II)'' LTCHs receive payment under the LTCH PPS that is generally equivalent to an amount determined under the reasonable cost-based payment rules for both operating and capital-related costs under 42 CFR part 413 (that is, an amount generally equivalent to an amount determined under the TEFRA payment system methodology). This payment adjustment for ''subclause (II)'' LTCHs is specified at § 412.526. For more information on this payment adjustment, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50193 through 50197). As initially adopted, the ''TEFRA-like'' reasonable cost-based payment adjustment for ''subclause (II)'' LTCHs did not incorporate the limitation on charges to Medicare beneficiaries policies under the TEFRA payment system. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57109 through 57110), we amended the regulations at § 412.507 relating to the limitation on charges to address beneficiary charges for LTCH services provided by ''subclause (II)'' LTCHs as part of our refinement of the payment adjustment for ''subclause (II)'' LTCHs under § 412.526. Under this refinement, ''subclause (II)'' LTCHs are treated the same as IPPS-excluded hospitals paid under the TEFRA payment system for purposes of the limitation on charges to beneficiaries and related billing requirements.

Section 15008 of Public Law 114–225 provides for a change in Medicare classification for ''subclause (II)'' LTCH by redesignating such hospitals from section 1886(d)(1)(B)(iv)(II) to section 1886(d)(1)(B)(vi) of the Act. In addition, subsection (b) of section 15008 specifies that, for cost reporting periods beginning on or after January 1, 2015, such hospitals classified under section 1886(d)(1)(B)(vi) of the Act are not subject to section 1886(m) of the Act, which sets forth the LTCH PPS. Section

15008 further specifies that, for cost reporting periods beginning on or after January 1, 2015, payment for inpatient operating costs is to be made as described in 42 CFR 412.526(c)(3), including any subsequent modifications, and payment for capital costs is to be made as described in 42 CFR 412.526(c)(4) as in effect on January 1, 2015. (We note that there have been no revisions to the regulations at 42 CFR 412.526, including § 412.526(c)(3) and § 412.526(c)(4), since January 1, 2015.)

In order to implement these requirements, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20029), we proposed to revise § 412.23(e)(2)(ii) so that the definition in that paragraph would apply to hospitals in cost reporting periods beginning on or after August 5, 1997 and on or before December 31, 2014. In addition, we proposed to add a new paragraph (j) to § 412.23 that would establish a new classification of IPPS-excluded hospital (formerly named ''long-term care neoplastic disease hospitals'' but renamed ''extended neoplastic disease care hospital'') that would identify hospitals classified under new section 1886(d)(1)(B)(vi) of the Act. Proposed new paragraph (j) would further specify in paragraph (j)(2) that payment for inpatient operating costs for these hospitals is made as described in § 412.526(c)(3) and payment for capital costs for these hospitals is made as described in § 412.526(c)(4). (We note that we did not propose to make changes to Subpart O by removing references to ''subclause (II) LTCHs'' due to the sunset date we proposed to add to § 412.23(e)(2)(ii).) We sought public comments on our proposal.

In section VII.A of the preamble of this final rule, we summarize and respond to the public comments on these proposals. In summary, as discussed in greater detail in section VII.A of this preamble, we are finalizing our proposal, without modification, to revise § 412.23(e)(2)(ii) so that the definition in that paragraph will apply to hospitals in cost reporting periods beginning on or after August 5, 1997 and on or before December 31, 2014; and in response to public comments we are making our changes to payment regulations at new paragraph (i) under § 412.22 (which is identical, with the exception of minor technical editing for cross-references, to the language we proposed at § 412.23(j)) that establishes a new classification of IPPS-excluded hospital (formerly termed ''long-term care neoplastic disease hospitals,'' but renamed ''extended neoplastic disease care hospitals'') that will identify hospitals classified under new section 1886(d)(1)(B)(vi) of the Act.

IX. Quality Data Reporting Requirements for Specific Providers and Suppliers

We seek to promote higher quality and more efficient healthcare for Medicare beneficiaries. This effort is supported by the adoption of widely agreed-upon quality measures. We have worked with stakeholders to define quality measures for most settings and to measure various aspects of care for most Medicare beneficiaries. These measures assess structural aspects of care, clinical processes, care coordination, and improving patient outcomes (including patient experiences with care).

We have implemented quality reporting programs for multiple care settings, including, for example:

- Hospital inpatient services under the Hospital Inpatient Quality Reporting (IQR) Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program);
- Prospective Payment System (PPS)-exempt cancer hospitals under the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program;
- Long-term care hospitals under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP) (also referred to as the LTCHQR Program);
- Inpatient psychiatric facilities under the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program;
- Hospital outpatient services under the Hospital Outpatient Quality Reporting (OQR) Program (formerly referred to as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP));
- Ambulatory surgical centers under the Ambulatory Surgical Center Quality Reporting (ASCQR) Program;
- Inpatient rehabilitation facilities under the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP);
- Care furnished by physicians and other eligible professionals under the Physician Quality Reporting System (PQRS). We note that beginning in CY 2019, PQRS will be replaced by the Quality Payment Program (QPP), as stated in the MIPS APM final rule with comment period (81 FR 77008);
- Skilled nursing facilities under the Skilled Nursing Facility Quality Reporting Program (SNF QRP);
- Home health agencies under the Home Health Quality Reporting Program (HH QRP); and
- Hospices under the Hospice Quality Reporting Program (HQRP).

We have also implemented programs which link payment to performance including: The Hospital Readmissions Reduction Program (HRRP); the Hospital Value-Based Purchasing (VBP) Program (described further below); the Hospital-Acquired Condition (HAC) Reduction Program; the End-Stage Renal Disease Quality Incentive Program (ESRD QIP); and the Quality Payment Program (QPP).

In implementing the Hospital IQR Program and other quality reporting programs, we have focused on measures which have high impact and support CMS and HHS priorities for improved quality and efficiency of care for Medicare beneficiaries. We have made significant progress over recent program years in reaching our goal of aligning the clinical quality measure requirements of the Hospital IQR Program with various other Medicare and Medicaid programs, including those authorized by the Health Information Technology for Economic and Clinical Health (HITECH) Act, so that the reporting burden of multiple programs on providers will be reduced. We outline the aligned policies between the Hospital IQR Program and the Medicare and Medicaid EHR Incentive Programs in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57172). Our goal for the future is to continue to align those quality measurement requirements and to adopt a more streamlined set of clinical quality measures with electronic specifications aligned to standardized data elements so that electronic collection of performance information is a seamless component of care delivery. We believe the electronic collection and reporting of quality data using health IT will greatly simplify and streamline reporting for various CMS quality reporting programs, and hospitals will experience decreased financial and administrative burden as they are able to switch primarily to health IT based data reporting for many measures that are currently manually chart-abstracted.

We also have implemented a Hospital VBP Program under section 1886(o) of the Act, described in the FY 2013 Hospital Inpatient VBP Program final rule (76 FR 26490 through 26547); the FY 2014 the FY 2014 IPPS/LTCH PPS final rule (78 FR 50676 through 50707); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50048 through 50087); the FY 2016 IPPS/LTCH PPS final rule (80 FR 49544 through 49570); the FY 2017 IPPS/LTCH PPS final rule (81 FR 56979 through 57011); and the CY 2017 OPPS/ASC final rule with comment period (81

FR 79855 through 79862). Under the Hospital VBP Program, performance standards are set and applied to a performance period for the applicable FY. Hospitals receive value based incentive payments based on these performance standards. The measures under the Hospital VBP Program must be selected from current measures (other than readmission measures) specified under the Hospital IQR Program as required by section 1886(o)(2)(A) of the Act.

In selecting measures for the Hospital IQR Program, we are mindful of the conceptual framework we have developed for the Hospital VBP Program. Because measures adopted for the Hospital VBP Program must first have been adopted and publicly reported under the Hospital IQR Program, these two programs are linked. We view the Hospital VBP Program as the next step in promoting higher quality care for Medicare beneficiaries by transforming Medicare from a passive payer of claims into an active purchaser of quality healthcare for its beneficiaries. Value-based purchasing is an important step to revamping how care and services are paid for, moving increasingly toward rewarding better value, outcomes, and innovations.

We also view the HAC Reduction Program, authorized by section 1886(p) of the Act, and the Hospital VBP Program as related but separate efforts to reduce HACs. The Hospital VBP Program is an incentive program that awards payments to hospitals based on quality performance on a wide variety of measures (scoring performance on each measure on the greater of improvement or achievement), while the HAC Reduction Program creates a payment adjustment resulting in payment reductions for hospitals with scores in the lowest performing quartile based on their rates of HACs.

In the preamble of FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20030 through 20064), we proposed changes to the following Medicare quality reporting systems:

- In section IX.A., the Hospital IQR Program.
- In section IX.B., the PCHQR Program.
- In section IX.C., the LTCH QRP.
- In section IX.D., the IPFQR Program.

In addition, in section IX.E. of the preamble of the proposed rule (82 FR 20130 through 20139), we proposed changes to the Medicare and Medicaid EHR Incentive Programs for eligible hospitals and critical access hospitals (CAHs).

A. Hospital Inpatient Quality Reporting (IQR) Program

1. Background

a. History of the Hospital IQR Program

We seek to promote higher quality and more efficient health care for Medicare beneficiaries. This effort is supported by the adoption of widely-agreed upon quality measures. We have worked with relevant stakeholders to define measures of quality in almost every setting and currently measure some aspect of care for almost all Medicare beneficiaries. These measures assess structural aspects of care, clinical processes, patient experiences with care, and outcomes. We have implemented quality measure reporting programs for multiple settings of care. To measure the quality of hospital inpatient services, we implemented the Hospital Inpatient Quality Reporting (IQR) Program, previously referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program. We refer readers to the FY 2010 IPPS/LTCH PPS final rule (74 FR 43860 through 43861) and the FY 2011 IPPS/LTCH PPS final rule (75 FR 50180 through 50181) for detailed discussions of the history of the Hospital IQR Program, including the statutory history, and to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50217 through 50249), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49660 through 49692), and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57148 through 57150) for the measures we have adopted for the Hospital IQR Program measure set through the FY 2019 payment determination and subsequent years.

We strive to put patients first, ensuring they are empowered to make decisions about their own healthcare along with their clinicians using information from data-driven insights that are increasingly aligned with meaningful quality measures. We support technology that reduces burden and allows clinicians to focus on providing high-quality healthcare for their patients. We also support innovative approaches to improve quality, accessibility, and affordability of care while paying particular attention to improving clinicians' and beneficiaries' experience when interacting with our programs. In combination with other efforts across the Department of Health and Human Services, we believe the Hospital IQR Program helps to incentivize hospitals to improve healthcare quality and value, while giving patients and providers the tools and information needed to make the best decisions for them. Recognizing that the Hospital IQR Program represents a key component of the way that we bring quality measurement and improvement together with payment, we have taken efforts to review existing policies to identify how to move the program forward in the least burdensome manner possible while continuing to incentivize improvement in the quality of care provided to patients.

b. Maintenance of Technical Specifications for Quality Measures

The technical specifications for chart-abstracted clinical process of care measures used in the Hospital IQR Program, or links to Web sites hosting technical specifications, are contained in the CMS/The Joint Commission (TJC) Specifications Manual for National Hospital Inpatient Quality Measures (Specifications Manual). This Specifications Manual is posted on the QualityNet Web site at: *http://www.qualitynet.org/*. We generally update the Specifications Manual on a semiannual basis and include in the updates detailed instructions and calculation algorithms for hospitals to use when collecting and submitting data on required chart-abstracted clinical process of care measures.

The technical specifications for electronic clinical quality measures (eCQMs) used in the Hospital IQR Program are contained in the CMS Annual Update for Hospital Quality Reporting Programs (Annual Update). This Annual Update is posted on the eCQI Resource Center webpage at: *https://ecqi.healthit.gov/*. We generally update the measure specifications on an annual basis through the Annual Update, which includes code updates, logic corrections, alignment with current clinical guidelines, and additional guidance for hospitals and EHR vendors to use in order to collect and submit data on eCQMs from hospital EHRs.

In addition, we believe that it is important to have in place a sub-regulatory process to incorporate non-substantive updates to the measure specifications for measures we have adopted for the Hospital IQR Program so that these measures remain up-to-date. We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53504 through 53505) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50203) for our policy for using a sub-regulatory process to make non-substantive updates to measures used for the Hospital IQR Program.

We recognize that some changes made to measures undergoing maintenance review are substantive in nature and

might not be appropriate for adoption using a sub-regulatory process. We will continue to use rulemaking to adopt substantive updates made to measures we have adopted for the Hospital IQR Program. We refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57111) for additional discussion of the maintenance of technical specifications for quality measures for the Hospital IQR Program. We also refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50202 through 50203) for additional details on the measure maintenance process.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20031), we did not propose any changes to our policies on the measures maintenance process, including the maintenance of non-substantive updates to measures used for the Hospital IQR Program.

c. Public Display of Quality Measures

Section 1886(b)(3)(B)(viii)(VII) of the Act was amended by the Deficit Reduction Act (DRA) of 2005. Section 5001(a) of the DRA requires that the Secretary establish procedures for making information regarding measures submitted available to the public after ensuring that a hospital has the opportunity to review its data before they are made public. Our current policy is to report data from the Hospital IQR Program as soon as it is feasible on CMS Web sites such as the *Hospital Compare* Web site, *http://www.medicare.gov/hospitalcompare* after a 30-day preview period (78 FR50776 through 50778).

Information is available to the public on the *Hospital Compare* Web site. *Hospital Compare* is an interactive web tool that assists beneficiaries by providing information on hospital quality of care to those who need to select a hospital. The Hospital IQR Program currently includes process of care measures, risk-adjusted outcome measures, the HCAHPS patient experience-of-care survey measure, structural measures, Emergency Department throughput measures, patient safety and adverse event measures, immunization measures, hospital-acquired infection measures, and payment measures, all of which are featured on the *Hospital Compare* Web site. For more information on measures reported to *Hospital Compare,* we refer readers to the Web site at: *http://www.medicare.gov/hospitalcompare*.

Other information that may not be as relevant to or easily understood by beneficiaries and information for which there are unresolved display issues or design considerations are not reported on *Hospital Compare* and may be made available on other CMS Web sites, such as *https://data.medicare.gov*. CMS also provides stakeholders access to archived data from *Hospital Compare,* which can be found at: *https://data.medicare.gov/data/archives/hospital-compare*.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20031 through 20032), we did not propose any changes to these policies.

d. Accounting for Social Risk Factors in the Hospital IQR Program

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20032 through 20033), we discussed the accounting for social risk factors in the Hospital IQR Program. We understand that social risk factors such as income, education, race and ethnicity, employment, disability, community resources, and social support (certain factors of which are also sometimes referred to as socioeconomic status (SES) factors or socio-demographic status (SDS) factors) play a major role in health. One of our core objectives is to improve beneficiary outcomes including reducing health disparities, and we want to ensure that all beneficiaries, including those with social risk factors, receive high quality care. In addition, we seek to ensure that the quality of care furnished by providers and suppliers is assessed as fairly as possible under our programs while ensuring that beneficiaries have adequate access to excellent care.

We have been reviewing reports prepared by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) [99] and the National Academies of Sciences, Engineering, and Medicine on the issue of measuring and accounting for social risk factors in CMS' quality measurement and payment programs, and considering options on how to address the issue in these programs. On December 21, 2016, ASPE submitted a Report to Congress on a study it was required to conduct under section 2(d) of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. The study analyzed the effects of certain social risk factors of Medicare beneficiaries on quality measures and measures of resource use used in one or more of nine Medicare value-based purchasing programs.[100] The report also included considerations for strategies to account for social risk factors in these programs. In a January 10, 2017 report released by the National Academies of Sciences, Engineering, and Medicine, that body provided various potential methods for measuring and accounting for social risk factors, including stratified public reporting.[101]

As noted in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57124), the NQF undertook a 2-year trial period in which new measures, measures undergoing maintenance review, and measures endorsed with the condition that they enter the trial period could be assessed to determine whether risk adjustment for selected social risk factors is appropriate for these measures. This trial entailed temporarily including social risk factors in the risk-adjustment approach for these measures. Since publication of the FY 2018 IPPS/LTCH PPS proposed rule, we have learned that the trial period ended in April 2017 and a draft report is available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*.

As we continue to consider the analyses and recommendations from these reports, we are continuing to work with stakeholders in this process. As we have previously communicated, we are concerned about holding providers to different standards for the outcomes of their patients with social risk factors because we do not want to mask potential disparities or minimize incentives to improve the outcomes for disadvantaged populations. Keeping this concern in mind, while we sought input on this topic previously, we continue to seek public comment on whether we should account for social risk factors in the Hospital IQR Program, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors. Examples of methods include: Confidential reporting to providers of measure rates stratified by social risk factors; public reporting of stratified measure rates; and potential risk adjustment of a particular measure as appropriate based on data and evidence.

In addition, in the proposed rule (82 FR 20032), we sought public comment on which social risk factors might be most appropriate for reporting stratified measure scores and/or potential risk adjustment of a particular measure. Examples of social risk factors include, but are not limited to: Dual eligibility/low-income subsidy, race and ethnicity, and geographic area of residence. We also sought comments on which of these

[99] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[100] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[101] National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

factors, including current data sources where this information would be available, could be used alone or in combination, and whether other data should be collected to better capture the effects of social risk. We will take commenters' input into consideration as we continue to assess the appropriateness and feasibility of accounting for social risk factors in the Hospital IQR Program. We note that any such changes would be proposed through future notice-and-comment rulemaking.

We refer readers to section IX.A.13. of the preamble of this final rule, where we discuss the potential future confidential reporting of stratified measure data for the Hospital 30-day, All-Cause, Risk-Standardized Readmission Rate Following Pneumonia Hospitalization (NQF #0506) and the Hospital 30-day, All-Cause, Risk Standardized Mortality Rate (RSMR) for Pneumonia measures. Our goal is to provide examples from several domains for the same issue (pneumonia). We want the reader to understand the approaches from as many perspectives as possible. In addition, we sought comments on options for publicly displaying stratified rates using social risk factors as well as which other social risk factors besides dual eligibility should be used.

Of note, implementing any of the above methods would be taken into consideration in the context of how this and other CMS programs operate (for example, data submission methods, availability of data, statistical considerations relating to reliability of data calculations, among others), so we also welcomed comment on operational considerations.

We received extensive comments in response to our request for public comment on whether we should account for social risk factors in the Hospital IQR Program, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors.

Comment: Several commenters were generally supportive of accounting for social risk factors in the Hospital IQR Program. The commenters expressed appreciation for CMS' interest in providing data to hospitals and to the public to inform these efforts, and urged CMS to provide data in a way that minimizes the risk of providing divergent signals to hospitals. The commenters noted that risk stratification and adjustment are equally significant components of valid quality assessment. Specifically, the commenters believed that risk-adjusting quality measures would: (1) Have a positive impact on provider performance; (2) provide information essential to allocating resources in high-risk areas; (3) encourage equitable care delivery, while also accounting for the currently disproportionate penalties for safety net and academic medical centers; (4) reduce costs; and (5) prevent weakening of the network of providers that serve disadvantaged populations, which could have the unintended consequence of worsening health disparities. Conversely, some commenters voiced concerns such as: (1) This approach will not address the underlying disparities that are often associated with poor health outcomes and might instead, mask potential disparities or minimize incentives to improve the outcomes for disadvantaged populations; and (2) adjustments to quality measures could create a two-tier system of care where those with few economic or social resources are diminished in the calculation of quality measures. Some commenters stated that providers should not be financially penalized while caring for patients with greater needs.

Several commenters recommended that comorbidities, functional impediments, and cognitive limitations must be accounted for when assessing quality and costs. The commenters suggested that CMS conduct analyses to determine the degree to which certain variables, such as insurance, age, race, and ethnicity, impact admission rates before these factors are weighted as part of any quality scoring metrics. Where meaningful and comprehensive neighborhood level SDS-data currently exist, several commenters stated that CMS should encourage empirical tests of quality metrics adjusted for those factors to assess the impact of said adjustments on local provider performance metrics. Based on these tests, CMS and other agencies would be able to prioritize the national collection of data most essential for valid risk adjustment methodologies.

Many commenters suggested that CMS explore a variety of approaches for accounting for social risk factors, including; risk adjustment, stratification of measure rates for public reporting, and confidential stratification of measures. The commenters also encouraged CMS to work with measure developers and relevant medical societies to ensure social risk factors are considered during the measure development and update processes. Some commenters recommended that stratification or risk-adjustment decisions should be made on a measure by measure level and incorporated into the measure specifications. Some commenters recommended that CMS require measure developers to test a range of national-level socio-demographic data elements, identified in the ASPE [102] and NAM [103] reports, into the risk adjustment methodology of accountability metrics.

Many commenters recommended providing this risk-adjusted data alongside unadjusted data so that interventions can be appropriately targeted, but discouraged the use of unadjusted data in publicly reported and pay-for-performance measures. Some commenters stated that CMS should work with stakeholders after the hospitals' review is complete to publicly report this data in an appropriate fashion. Other concerns expressed by some commenters included that data should not be publicly reported until hospitals have had sufficient time to review and understand the results and correct any errors that may stem from the initial implementation of any new methodology. Some commenters suggested that CMS provide hospitals with confidential reports of performance on accountability measures stratified by dual eligible status or other nationally available data elements within a year of this testing.

Commenters encouraged CMS to continue to work on developing more precise approaches to risk adjustment to account for social factors in the rural context. Some commenters stated that CMS should implement demonstration projects to encourage hospitals to collect SDS data through their electronic health records (EHR). Some commenters advised CMS to monitor the effects of changes to quality programs on hospitals serving beneficiaries with social risk factors so that future programmatic changes are made with these concerns in mind. Some commenters also encouraged CMS to reconsider the use of a 3-year look back period historically used to calculate readmission rates as it moves forward with changes to this program.

Response: We appreciate all the comments and interest in this topic. As we have previously stated, we are concerned about holding providers to different standards for the outcomes of their patients with social risk factors, because we do not want to mask potential disparities or minimize

[102] Office of the Assistant Secretary for Planning and Evaluation. 2016. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[103] National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

incentives to improve outcomes for disadvantaged populations. We believe that the path forward should incentivize improvements in health outcomes for disadvantaged populations while ensuring that beneficiaries have access to excellent care. We appreciate that some commenters recommended risk adjustment as a strategy to account for social risk factors, while others stated a concern that risk adjustment could minimize incentives and reduce efforts to address disparities for patients with social risk factors. We will consider all suggestions as we continue to assess the issue of accounting for social risk factors within individual measures and the program as a whole, and will actively perform additional research and monitor for trends to prevent unintended consequences. We intend to explore options including, but not limited to, measure stratification by social risk factors in a consistent manner across programs when appropriate, informed by considerations described in section IX.A.13. of the preamble of this final rule, which describes options of: (1) Stratified reporting of a measure by patient factors, which highlights disparities in outcomes by patient subgroup; and (2) peer-to-peer benchmarking based on hospital's share of patient factors, which allows hospitals to compare their performance with like-peers. We also intend to conduct further analyses on the impact of different approaches such as measure-level risk adjustment and stratifying performance scoring to account for social risk factors including the options suggested by commenters. In addition, we will consider the commenters' suggestion that we conduct empirical testing of risk-adjusted quality metrics, and assess the potential impact of the findings from such testing on the prioritization of national data collection, in relation to risk adjustment methodologies.

We appreciate commenters' recommendations regarding specific social risk factor variables and will work to determine the feasibility of collecting these patient-level variables. As we consider the feasibility of collecting patient-level data and the impact of strategies to account for social risk factors through further analysis, we will also continue to evaluate the reporting burden on providers.

We are committed to ensuring that CMS beneficiaries have access to and receive excellent care and that the quality of care furnished by providers and suppliers is assessed fairly in CMS programs. We thank the commenters, and we will consider their views as we develop further policy regarding social risk factors in the Hospital IQR Program. Any proposals would be made in future rulemaking after further research and continued stakeholder engagement.

2. Retention of Previously Adopted Hospital IQR Program Measures for Subsequent Payment Determinations

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53512 through 53513) for our finalized measure retention policy. Pursuant to this policy, when we adopt measures for the Hospital IQR Program beginning with a particular payment determination, we automatically re-adopt these measures for all subsequent payment determinations unless we propose to remove, suspend, or replace the measures. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20033), we did not propose any changes to this policy.

3. Removal and Suspension of Previously Adopted Hospital IQR Program Measures

As discussed above, we generally retain measures from the previous year's Hospital IQR Program measure set for subsequent years' measure sets except when we specifically propose to remove, suspend, or replace a measure. We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50185) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50203 through 50204) for more information on the criteria we consider for removing quality measures. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49641 through 49643) for more information on the additional factors we consider in removing quality measures and the factors we consider in order to retain measures. We note in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50203 through 50204), we clarified the criteria for determining when a measure is ''topped-out.'' In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20033), we did not propose any changes to these policies.

We refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57112 through 57120) for the list of 15 measures finalized for removal for the FY 2019 payment determination and subsequent years. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20033), we did not propose any measures for removal.

4. Previously Adopted Hospital IQR Program Measures for the FY 2019 Payment Determination and Subsequent Years

The Hospital IQR Program has previously finalized 62 measures for the FY 2019 payment determination and subsequent years as outlined in the table below:

HOSPITAL IQR PROGRAM MEASURES FOR THE FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Short name	Measure name	NQF #
Healthcare-Associated Infection Measures		
CAUTI	National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.	1717
CLABSI	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI.	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
HCP	Influenza Vaccination Coverage Among Healthcare Personnel	0431
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	1716
Claims-Based Patient Safety Measures		
Hip/knee complications	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550

HOSPITAL IQR PROGRAM MEASURES FOR THE FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

Short name	Measure name	NQF #
PSI 04	Death Rate among Surgical Inpatients with Serious Treatable Complications	0351
PSI 90	Patient Safety for Selected Indicators Composite Measure, Modified PSI 90 (Updated Title: Patient Safety and Adverse Events Composite).	0531
Claims-Based Mortality Outcome Measures		
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0230
MORT–30–CABG	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery.	2558
MORT–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1893
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization.	0229
MORT–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization.	0468
MORT–30–STK	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Ischemic Stroke.	N/A
Claims-Based Coordination of Care Measures		
READM–30–AMI	Hospital 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0505
READM–30–CABG	Hospital 30-Day, All-Cause, Unplanned, Risk-Standardized Readmission Rate (RSRR) Following Coronary Artery Bypass Graft (CABG) Surgery.	2515
READM–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1891
READM–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Heart Failure (HF) Hospitalization.	0330
READM–30–HWR	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	1789
READM–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization.	0506
READM–30–STK	30-Day Risk Standardized Readmission Rate Following Stroke Hospitalization	N/A
READM–30–THA/TKA	Hospital-Level 30-Day, All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1551
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI).	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF).	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia.	2579
THA/TKA Payment	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty.	N/A
MSPB	Payment-Standardized Medicare Spending Per Beneficiary (MSPB)	2158
Cellulitis Payment	Cellulitis Clinical Episode-Based Payment Measure	N/A
GI Payment	Gastrointestinal Hemorrhage Clinical Episode-Based Payment Measure	N/A
Kidney/UTI Payment	Kidney/Urinary Tract Infection Clinical Episode-Based Payment Measure	N/A
AA Payment	Aortic Aneurysm Procedure Clinical Episode-Based Payment Measure	N/A
Chole and CDE Payment	Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment Measure.	N/A
SFusion Payment	Spinal Fusion Clinical Episode-Based Payment Measure	N/A
Chart-Abstracted Clinical Process of Care Measures		
ED–1*	Median Time from ED Arrival to ED Departure for Admitted ED Patients	0495
ED–2*	Admit Decision Time to ED Departure Time for Admitted Patients	0497
Imm–2	Influenza Immunization	1659
PC–01*	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
VTE–6	Incidence of Potentially Preventable Venous Thromboembolism	+
EHR-Based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs))		
AMI–8a	Primary PCI Received Within 90 Minutes of Hospital Arrival	+
CAC–3	Home Management Plan of Care Document Given to Patient/Caregiver	+
ED–1*	Median Time from ED Arrival to ED Departure for Admitted ED Patients	0495

HOSPITAL IQR PROGRAM MEASURES FOR THE FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

Short name	Measure name	NQF #
ED–2*	Admit Decision Time to ED Departure Time for Admitted Patients	0497
EHDI–1a	Hearing Screening Prior to Hospital Discharge	1354
PC–01*	Elective Delivery	0469
PC–05	Exclusive Breast Milk Feeding	0480
STK–02	Discharged on Antithrombotic Therapy	0435
STK–03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK–05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK–06	Discharged on Statin Medication	0439
STK–08	Stroke Education	+
STK–10	Assessed for Rehabilitation	0441
VTE–1	Venous Thromboembolism Prophylaxis	0371
VTE–2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Patient Experience of Care Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems	0166
	(including Care Transition Measure (CTM-3))	(0228)
Structural Patient Safety Measures		
Patient Safety Culture	Hospital Survey on Patient Safety Culture	N/A
Safe Surgery Checklist	Safe Surgery Checklist Use	N/A

* Measure listed twice, as both chart-abstracted and electronic clinical quality measure.
+ NQF endorsement has been removed.

5. Considerations in Expanding and Updating Quality Measures

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53510 through 53512) for a discussion of the considerations we use to expand and update quality measures under the Hospital IQR Program. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20035), we did not propose any changes to these policies.

6. Refinements To Existing Measures in the Hospital IQR Program for the FY 2020 Payment Determination and Subsequent Years

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20035 through 20043), we proposed refinements to two measures. First, we proposed refinements to the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey (NQF #0166) measure for the FY 2020 payment determination and subsequent years. Second, we proposed refinements to the Stroke 30-Day Mortality Rate (MORT–30–STK) measure for the FY 2023 payment determination and subsequent years. We discuss these refinements in more detail below.

a. Refining the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey (NQF #0166) Measure for the FY 2020 Payment Determination and Subsequent Years

For the FY 2020 payment determination and subsequent years, we proposed to refine the existing Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey by refining the current Pain Management questions (HCAHPS Q12, Q13, and Q14) to focus on the hospital's communications with patients about the patients' pain during the hospital stay. In accord with this new focus, we proposed to update the name of the composite measure from ''Pain Management'' to ''Communication About Pain.''

(1) Background

The HCAHPS Survey (NQF #0166) was adopted in the Reporting Hospital Quality Data Annual Payment Update Program in the CY 2007 OPPS final rule (71 FR 68202 through 68204), beginning with the FY 2008 payment determination and for subsequent years. This Survey includes three Pain Management questions, Q12, Q13 and Q14. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53513 through 53516), we added the Care Transition Measure (CTM–3) (NQF #0228) to the existing HCAHPS Survey, NQF #0166. The HCAHPS Survey, combining both NQF #0166 for the original survey and NQF #0228 for the Care Transition Measure adopted into the HCAHPS Survey in 2013, is the first national, standardized, publicly reported survey of patients' experience of hospital care. The HCAHPS Survey asks discharged patients 25 questions about their recent hospital stay and 7 ''About You'' questions. Survey results have been publicly reported on the *Hospital Compare* Web site since 2008. We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50220), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641 through 51643), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537 through 53538), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819 through 50820) for details on previously-adopted HCAHPS requirements. We also refer hospitals and HCAHPS Survey vendors to the official HCAHPS Web site at: *http://www.hcahpsonline.org* for new information and program updates regarding the HCAHPS Survey, its administration, oversight, and data adjustments.

The HCAHPS Survey (OMB control number 0938–0981) is administered to a random sample of adult patients who receive medical, surgical, or maternity care between 48 hours and 6 weeks (42 calendar days) after discharge and is not restricted to Medicare beneficiaries. Hospitals must survey patients throughout each month of the year. The HCAHPS Survey is available in official English, Spanish, Chinese, Russian, Vietnamese, and Portuguese versions. The HCAHPS Survey and its protocols for sampling, data collection and coding, and file submission can be found in the current HCAHPS *Quality Assurance Guidelines,* which is available on the official HCAHPS Web site at: *http://www.hcahpsonline.org/qaguidelines.aspx*. AHRQ carried out a rigorous, scientific process to develop and test the HCAHPS instrument. This process entailed multiple steps, including: A public call for measures; literature reviews; cognitive interviews, consumer focus groups; multiple

opportunities for additional stakeholder input; a 3-State pilot test; small-scale field tests; and notice-and-comment rulemaking.[104] We refer readers to the CY 2007 OPPS final rule (71 FR 68201) for a more in-depth discussion about this process. The HCAHPS Survey was endorsed by the NQF on August 5, 2005 (#0166).

The Pain Management questions currently included in the HCAHPS Survey are as follows:

12. During this hospital stay, did you need medicine for pain?

[1]☐ Yes

[2]☐ No ➔ If No, Go to Question 15

13. During this hospital stay, how often was your pain well controlled?

[1]☐ Never

[2]☐ Sometimes

[3]☐ Usually

[4]☐ Always

14. During this hospital stay, how often did the hospital staff do everything they could to help you with your pain?

[1]☐ Never

[2]☐ Sometimes

[3]☐ Usually

[4]☐ Always

In the CY 2017 OPPS/ASC final rule with comment period in the context of the Hospital VBP Program (81 FR 79856), we stated that we received feedback that some stakeholders are concerned about the Pain Management dimension questions being used in a program where there is any link between scoring well on the questions and higher hospital payments (81 FR 79856). The Pain Management dimension used in the Hospital VBP Program is identical in composition to the Pain Management measure used in the Hospital IQR Program, questions Q12, Q13 and Q14 with one difference: The HCAHPS dimension score in the Hospital VBP program is based on the percentage of patients who chose the most positive response option (''top-box'' response). For more information about the Hospital VBP Program scoring methodology, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57006).

Some stakeholders believed that the linkage of the Pain Management dimension questions to the Hospital VBP Program payment incentives created pressure on hospital staff to prescribe more opioids in order to achieve higher scores on this dimension (81 FR 79856). We stated that we continue to believe that pain control is an appropriate part of routine patient care that hospitals should manage and is an important concern for patients, their families, and their caregivers (81 FR 79856). Further, we stated that it is important to note that the HCAHPS Survey does not specify any particular type of pain control method (81 FR 79856). We added that appropriate pain management includes communication with patients about pain-related issues, setting expectations about pain, shared decision-making, and proper prescription practices (81 FR 79856). Furthermore, we stated that although we were not aware of any scientific studies that support an association between scores on the Pain Management dimension questions and opioid prescribing practices, we were developing alternative questions for the Pain Management dimension in order to remove any potential ambiguity in the HCAHPS Survey. We noted that we believe that removing the Pain Management dimension from the

[104] ''*Development, Implementation, and Public Reporting of the HCAHPS Survey.*'' L.A. Giordano, M.N. Elliott, E. Goldstein, W.G. Lehrman and P.A. Spencer. Medical Care Research and Review, 67 (1): 27–37. 2010.

Hospital VBP Program scoring calculations would address potential confusion about the appropriate use of the Pain Management dimension, and provide us with an opportunity to further refine the pain management questions used in the HCAHPS Survey (81 FR 79859).

In the same final rule, we stated we would follow our standard survey development processes, which included drafting alternative questions, cognitive interviews and focus group evaluation, field testing, statistical analysis, stakeholder input, the Paperwork Reduction Act, and NQF endorsement (81 FR 79856).

In that final rule, numerous commenters supported the development of modified questions regarding pain management for the HCAHPS Survey and some commenters expressed particular support for modified pain management questions that focused on effective communication with patients about pain management-related issues (81 FR 79859 through 79860). Specifically, a number of commenters recommended modified pain management questions focused on shared decision-making, discussion of treatment options, including non-opioid pain management therapies, patient understanding of pain management options, and patient engagement in their care (81 FR 79860).

Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20035 through 20039), for the FY 2020 payment determination and subsequent years, we proposed to update and refine the existing HCAHPS Survey questions (HCAHPS Q12, Q13, and Q14) to focus more directly on communication with patients about their pain during the hospital stay.

These proposed revised questions would be used to form the composite measure ''Communication About Pain.'' The proposed revised Communication about Pain composite measure would be a part of the HCAHPS Survey and would be publicly reported in the Hospital IQR Program. More information about the revised questions/composite measure is included below.

In compliance with section 1890A(a)(2) of the Act, measures proposed for the Hospital IQR Program were included in a publicly available document: ''List of Measures under Consideration for December 1, 2016'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/Measures-under-Consideration-List-for-2016.pdf*.

The Measure Applications Partnership (MAP), a multi-stakeholder group convened by the NQF, reviews the measures under consideration for the Hospital IQR Program, among other Federal programs, and provides input on those measures to the Secretary. The MAP's 2017 recommendations for quality measures under consideration are captured in the following documents: ''2016–2017 Process and Approach for MAP Pre Rulemaking Deliberations'' available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=84455* and ''2016–2017 Spreadsheet of Final Recommendations to HHS and CMS'' available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=84452*.

We considered the input and recommendations provided by the MAP.

The Communication About Pain (MUC16–263) composite measure was reviewed by the MAP in December 2016. The MAP recommended that this composite measure be refined and resubmitted prior to rulemaking. The MAP emphasized the need to include non-pharmacological options used to treat pain. The MAP recommended that the testing results demonstrate reliability and validity for the Hospital IQR Program. The MAP also recommended that the measure be submitted to NQF for review and endorsement.[105] We plan to resubmit the proposed refined Communication About Pain composite measure to the MAP at the next opportunity. As we discuss in more detail below, the proposed refined Communication About Pain composite measure underwent field testing in 2016. Results were not yet available for the MAP's review in December 2016, but are now complete and are posted on the official HCAHPS On-Line Web site, ''Development of a New *Communication About Pain* Composite Measure for the HCAHPS Survey,'' available at: *http://www.hcahpsonline.org/modeadjustment.aspx*. We believe the measure is now fully developed and tested and we intend to provide feedback to the MAP Hospital Workgroup for review of testing results.

In early 2016, we empirically tested as part of the field test the reliability and validity of the proposed refined Communication About Pain composite measure in a large-scale experiment that involved patients from 51 hospitals across the nation. (We note that we are correcting a technical error here; the proposed rule (82 FR 20037) stated ''50 hospitals.'') Our analyses suggest the proposed refined Communication About Pain composite measure, which includes two substantive items regarding how often staff talked about pain and how often staff discussed how to treat pain while in the hospital (Q13 and Q14), as well as a screener item (Q12), have strong reliability (evidence that scores for hospitals are precisely measured) and validity (evidence that the measure does measure the intended construct of patient experience).[106] These properties of the individual questions used in the proposed refined Communication About Pain composite measure are as good as or better than the current Pain Management questions. The new questions are not subject to floor or ceiling effects (which would occur if almost all responses were in the lowest or highest response category), have excellent hospital-level reliability (here 0.88 or higher, where 0.70 or higher is the conventional standard) at recommended sample sizes, are not redundant with other current questions, are related in a predictable manner with the standard patient-mix characteristics, positively correlate with the two HCAHPS questions that assess overall patient experience (rating and recommendation) with the hospital, providing evidence of validity and do not vary systematically by survey mode, patient race/ethnicity, or hospital characteristics after adjusting for patient mix. They also have higher internal consistency as a composite measure (Cronbach's alpha = 0.81), with 0.70 or higher being the conventional threshold, providing further evidence of reliability.[107]

As stated above, the MAP recommended the proposed refined Communication About Pain composite measure be submitted to the NQF for review and endorsement once testing has been completed.[108] The proposed refined Communication About Pain composite measure is not yet NQF endorsed; however, we intend to submit the measure to the NQF for endorsement when the Person and Family Centered Care Project has a call for measures.

Whenever feasible, we adopt measures that are NQF-endorsed, but note sometimes there are important

[105] ''2016–2017 Spreadsheet of Final Recommendations to HHS and CMS'' available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=84452*.

[106] Judd, C.M., & McClelland, G.H. (1998). Measurement. In D.T. Gilbert, S.T. Fiske, & G. Lindzey (Eds.), *The handbook of social psychology* (4th ed., Vol. 1, pp. 180–232). New York: McGraw-Hill.

[107] Cronbach, L.J. (1984). *Essentials of psychological testing* (4th ed.). New York: Harper.

[108] ''2017 Considerations for Implementing Measures Hospitals-Final Report,'' available at: *http://www.qualityforum.org/map/*.

areas of clinical concern for which NQF-endorsed measures do not exist. Section 1886(b)(3)(B)(IX)(bb) of the Act provides that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. (The NQF currently holds this contract.) We considered other existing measures which have been endorsed by the NQF and other consensus organizations, but we were unable to identify any NQF-endorsed (or other consensus organization endorsed) measures that were feasible and practical.

While we consider MAP recommendations and NQF endorsement status as part of our decision-making process for which measures to include in the Hospital IQR Program, we believe it is important to adopt this proposed refined Communication About Pain composite measure, because communicating with patients about their pain is an integral part of delivering high quality, person-centered care.[109] In developing the proposed refined Communication About Pain composite measure, we followed our standard survey development processes,[110] which included drafting alternative questions, cognitive interviews, focus group evaluation, field testing, statistical analysis, and stakeholder input. We believe the proposed refined Communication About Pain composite measure has been sufficiently tested, demonstrating high levels of reliability and validity, as noted above.

Further, we have consistently received feedback from some stakeholders expressing concern that the current Pain Management questions encourage overprescribing of opioids as discussed in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79856). As a result, we believe it is important to refine the existing Pain Management measure. In the proposed rule (82 FR 20038), we noted that if our proposal to revise the current Pain Management measure questions with those in the proposed refined Communication About Pain composite measure is not finalized, we would continue to use the Pain Management questions as previously finalized.

The proposed refined Communication About Pain composite measure is discussed below. We proposed to revise the current Pain Management questions (Q12, Q13, and Q14) in the HCAHPS Survey for the FY 2020 payment determination and subsequent years by adopting the proposed refined Communication About Pain composite measure in the HCAHPS Survey beginning with the FY 2020 payment determination, which would be applicable to surveys administered to patients beginning with January 1, 2018 discharges and for subsequent years.

In compliance with section 1886(b)(3)(B)(viii)(VII) of the Act, we calculate and publicly report HCAHPS measures from four consecutive quarters of data. From that point and forward, the oldest quarter of data is rolled off, the newest quarter is rolled on, and the measure scores are calculated for this unique set of four quarters and are publicly reported on the *Hospital Compare* Web site and available for payment determination. Data submitted for the current Pain Management measure in CY 2017 for the FY 2019 payment determination will be publicly reported on the *Hospital Compare* Web site in October 2018. In the proposed rule (82 FR 20038), we noted that if our proposal to revise the HCAHPS Pain Management measure with the HCAHPS Communication About Pain composite measure is finalized, we would begin to use the new Pain Management questions on the HCAHPS Survey in January of 2018. Once we have collected four consecutive quarters of the HCAHPS Communication About Pain composite measure questions, we would create scores for the Communication About Pain composite measure.

We would be unable to report or use for payment determination either the original or new Pain Management measure unless and until we have collected 4 quarters of data for the measure. The CY 2017 reporting period/FY 2019 payment determination would be the last period for which we have four quarters of the original Pain Management measure data which, as stated above, would be publicly reported on the *Hospital Compare* Web site in October 2018. We would be unable to publicly report either the original or proposed refined Communication About Pain composite measure on the *Hospital Compare* Web site in December 2018, April 2019, or July 2019 because there would be fewer than 4 quarters of data for both the original and the new measure. The CY 2018 reporting period/FY 2020 payment determination would be the first period for which we have four quarters of the proposed refined Communication About Pain composite measure. Therefore, the first opportunity to publicly report the Communication About Pain composite measure on the *Hospital Compare* Web site would be in October 2019. From this point forward, the proposed refined Communication About Pain composite measure could be used for payment determinations.

(2) Overview of Measure

The refined questions that comprise the proposed refined Communication About Pain composite measure closely mirror the structure and style of the existing Pain Management questions. However, the new questions address how providers communicate with patients about pain while removing any ambiguities in the wording or intent of the questions. This refinement is consistent with the HCAHPS Survey's original design, development, and NQF endorsement (NQF #0166). Further, we designed the Communication About Pain composite measure to be consistent and compatible with existing HCAHPS questions and HCAHPS sampling and survey administration protocols. The three Communication About Pain composite measure questions are as follows:

[109] ''A Special Contribution from the Centers for Medicare and Medicaid Services: Valuing Patient Experience While Addressing the Prescription Opioid Epidemic.'' L. Tefera, W.G. Lehrman, E.G. Goldstein and S. Agrawal. Annals of Emergency Medicine. 2016. Published online, 7–19–16. *http://www.annemergmed.com/article/S0196-0644(16)30367-5/fulltext.*

[110] ''Development, Implementation, and Public Reporting of the HCAHPS Survey.'' L.A. Giordano, M.N. Elliott, E. Goldstein, W.G. Lehrman and P.A. Spencer. Medical Care Research and Review, 67 (1): 27–37. 2010.

- HP1: "During this hospital stay, did you have any pain?"

☐ Yes

☐ No → *If No, Go to Question* __

- HP2: "During this hospital stay, how often did hospital staff talk with you about how much pain you had?"

☐ Never

☐ Sometimes

☐ Usually

☐ Always

- HP3: "During this hospital stay, how often did hospital staff talk with you about how to treat your pain?"

☐ Never

☐ Sometimes

☐ Usually

☐ Always

As stated above, in light of the ongoing opioid epidemic, we believe it is important the Communication About Pain composite measure is abundantly clear in its focus on communication about pain between providers and their patients, and it is applicable to all patients who experienced pain during their hospital stay.

(3) Data Collection

The proposed refined Communication About Pain composite measure questions would be administered and data collected in exactly the same manner as the current Pain Management measure questions. There would be no changes to HCAHPS patient eligibility or exclusion criteria. Detailed information on HCAHPS data collection protocols can be found in the current HCAHPS Quality Assurance Guidelines, located at: *http://www.hcahpsonline.org/qaguidelines.aspx*. We reiterate that other than the revision of the HCAHPS Pain Management questions, the HCAHPS Survey and its administration and data collection protocols would be unchanged. The survey adjustment and patient-mix adjustment for the proposed refined Communication About Pain composite measure would be made available on the official HCAHPS On-Line Web site at: *http://www.hcahpsonline.org/modeadjustment.aspx*.

(4) Public Reporting

The scoring of the proposed refined Communication About Pain composite measure would be the same as the current Pain Management measure. Detailed information on how the measure would be scored for purposes of public reporting can be found on the HCAHPS Web site at: *http://www.hcahpsonline.org/Files/Calculation%20of%20HCAHPS%20Scores.pdf*.

We invited public comment on our proposal to revise the current Pain Management questions (Q12, Q13, and Q14) in the HCAHPS Survey for the FY 2020 payment determination and subsequent years by adopting the proposed refined Communication About Pain composite measure in the HCAHPS Survey beginning with the FY 2020 payment determination and subsequent years, which would be applicable to surveys administered to patients beginning with January 1, 2018 discharges and for subsequent years as discussed above.

Comment: There was a consensus among commenters that pain care is a critical matter to measure as part of HCAHPS. Many commenters supported the proposed refinement to the HCAHPS Survey measure pain management questions. The commenters noted reframing the HCAHPS pain measures as ''Communication About Pain'' is a positive change that would help ensure care is more patient-centered. The commenters appreciated the fact the new questions focus more directly on communication with patients about their pain during the hospital stay, as

opposed to patients' perceptions of the adequacy of pain treatment during the hospital stay. One commenter commended CMS on its responsiveness to concerns about pain and the development of new items focusing less on pharmacotherapy items. Another commenter noted that pain management measures address an important aspect of patient care. Another commenter noted that Pain Management questions are needed for improved delivery of care, proper pain management, and shared decision making. Another commenter noted that the revised pain management questions are an improvement. One commenter supported refining the pain management questions to dissuade over-prescription of opioids and remove ambiguities, and appreciated the steps taken by CMS to test for reliability and validity. One commenter noted that the new focus on pain communication is positive, ensuring that care is more patient-centered. Another commenter noted that CMS should proceed with the proposed changes to the pain management questions.

Response: We thank the commenters for their support. We believe that the proposed refined pain management questions as formulated shift focus from the method of pain management to patient-centered communication between provider and patient. We believe the proposed refined Communication About Pain composite measure adequately reflects shared decision making and pain management by focusing on communication between patients and providers rather than the particular course of treatment. We engaged the patient and caregiver community in evaluating and refining the questions related to pain management as part of our standard survey development process.

Comment: Several commenters supported complete removal of the pain management questions from the HCAHPS Survey measure, arguing that questions evaluating how pain is discussed offer no benefit to patients.

Another commenter encouraged CMS to reduce external pressure on providers to prescribe opioids inappropriately by completely removing the current Pain Management questions from the HCAHPS Survey measure beginning in CY 2018 because doing so would help ensure physicians have the ability to treat patients in the most appropriate manner. In addition, the commenter urged CMS to eliminate pain as a ''fifth vital sign'' from all professional standards because the current culture of pain as a fifth vital sign minimizes investigation into causes of pain and incentivizes methods of addressing pain in a manner that may not support the patient's health in the long term.

Response: Pain management is an important component of the quality of care provided at a hospital, and we believe continued inclusion of the HCAHPS Survey measure in the Hospital IQR Program provides patients with critical information for use in selecting a hospital setting for their care, ensures hospitals continue to appropriately manage patients' pain, and encourages hospitals to engage in quality improvement efforts in addressing pain management and communication about pain. We continue to believe pain control is a critical part of routine patient care that hospitals should manage and is an important concern for patients, their families, and patient caregivers. Furthermore, as revised, the pain management questions focus entirely on communication about pain with patients and do not refer to, recommend, or imply that any particular type of treatment is appropriate. We believe the revised Communication About Pain composite measure questions should encourage more and better communication between hospital staff and patients about pain and should not affect patient treatment. Therefore, we believe there is continued benefit to include and publicly report the HCAHPS Survey Pain Management questions in this and other CMS quality programs that use the HCAHPS Survey.

Finally, we acknowledge the commenter's recommendation that we eliminate pain as a ''fifth vital sign'' from professional standards, and we note that such requests should be referred to and addressed by relevant professional societies.

Comment: Many commenters supported the proposed refinement of the HCAHPS Survey measure pain management questions to focus more on communication about pain, but only if first endorsed by the NQF. The commenters stated that having the NQF endorse the revised questions would allow the measure to be publicly vetted by different stakeholders, including hospitals and patient advocates and address concerns about the reliability and validity of the proposed refined Communication About Pain composite measure before they are implemented. The commenters expressed concern that CMS intends to resubmit the measure to the MAP Hospital Workgroup and to NQF for endorsement when there is a call for measures by the Person and Family Centered Care Project, after the measure is proposed to have been implemented in Hospital IQR Program already. In addition, one commenter believed the potential unintended consequences of the current pain management questions has resulted in CMS working too quickly to develop the proposed refined Communication About Pain composite measure, and cautioned that field testing including patients from 51 hospitals does not produce strong reliability and validity that are better than the current questions.

Many commenters requested CMS release findings from the field testing of these proposed refined Communication About Pain composite measure and move the measure forward through the NQF process prior to considering adoption into the Hospital IQR Program.

Response: We thank the commenters for their support. We continue to believe the HCAHPS Survey measure Pain Management questions, and the HCAHPS Survey as a whole, are valid and reliable measures of hospital quality that encourage hospitals to assess and improve the patient experience.[111] [112] The HCAHPS Survey as a whole is already NQF-endorsed (NQF #0166). We anticipate the proposed refined Communication About Pain composite measure will receive NQF-endorsement when there is a call for measures by the Person and Family Centered Care Project. We intend to resubmit the measure to the MAP and submit the measure to the NQF for endorsement after the measure refinement has already been implemented in the Hospital IQR Program. However, we have had to weigh the potential, unintended public health concerns against the necessary time to complete these reviews. Out of an abundance of caution, in the face of a nationwide epidemic of opioid over-prescription, we believe implementing the proposed refined Communication About Pain composite measure as soon as feasible is necessary to address any perceived conflict between appropriate management of opioid use and patient satisfaction by relieving any potential pressure physicians may feel to overprescribe opioids. We believe that replacing the current pain management questions in the HCAHPS Survey with revised questions that focus on the adequacy and frequency of communication about pain will remove any perceived ambiguity or confusion about the intent of the pain items and

[111] ''Do Hospitals Rank Differently on HCAHPS for Different Patient Subgroups?'' M.N. Elliott, W.G. Lehrman, E. Goldstein, K. Hambarsoomian, M.K. Beckett and L.A. Giordano. Medical Care Research and Review, 67 (1): 56–73. 2010.

[112] National Quality Forum. NQF-Endorsed Measures for Person- and Family-Centered Care. Phase 1 Technical Report March 4, 2015. Pp. 26–40.

enhance communication about the particular needs individual patients have with respect to pain. We hope the refined pain management questions will shift focus from the method of pain management to patient-centered communication between provider and patient.

As discussed in our proposal above, whenever feasible, we adopt measures that are NQF-endorsed, but note sometimes there are important areas of clinical concern for which NQF-endorsed measures do not exist. Section 1886(b)(3)(B)(IX)(bb) of the Act provides that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. (The NQF currently holds this contract.) We considered other existing measures which have been endorsed by the NQF and other consensus organizations, but we were unable to identify any NQF-endorsed (or other consensus organization endorsed) measures that were feasible and practical.

In addition, while we consider MAP recommendations and NQF endorsement status as part of our decision-making process for which measures to include in the Hospital IQR Program, we believe it is important to adopt the proposed refined Communication About Pain composite measure. In addition, in response to the MAP's request to receive an update on the status of measures that received a Refine and Resubmit recommendation, we intend to update the MAP about these Communication About Pain composite measure questions.

The refined Communication About Pain composite measure was informed by input and guidance on survey content and approach from a technical expert panel, focus groups and cognitive testing to explore patient experience and interpretation of survey items, and field testing of survey items to test item properties and psychometric performance and composite measures. We disagree that field testing including patients from 51 hospitals does not produce strong reliability and validity that are better than the current questions. As described in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20037), in early 2016, we empirically tested, as part of the field testing, the reliability and validity of the proposed refined Communication About Pain composite measure in a large-scale experiment that involved patients from 51 hospitals across the nation. The 51 hospitals were carefully selected to be nationally representative, and the sample sizes of patients and hospitals exceeded requirements for assessing reliability and validity. The statistical reliability and validity of the new proposed items meet high psychometric standards and have undergone testing that meets the standards of the field. Our analyses suggest the proposed refined Communication About Pain composite measure has strong reliability (evidence that scores for hospitals are precisely measured) and validity (evidence that the measure does measure the intended construct of patient experience).[113] These properties of the individual questions used in the proposed refined Communication About Pain composite measure are as good as or better than the current Pain Management questions. The new questions are not subject to floor or ceiling effects (which would occur if almost all responses were in the lowest or highest response category), have excellent hospital-level reliability (here 0.88 or higher, where 0.70 or higher is the conventional standard) at recommended sample sizes, are not redundant with other current questions, are related in a predictable manner with the standard patient-mix characteristics, positively correlate with the two HCAHPS questions that assess overall patient experience (rating and recommendation) with the hospital, providing evidence of validity and do not vary systematically by survey mode, patient race/ethnicity, or hospital characteristics after adjusting for patient mix. They also have higher internal consistency as a composite measure (Cronbach's alpha = 0.81), with 0.70 or higher being the conventional threshold, providing further evidence of reliability.[114] Therefore, we disagree that the field testing does not produce strong reliability and validity. With respect to commenters' request that we release findings from the field testing of the proposed refined Communication About Pain questions, a summary of the results of the field testing of the proposed refined Communication About Pain composite measure, among others, became available in early July 2017 on our HCAHPS On-Line Web site. We refer readers to ''Development of a New *Communication About Pain* Composite Measure for the HCAHPS Survey,'' available at: *http://www.hcahpsonline.org/modeadjustment.aspx*.

As discussed in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79855 through 79862), and in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20035), we followed our standard survey development processes, which included drafting alternative questions, cognitive interviews and group evaluation, field testing, statistical analysis, and soliciting stakeholder input. We believe the proposed refined Communication About Pain questions represent stakeholder consensus and have been specifically designed to reduce the probability of unintended consequences and to maximize improved patient outcomes. We will monitor the proposed refined Communication About Pain composite measure for any possible unintended consequences.

Comment: A few commenters supported the proposed refinements to the HCAHPS pain management questions, but recommended suspending public reporting of pain management questions on the *Hospital Compare* Web site until the questions have been fully vetted by the NQF.

One commenter encouraged CMS to consider publicly reporting less than four quarters of data in the interim period in which less than four quarters of data are available so that this important measure can be brought to the public sooner.

Response: We believe continued public reporting of Pain Management performance rates provides the public with important quality data for use in health care decision-making and incentivizes quality improvement regarding pain management and communication. We further believe continued public reporting of the score for the composite Pain Management measure performance rates provides valuable information to patients and consumers and encourages hospitals to appropriately manage patients' pain and continue engaging in quality improvement efforts.[115] However, in order to be responsive to stakeholder concerns, we are finalizing a modification of our proposal, to delay public reporting of the revised Communication About Pain composite measure. Instead of publicly reporting

[113] Judd, C. M., & McClelland, G.H. (1998). Measurement. In D.T. Gilbert, S.T. Fiske, & G. Lindzey (Eds.), *The handbook of social psychology* (4th ed., Vol. 1, pp. 180–232). New York: McGraw-Hill.

[114] Cronbach, L.J. (1984). *Essentials of psychological testing* (4th ed.). New York: Harper.

[115] L. Tefera, W.G. Lehrman, and P. Conway. ''Measurement of the Patient Experience: Clarifying Facts, Myths, and Approaches.'' *Journal of the American Medical Association*. Published online, 3–10–16. *http://jama.jamanetwork.com/article.aspx?articleid=2503222*.

in October 2019 using data from the CY 2018 reporting period/FY 2020 payment determination, we will delay public reporting of the refined Communication About Pain composite measure on the *Hospital Compare* Web site until October of 2020, using data from the CY 2019 reporting period/FY 2021 payment determination. After this initial public reporting, public reporting will continue for subsequent years.

In the meantime, we will provide results on the refined Communication About Pain composite measure questions to hospitals in confidential preview reports upon the availability of four quarters of data based on CY 2018 data. We anticipate that the confidential preview reports will be disseminated in the summer of 2019. We note hospitals may have access to their raw HCAHPS data and to unofficial HCAHPS scores through their survey vendor prior to the submission of their HCAHPS data to CMS and prior to the dissemination of the Hospital Specific Confidential Preview Reports that contain official HCAHPS scores.

As stated above, we intend to resubmit the measure to the MAP Hospital Workgroup and to the NQF for endorsement when there is a call for measures by the Person and Family Centered Care Project and we anticipate the proposed refined Communication About Pain composite measure will receive MAP approval and NQF endorsement. Delaying public reporting of the proposed refined Communication About Pain composite measure on the *Hospital Compare* Web site until October of 2020 should provide sufficient time for NQF review prior to public display of this measure data. In addition, delaying public reporting of this measure until October of CY 2020 will give hospitals one year to review their performance data on the refined Communication About Pain composite measure questions prior to public reporting of their performance data on the *Hospital Compare* Web site.

In response to the commenter's suggestion that we consider publicly reporting less than four quarters of data in the interim period in which less than four quarters of data are available so this measure can be brought to the public sooner, while we agree the Pain Management questions convey important information about hospital quality, we believe the value of the proposed refined Communication About Pain composite measure would be enhanced by adhering to the established practice of collecting four quarters of data for public reporting. Doing so ensures that publicly reported HCAHPS measures are based on the same discharge period and provides more time for hospitals to attain the minimum number of completed surveys required for public reporting.

Comment: Many commenters supported removal of the existing pain management questions from the HCAHPS Survey measure, but expressed concern with the wording of the refined Communication About Pain composite measure. The commenters believed the exact wording of the pain management questions is important because results from patient satisfaction surveys influence quality improvement initiatives since hospitals are partially reimbursed based on patient satisfaction scores. While commenters agreed it is important to remove ambiguities in the wording or intent of the questions and appreciated CMS' steps to appropriately test the measure for reliability and validity, some commenters expressed concern the proposed refined Communication About Pain composite measure may not assist with quality improvement activities to ensure that patients receive appropriate pain management. The commenters provided a variety of alternate formulations for the pain questions for CMS to consider. Several commenters provided specific suggested language with which to replace the three existing pain management questions. In addition to specific language changes, some commenters made more general recommendations with respect to the refinement of the Pain Management questions.

One commenter expressed concern with the use of the word ''treat'' in question HP3. The commenter believed the word ''treat'' implies complete pain relief should be achieved, which is not always possible. As such, the commenter suggested question HP3 be re-worded to replace the word ''treat'' with the words ''manage or treat.'' The commenters asserted this wording revision would be a better way to encompass all methods of pain management, rather than just medication.

Another commenter challenged the terminology used in all three questions because the word ''pain'' has a negative connotation and suggested that asking a patient about their ''comfort,'' instead of ''pain'' would be more appropriate.

Finally, one commenter suggested all three revised pain management questions be modified to explicitly include the type of clinical staff (that is, nurses, primary care giver, or physician) communicating with the patient at the time the pain is being assessed.

Response: We thank the commenters for their recommendations regarding alternative refinements to the wording of the Pain Management questions in the HCAHPS Survey measure. We would like to reiterate that the HCAHPS Survey is a patient experience of care survey and not a patient satisfaction survey. The HCAHPS Survey asks recently discharged patients about aspects of their hospital experience that they are uniquely suited to address. The survey asks ''how often'' or whether patients experienced a critical aspect of hospital care, rather than whether they were ''satisfied'' with their care.[116] Furthermore, we are unaware of any empirical evidence demonstrating that failing to prescribe opioids lowers a hospital's HCAHPS Survey scores. However, we believe the potential confusion about the appropriate use and interpretation of the Pain Management questions, coupled with the public health concern about the opioid epidemic, warrants refinement to the existing Pain Management questions. As outlined above, we received multiple suggestions for alternate wording of the Pain Management questions. We appreciate the alternative survey question wording submitted by numerous commenters and will consider them for future use. In some instances, we have given consideration to similar concepts and formulations, but we note that for use in relatively short, national surveys of patient experience of care, items must be widely applicable, simple, clear, easily understood, and unambiguous.

As discussed in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79855 through 79862), and in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20035), in developing the proposed refined Pain Management questions, we have followed our standard survey development processes, working with our contractors, which included drafting alternative questions, cognitive interviews and group evaluation, field testing, statistical analysis, empirical testing in a large-scale experiment, and soliciting stakeholder input. We conducted interviews with providers and patients as well as cognitive testing with patients.

We developed and submitted two measures related to the refinement of the pain management questions for consideration by the MAP and, subsequently, narrowed consideration to just one measure, ''Communication about pain during the hospital stay,'' withdrawing the measure ''Communication about pain after

[116] HCAHPS Fact Sheet available at: *http://www.hcahpsonline.org/Facts.aspx.*

discharge.''[117] The proposed refined Communication About Pain composite measure has proceeded through the pre-rulemaking process, including addition onto the ''Measures Under Consideration'' list and review by the MAP, as well as notice-and-comment rulemaking through this final rule. Furthermore, we intend to seek NQF endorsement for the proposed refined Pain Management questions. We believe the proposed refined pain management questions as formulated shift focus from the method of pain management to patient-centered communication between provider and patient.

Moreover, we cognitively tested with both English- and Spanish-speaking patients how the words ''treat,'' ''manage,'' and ''reduce'' pain were interpreted. After assessing the results, we decided we decided to use ''treat'' in the refined Communication About Pain composite measure.

While we appreciate the suggestion, we believe that use of the word ''comfort'' may lead to more misunderstanding than use of the word ''pain'' because the concept of ''comfort'' is even more subjective than the concept of the word ''pain.'' Finally, in response to the commenter's suggestion that the Pain Management questions be modified to explicitly include the type of clinical staff communicating with the patient, doing so would entail adding more questions to the survey, which would result in an increase in the length and complexity of the survey, and thus, also increase the burden for both patients and hospitals, which we believe is inadvisable and unnecessary.

Comment: Several commenters supported the refinements to the HCAHPS Survey measure pain management questions, but lacked confidence that simply including communication questions regarding pain management would reflect the true perception the patients have of their experience relative to pain management. These commenters encouraged CMS to continue to explore other ways to ensure better measurement of patients' experience with pain management, such as including additional questions about whether hospital staff talked about alternatives to medication for pain management and clearly communicated to the patients the addictive potential of opioid medications. The commenters also expressed concerns the questions related to pain management pertain only to whether the caregiver discussed the patient's pain but do not reflect the patient's engagement in this discussion.

Several commenters recommended incorporating concepts of care quality for pain management, such as: (1) The degree to which hospital staff listened to patients and responded to their pain (including offering non-opioid or non-medication options); and (2) the degree to which patients felt the hospital staff helped them understand their options to manage their pain.

Response: We thank the commenters for their support. In the comments received, there was broad support for shifting the focus of the pain management questions in the HCAHPS Survey from assessment of the adequacy and effectiveness of pain control efforts among patients who needed medicine for pain, to assessment of the frequency of hospital staff's efforts to talk about pain and its treatment among patients who experienced pain during their hospital stay. We continue to believe pain control is a critical part of routine patient care that hospitals should manage and is an important concern for patients, their families, and their caregivers.

With respect to how pain is captured and monitored, we believe that adequate pain management is an important goal for hospitals and a concern of patients and consumers. By focusing directly on communication about pain with the patient, we believe that the refined Communication About Pain composite measure will encourage and enhance hospital staff's discussions with patients about patients' particular circumstances while reducing the potential for misinterpretation that could lead hospital staff to using inappropriate treatment. During measure development, in the 2016 HCAHPS mode experiment, we tested a question that asked patients about various non-prescription pain treatments. However, the question did not meet statistical criteria for acceptability,[118] and could cause providers to infer that these treatments are appropriate for every patient. We will continue to evaluate this question for possible future inclusion as a question on the HCAHPS Survey.

In addition, regarding the comment raising concerns that the questions pertain only to whether the caregiver discussed the patient's pain, but do not reflect the patient's engagement in this discussion, we had tested different words during measure development to determine which would give better responses. Through cognitive interviews with patients and interviews with providers, we have learned that ''talking'' with hospital staff about how much pain the patient had or how to treat pain indicated greater patient engagement than did ''discussing'' or ''telling'' patients.

Furthermore, although important, Pain Management is only one of nine aspects of patient experience explored by the HCAHPS Survey. Because parsimony and brevity are fundamental to the success of the survey, we believe there are limits on the number and specificity of the questions that can be devoted to any particular topic. Therefore, we had to balance brevity with utility in determining the ultimate version of the refined Communication About Pain composite measure questions. However, we will take into consideration commenters' suggestions for the future and continue to investigate effective means of exploring patients' pain management experience and ways to ensure better measurement of patients' experiences with pain management.

Comment: One commenter believed these answers still would not provide much real, significant information about the patients' experience or provide information about whether their pain was addressed. The commenter suggested formulating questions that focus on patient function and regular assessment and treatment of their overall status rather than solely on their pain. A few commenters suggested that the Communication About Pain composite measure reflect current best practice for both acute and chronic pain, which is the use of multi-modal therapy and poly-pharmacy. The commenters suggested that treating pain using different receptors and mechanisms not only allows for the reduction of opioid use and morbidity, but allows an opportunity to optimize the patient's pain experience. One commenter recommended the HCAHPS Survey measure's pain management questions should capture whether this multi-modal pain pathway process happened during a hospitalization.

Response: We note that some stakeholders have criticized the current Pain Management questions because they believed that asking patients who needed medicine for pain how often their pain was well controlled and how often hospital staff did everything they could to help with pain had the unintended consequence of creating pressure on physicians to over-prescribe opioid treatment for pain. In response to

[117] List of Measures Under Consideration for December 1, 2016.'' Available at: *https://www.qualityforum.org/Projects/i-m/MAP/2016_Measures_Under_Consideration_List.aspx.*

[118] ''Development of a New *Communication About Pain* Composite Measure for the HCAHPS Survey,'' *http://www.hcahpsonline.org/modeadjustment.aspx.*

this criticism, in the face of a national epidemic of overuse of opioids, the refined Communication About Pain questions shift the focus from patient assessments of the adequacy and vigor of pain management efforts to the frequency of communication about pain and addressing the availability of treatments.

We agree that the concepts of care quality for pain management and use of multi-modal therapy and poly-pharmacy are important components in pain management for patients, as are differences in chronic and acute pain. In developing the new Communication About Pain measure, we explored these concepts in cognitive interviews and focus groups with patients. We note that the questions in the HCAHPS Survey were designed to be applicable to and easily understood by the wide spectrum of patients in American hospitals, and that its results are intended primarily for public reporting. As such, we are constrained to use questions in which the wording and intent are applicable and correctly understood by a wide spectrum of patients. However, we will consider use of multi-modal therapy and poly-pharmacy and other steps to address pain management, including additional questions about pain management in the HCAHPS Survey in the future.

Comment: Some commenters recommended further steps to address pain management including analysis of: (1) The complete care continuum to identify breakdowns in communication (such as insufficient medication reconciliation on admission) that lead to opioid misuse; (2) additional considerations (pre-admission pain, unclear guidance on pain management, failure of the provider to identify non-opioid approaches to pain management, etc.) that may affect the patient's pain management; and (3) enhancement of the Communication About Pain composite measure (MUC16–263) with additional questions related to pain.

Response: We acknowledge the commenters' recommendations that we analyze the complete care continuum to identify breakdowns in communication and additional considerations that may affect the patient's pain management, however, we note the HCAHPS Survey asks patients only about care experiences during a specific hospital stay. The HCAHPS Survey does not inquire about specific individuals, departments, or wards within the hospital. HCAHPS data submitted to us are patient de-identified. As such, it is not possible to link the patient or survey to anything that occurs pre-admission or post-discharge, or to clinical records, thus we are prevented from following patients through the continuum of care. Furthermore, as stated above, although important, Pain Management is only one of nine aspects of patient experience explored by the HCAHPS Survey. Because parsimony and brevity are fundamental to the success of the survey, we believe there are limits on the number and specificity of items that can be devoted to any particular topic. As noted above, we had to balance brevity with utility in determining the ultimate version of pain management questions proposed.

Comment: Another commenter urged CMS to revisit how pain is captured and monitored because asking only about the presence of pain does not provide enough information to improve an individual's overall quality of life. For example, pain levels may never change, even when the function/ability of the patient improves. Therefore, the focus on pain should be on how the patient's pain limits their functioning and physical abilities.

A few commenters suggested the focus of the revised HCAHPS pain questions include a discussion of patient safety options, as well as the effectiveness of the provided pain treatment options, as opposed to solely focusing on pain treatment options and suggested that CMS cannot effectively evaluate the efficacy of treatment merely by including a question that asks whether or not hospital staff discussed pain treatment. One commenter supported the proposed refinements to the HCAHPS Survey measure Pain Management questions, but recommended CMS also consider the measurement of an overall analgesia strategy as part of an enhanced recovery pathway (ERP).[119] The commenter noted that while the need for patient reported experiences in the management and communication of pain will continue to be critical, the ERP analgesia approach through enhanced recovery after surgery (ERAS) is a more comprehensive and patient-centered approach to optimize patient pain relief.

Response: In response to the commenters' concern that the Communication About Pain composite measure does not effectively evaluate the efficacy of treatment, the HCAHPS Survey is not intended to evaluate the efficacy of treatment. The refined Communication About Pain composite measure shifts the focus to communication with patients to promote more patient-centered care. As discussed earlier, in response to numerous public comments and out of an abundance of caution, we revised these pain management questions in the face of a nation-wide epidemic of opioid over-prescription. We believe that replacing the current Pain Management question in the HCAHPS Survey with revised questions that focus on the adequacy and frequency of communication about pain will remove any perceived ambiguity or confusion about the intent of the pain questions and enhance communication about the particular needs individual patients have with respect to pain. We hope the refined Communication About Pain questions will shift focus from the method of pain management to patient-centered communication between provider and patient.

We appreciate the commenter's suggestion that we consider the measurement of an overall analgesia strategy as part of an ERP, but the HCAHPS Survey was not intended or designed to ask patients about the efficacy or outcome of clinical care or treatment.

Comment: Some commenters supported the proposed refinements to the HCAHPS Survey measure, but expressed concern with frequency rating scale, observing that the response options do not seem to align realistically with the questions themselves. The commenters criticized the refined questions for being intangible and insufficient for the purpose of supporting beneficial initiatives tailored to promote pain management. Several commenters recommended changing from the ''Never-Always'' response scale to a ''Yes/No'' response option. One commenter expressed concerns about asking the frequency of the communications and not necessarily the quality or impact of the communication on the patient's perception of their pain control. The commenter urged CMS to shift from the physical experience of pain to focus more on communication about pain and ways to manage it, both pharmacological and non-pharmacological. Another commenter was concerned that the proposed refined Communication About Pain composite measure may inappropriately lead to scores that are not meaningful, specifically because the ''Never-Always'' response scale is unclear with respect to how patients or providers should assess the term ''Always.''

Response: We designed the refined Communication About Pain composite measure in conformance with CAHPS

[119] An ''Enhanced Recovery Pathway'' is a care pathway designed to achieve early recovery after surgical procedures. Definition ascertained from the American Association of Nurse Anesthetist, available at: *http://www.aana.com/resources2/professionalpractice/Pages/Enhanced-Recovery-After-Surgery.aspx.*

survey principles and the established format of the HCAHPS Survey, including asking patients about the frequency of communication rather than whether such communication had ever occurred. From its inception, HCAHPS has inquired about frequency of experiences and employed the ''Never-Always'' response options for most survey items. This scale and the associated structure of survey questions allows more granular responses than binary options such as ''Yes-No,'' and it is less susceptible to ceiling or floor effects, enhances commonality among survey questions, and maintains continuity over time. Testing of the HCAHPS Survey and other CAHPS surveys with patients and caregivers supports the understandability and utility of the ''Never-Always'' response scale.[120] Further, the development of the refined Communication About Pain composite measure was in response to stakeholder concerns that the existing survey items, which inquire about patients' assessment of the efficacy of pain management, unintentionally created pressure on physicians to over-prescribe opioid medications. Therefore, we decided to shift away from the patient's assessment of the efficacy of pain treatment and instead focus on whether providers communicated with patients about their pain.

Comment: One commenter supported the refinements to the HCAHPS Survey measure Pain Management questions, but recommended CMS also consider the measurement of an overall analgesia strategy as part of an ERP.[121] The commenter noted that while the need for patient reported experiences in the management and communication of pain will continue to be critical, the ERP analgesia approach through enhanced recovery after surgery (ERAS) is a more comprehensive and patient-centered approach to optimize patient pain relief.

Response: We appreciate the commenter's suggestion that we consider the measurement of an overall analgesia strategy as part of an ERP (a pathway for a surgical specialty), but the HCAHPS Survey was not intended or designed to ask patients about the efficacy or outcome of clinical care or treatment.

Comment: Several commenters supported the refinements to the HCAHPS Survey measure, but expressed concern about potential unintended consequences associated with the proposed refined Communication About Pain composite measure, given the toll of the opioid epidemic on communities. One commenter commended CMS for previously removing the HCAHPS Survey questions related to pain management from the Hospital VBP Program because it eliminated any perceived expectation that pain management should always include the use of powerful prescription drugs such as opioids. The commenter recommended CMS focus on overall patient satisfaction, rather than the granular level of detail currently included in many of the HCAHPS questions, and encouraged CMS to leave this level of patient satisfaction data to providers to determine and measure. Another commenter believed the changes would result in doctors and hospitals denying patients their needed pain medications.

One commenter cautioned CMS that hospital payment incentives under the Hospital VBP Program should not be structured in such a manner to cause hospitals to change their opioid prescribing patterns in order to achieve higher scores on the HCAHPS pain management dimension.

Another commenter expressed concern the refined Pain Management questions may inappropriately lead to scores that are not meaningful. The commenter suggested additional testing and understanding of these measures is needed prior to implementation.

A few commenters urged CMS to conduct regular assessments to ensure no unintended or inappropriate consequences on legitimate patient access to needed medicines arise as a result of the changes. These commenters encouraged CMS to continue to evaluate the proposed refined Communication About Pain composite measure for impact on HCAHPS scoring and resulting prescribing habits, including collecting more data for the measure. In addition, commenters cautioned that the proposed refined Communication About Pain composite measure should be carefully monitored for other unexpected and unintended consequences that may arise, including altering patient expectations and negatively impacting the doctor-patient relationship.

Finally, several commenters urged CMS not to continue to use the existing pain questions if the proposed refined Communication About Pain composite measure are not finalized, but rather remove the pain management questions from the HCAHPS Survey measure from quality programs because the existing pain management questions may pose unintended consequences.

Response: We thank the commenters for their support. As stated above, we are not aware of any scientific studies or empirical evidence that support an association between scores on the Pain Management questions and opioid prescribing practices. In addition, we do not believe that removing the pain questions from the HCAHPS Survey is appropriate because: (1) Many factors outside the control of our quality program requirements may contribute to the perception of a link between the Pain Management questions and opioid prescribing practices, (2) pain control is an appropriate part of routine patient care that hospitals should manage, and (3) pain control is an important concern for patients, their families, and their caregivers.[122] To confront the opioid epidemic in America, our agency and other divisions of HHS have launched a multi-dimensional effort.[123] Removing the Pain Management dimension from the HCAHPS component of the Hospital VBP Program and revising the Pain Management questions on the HCAHPS Survey are among those efforts. We believe refining the Pain Management questions in the HCAHPS Survey measure will: (1) Help remove any perceived ambiguity, and (2) shift focus from strictly considering the method of pain management to patient-centered communication between provider and patient.

With regard to the recommendation that we focus on overall patient satisfaction, rather than the granular detail featured in most HCAHPS questions, we do not agree. We always have believed the survey should cover a spectrum of patient experience, rather than focus on patient satisfaction. The HCAHPS Survey was designed to ask about specific aspects of patient experience of care (not patient satisfaction) that are important to patients and consumers and actionable by hospitals. For that reason, the survey delves into nine specific and actionable aspects of the hospitals experience,

[120] Development and Evaluation of the CAHPS Hospital Survey. Health Services Research. Special Issue. Volume 40, Number 6, Part II. December 2005.

[121] An ''Enhanced Recovery Pathway'' (ERP) is a care pathway designed to achieve early recovery after surgical procedures. Definition ascertained from the American Association of Nurse Anesthetist, available at: *http://www.aana.com/resources2/professionalpractice/Pages/Enhanced-Recovery-After-Surgery.aspx*.

[122] L. Tefera, W.G. Lehrman, and P. Conway. ''Measurement of the Patient Experience: Clarifying Facts, Myths, and Approaches.'' *Journal of the American Medical Association*. Published online, 3–10–16. *http://jama.jamanetwork.com/article.aspx?articleid=2503222*.

[123] HHS' Opioid Initiative, available at: *https://www.hhs.gov/sites/default/files/Factsheet-opioids-061516.pdf*, focuses on improving opioid prescribing practices, expanding access to medication-assisted treatment, and increasing the use of naloxone to reverse opioid overdoses.

including pain management. We note that the survey does contain two questions about the overall experience: (1) The patient's overall rating of the hospital; and (2) whether the patient would recommend the hospital. We continue to believe that it is valuable for providers to understand patient experience of care (not satisfaction with care) in actionable areas that are important to patients. We note that providers are not prevented from gathering additional information from patients for their own purposes.

We do not believe the refined Communication About Pain composite measure will lead to scores that are not meaningful because we believe, as noted earlier, that large-scale testing of the new Communication About Pain measure questions has demonstrated that they are valid and reliable. We have thoroughly tested and evaluated the proposed refined Communication About Pain composite measure. We refer readers to a summary of this analysis which can be found on the HCAHPS On-Line Web site: ''Development of a New *Communication About Pain* Composite Measure for the HCAHPS Survey,'' at *http://www.hcahpsonline.org/modeadjustment.aspx*. To briefly summarize the findings of that analysis, as detailed earlier, a two-item version of Communication About Pain composite measure based on how often staff talked about pain and how often staff discussed how to treat pain, preceded by a screener item asking whether the patient had any pain during the hospital stay, has strong psychometric properties. The properties of the individual items used in the proposed refined Communication About Pain composite measure themselves are as good as or better than the two Pain Management questions currently on the HCAHPS Survey. The refined Communication About Pain questions in which a preponderance of responses fall into the highest or lowest response category are not subject to floor or ceiling effects, have good (>0.80) or excellent (>0.90) hospital-level reliability at recommended sample sizes, are not redundant with the current items, are related in a predictable manner with the standard patient-mix characteristics, are predictive of the global Hospital Rating question on the HCAHPS Survey, question number 21, and do not vary systematically by survey mode after adjusting for patient mix. They also have high internal consistency as a composite (Cronbach's alpha=0.81).[124] We reiterate that the HCAHPS Survey is a valid and reliable instrument for assessing patient experience of care at the hospital level, however, use of the survey to measure and compare individual practitioners is strongly discouraged.[125]

We acknowledge the commenters' concerns about unintended or inappropriate consequences on legitimate patient access to needed medicines, and we will actively monitor and analyze responses to the proposed refined Communication About Pain composite measure to understand performance, relationship to other survey measures, and possible unintended consequences.

With respect to the commenter who believed the changes would result in doctors and hospitals denying patients their needed pain medications, the refined Communication About Pain questions no longer reference any specific pain treatment or circumstance but rather focus on communication about pain to address the concern that the current items may have had an unintended consequence of encouraging opioid-based treatment of pain. We will monitor use of the refined Communication About Pain questions and any feedback we receive from stakeholders as they implement these questions.

With respect to the commenter who cautioned that hospital payment incentives under the Hospital VBP Program should not be structured in such a manner to cause hospitals to change their opioid prescribing patterns in order to achieve higher scores on the HCAHPS pain management dimension, we note that in the CY 2017 OPPS/ASC PPS final rule with comment period (81 FR 79862), we removed the Pain Management dimension from the Hospital VBP Program beginning with the FY 2018 program year. We are not intending to adopt the refined Communication About Pain questions as part of the HCAHPS pain management dimension in the Hospital VBP Program at this time. In addition, we note that, as required under section 1890A of the Act, measures must be reviewed by a multi-stakeholder group (currently the MAP, convened by the NQF) before they can be proposed for adoption by a program.

Comment: Several commenters supported the refinements to the HCAHPS Survey measure pain management questions, but expressed concerns about the timing of implementation of the proposed refined Communication About Pain composite measure.

One commenter generally requested CMS allow pharmacists, physicians, and other members of the healthcare team sufficient time and opportunity to provide meaningful input and recommendations prior to finalizing and implementing the refinements.

Another commenter suggested transition to the revised wording begin with January 1, 2018 discharges, as proposed, would be feasible and would provide enough time for hospitals to properly prepare.

Response: We thank the commenters for their support. As discussed in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79855 through 79862), and the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20035), in developing the proposed refined Pain Management questions, we have followed our standard survey development processes, which include drafting alternative questions, cognitive interviews and group evaluations, field testing, statistical analysis, and soliciting stakeholder input. In addition, the proposed refined Pain Management questions have proceeded through the pre-rulemaking process, including adding the measures to the ''Measures Under Consideration'' list and having them reviewed by the MAP, as well as including them in notice-and-comment rulemaking. In addition, we intend to seek NQF endorsement for the proposed refined Pain Management questions. We believe that all of these processes have allowed pharmacists, physicians, other members of the healthcare team, and the public at large, time and opportunity to provide meaningful input and recommendations. With respect to the suggestion that we transition to the revised wording beginning with January 1, 2018 discharges, we note that our proposal stated that the revised questions would be implemented beginning with October of 2019 using CY 2018 data, which is what we are finalizing. In addition, implementation of the proposed refined Communication About Pain composite measure beginning with patients discharged January 1, 2018 will produce a full

[124] ''A Special Contribution from the Centers for Medicare and Medicaid Services: Valuing Patient Experience While Addressing the Prescription Opioid Epidemic.'' L. Tefera, W.G. Lehrman, E.G. Goldstein and S. Agrawal. *Annals of Emergency Medicine.* 2016. Published online, 7–19–16. *http://www.annemergmed.com/article/S0196-0644(16)30367-5/fulltext.*

[125] ''Measurement of the Patient Experience: Clarifying Facts, Myths, and Approaches.'' L. Tefera, W.G. Lehrman and P. Conway. *Journal of the American Medical Association.* 2016. 315: 2167–2168. Published online, 3–10–16. *http://jama.jamanetwork.com/article.aspx?articleid=2503222.*

calendar year of data, which will provide prompt feedback to hospitals on their performance on this measure via their confidential Preview Reports. We will make information about the Pain Management questions available to HCAHPS Survey vendors and hospitals through HCAHPS training and information posted on the HCAHPS On-Line Web site, *www.HCAHPSonline.org*.

Comment: A few commenters did not support the refinements to the HCAHPS Survey Pain Management questions because there is no peer-reviewed evidence to suggest a link between opioid prescribing and the current pain management questions in this survey, nor do the existing questions even specify opioids as the treatment of choice for pain. The commenters disagreed with CMS' assessment that the HCAHPS pain management questions influence clinical decision-making in a manner that creates pressure on hospital staff to prescribe more opioids in order to achieve higher scores. The commenters suggested that rather than recreating new medication-oriented pain questions to incorporate back into HCAHPS at some future date, CMS should develop questions in collaboration with pain and palliative medicine specialists to measure a hospital's overall pain management strategies.

Response: We agree with the commenters' assertions that neither is there any peer-reviewed evidence to suggest a link between opioid prescribing and the existing HCAHPS questions regarding pain, nor the existing questions even specify opioids as the treatment of choice for pain. As we stated above, we are not aware of any scientific studies that support an association between scores on the Pain Management questions and opioid prescribing practices. Furthermore, we are unaware of any empirical evidence demonstrating that failing to prescribe opioids lowers a hospital's HCAHPS Survey scores. However, we believe the potential confusion about the appropriate use of the Pain Management questions, coupled with the public health concern about the opioid epidemic, warrants refinement of the Pain Management questions. We will consider the commenter's suggestion to develop questions that assess a hospital's overall pain management strategies in future rulemaking.

The current Pain Management questions in the HCAHPS Survey apply to patients who needed medicine for pain; whereas, the proposed refined Communication About Pain composite measure will apply to patients who experienced any pain during the hospital stay. As such, when implemented, more patients will have the opportunity to answer the proposed refined Communication About Pain composite measure, providing a broader perspective on pain management in hospitals. As stated in previous responses, out of an abundance of caution, in the face of a nation-wide epidemic of opioid over-prescription, we have chosen to focus the proposed refined Communication About Pain composite measure on communication between hospital staff and patients about patients' pain. We believe this will emphasize the importance of communication about pain and its treatment while avoiding any potential inference that medication is the best or only way to treat pain.

The Communication About Pain measure questions were developed in collaboration with pain and palliative medicine specialists; we refer readers to our response earlier in this section that details the testing we undertook.

Comment: Some commenters noted treating pain should be the objective of physicians and should be managed exclusively within the physician's scope of practice. However, another commenter stated that patient experience and satisfaction should not be used for accountability purposes because these are often not directly under the control of the physician.

Response: We note that the HCAHPS Survey assesses patient experience of care at the hospital level, not the physician level. We strongly advise hospitals against using the HCAHPS Survey to measure, assess, and/or compare individual hospital staff.[126]

Comment: One commenter noted patients' experience of pain is subjective and uniform guidelines dictating pain management could contribute to patients suffering as a result. Another commenter stated that patient experience and satisfaction should not be used for accountability purposes as these are: (1) Often subjective in nature; and (2) not necessarily true indicators of quality of overall care.

Response: We believe the HCAHPS Survey measure is an appropriate mechanism for hospital accountability because patient experience of care is a valid and vital measure of provider quality across the healthcare spectrum and is an essential element of public reporting of provider quality and, where appropriate, a basic component of pay-for-performance programs. Carefully constructed and thoroughly tested surveys that attain high levels of reliability and validity, such as the CAHPS family of surveys,[127] when implemented in a standardized manner by trained survey vendors and hospitals subject to constant oversight, such as HCAHPS, produce information that allows fair comparisons of providers. Thus, we do not agree that pain/patient experience and satisfaction is subjective. Not only do surveys such as HCAHPS produce information about the patient's perspective that is beneficial in its own right, but a growing body of empirical research finds that hospitals that perform well on the HCAHPS Survey also perform well on indicators of clinical process, outcomes, readmissions, and mortality.[128]

We also refer readers to our response above in which we detail the testing these questions underwent. We also disagree that the HCAHPS Survey dictates pain management or contributes to patient suffering. We continue to believe many factors outside the control of our quality program requirements may contribute to the perception of a link between the Pain Management questions and opioid prescribing practices, such as misuse of the survey, use of the survey with patients other than hospital inpatients (such as, emergency room patients, outpatients, or physician office patients), disaggregation of surveys results to assess the performance of individual hospital staff, and/or failure to recognize the HCAHPS Survey excludes certain populations from the sampling frame.

Comment: Several commenters did not support the refinements to the HCAHPS Pain Management questions and recommended that the pain management questions in the HCAHPS Survey measure remain unchanged. These commenters did not believe changing the questions will address the real issue—whether or not a patient's pain was controlled. This is because the questions do not rate care based on how pain was managed and the questions do not to hold hospitals accountable for failing to manage patients' pain.

[126] L. Tefera, W.G. Lehrman, and P. Conway. ''Measurement of the Patient Experience: Clarifying Facts, Myths, and Approaches.'' *Journal of the American Medical Association.* Published online, 3–10–16. *http://jama.jamanetwork.com/article.aspx?articleid=2503222.*

[127] R.A. Price, M.N. Elliott, A.M. Zaslavsky, R.D. Hays, W.G. Lehrman, L. Rybowski, S. Edgman-Levitan and P.D. Cleary. ''Examining the Role of Patient Experience Surveys in Measuring Health Care Quality.'' Medical Care Research and Review, 71 (5): 522–554. 2014.

[128] P. Chatterjee, T.C. Tsai and A.K. Jha. Delivering Value by Focusing on Patient Experience. American Journal of Managed Care, Published Online: October 09, 2015. *http://www.ajmc.com/journals/issue/2015/2015-vol21-n10/delivering-value-by-focusing-on-patient-experience.*

One commenter generally referenced studies demonstrating patients get healthier faster and are less prone to secondary illness if their pain is sufficiently treated, and suggested that it is counter-intuitive that the proposed refined Communication About Pain composite measure does not assess any action taken to reduce pain. The commenter encouraged CMS to keep the existing pain questions, or modify the proposed refined Communication About Pain composite measure to focus on efforts or actions taken to reduce pain. In addition, several commenters noted discussions about pain are an inadequate substitute for effective pain treatment, arguing that attempting to reduce addiction is not a valid reason for causing patients to endure physical and psychological pain.

Response: As stated above, we believe pain management is an important component of the quality of care provided at a hospital, and we believe the HCAHPS Survey measure provides patients with critical information for use in selecting a hospital setting for their care, ensures hospitals continue to appropriately manage patients' pain, and encourages hospitals to engage in quality improvement efforts addressing pain management and communication about pain. We believe that replacing the current Pain Management questions in the HCAHPS Survey, which are addressed to patients who needed medicine for pain, with items addressed to patients who had any pain during their hospital stay and that are focused on the adequacy and frequency of communication about pain, will remove any ambiguity about the intent of the pain items and enhance communication about the particular needs individual patients have with respect to pain.

We disagree the current Pain Management questions should be retained because we believe refining the Pain Management questions will address any potential confusion about appropriate pain management. Moreover, we believe the proposed refined pain management questions will shift focus from the method of pain management to patient-centered communication between provider and patient.

As noted in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79855 through 79862), some stakeholders believe that the current Pain Management items' focus on the vigor and efficaciousness of pain control efforts creates pressure on physicians to over-treat pain, therefore, the proposed refined Communication About Pain composite measure does not delve into these topics. The shift in focus away from patients' assessment of treatment and outcomes and toward patient communication brings the Pain Management questions into closer alignment with the other survey items. We believe that placing greater emphasis on communication with patients about pain should encourage appropriate pain management. We reiterate the HCAHPS Survey is designed to produce valid measures of hospital-level performance, not that of individual physicians or nurses.

Comment: A few commenters urged CMS to move away from medication-based pain questions entirely.

Response: We continue to believe pain control is an appropriate part of routine patient care that hospitals should manage and is an important concern for patients, their families, and patient caregivers. We believe the proposed refined Communication About Pain questions appropriately focus more clearly on patient-focused care than on the method of pain management.

Comment: Many commenters did not support the refinements to the HCAHPS Survey measure pain management questions because they stated the proposed revised questions do not assure and reflect quality pain management, fail to objectively address the existence of pain, and remain ambiguous and open-ended. Several commenters recommended CMS restart the process of developing new pain management questions with additional testing and research prior to implementation of these proposed questions.

One commenter advised CMS to test a variety of questions and answer options to see which questions provide the most accurate data without negatively affecting patient care. Specifically, the commenter suggested CMS work with stakeholders to reach consensus on the intent of the pain measures to ensure there are no unintended consequences, the measures are understood by patients, and the measures lead to improved patient outcomes.

One commenter expressed concern that neither the existing nor the proposed refined pain management questions adequately reflect either shared decision making or adequate pain management. The commenter urged CMS to engage the patient and caregiver community in evaluating and refining the questions related to pain management.

Another commenter believed the proposed refined questions fail to promise resolution of all pain or suggest that pain treatment should always include any one particular mode of therapy. The commenter urged CMS to lead the way in incentivizing evidence based multi-modal pain care through development of alternative methods for assessing pain management in quality reporting programs. Conversely, another commenter noted that ''no pain'' is not always a reasonable goal and decreasing pain should be the expectation for the patient.

Response: We disagree that the revised questions do not assure and reflect quality pain management, fail to objectively address the existence of pain, and remain ambiguous and open-ended, and that we should restart the process of developing new pain management questions with additional testing and research prior to implementation. We believe the refined Communication About Pain questions have already undergone rigorous development and testing, and we refer readers to our response earlier in this section that details the testing we undertook.

We thank the commenters for their suggestion that we lead the way in incentivizing evidence based multi-modal pain care through development of alternative methods for assessing pain management in quality reporting programs, but we believe that while potentially valuable, these activities are beyond the scope of the HCAHPS Survey. We reiterate that the primary purpose of the HCAHPS Survey is to collect and report patient experience of care in hospitals, not to collect clinical information, promote particular therapies, report patient outcomes or create standards of care. During this communication between patients and providers, reasonable pain goals should be addressed. Although ''no pain'' is not always an achievable outcome, the intent of the measure is to establish this frequent communication to achieve reasonable, mutually agreed upon pain goals. We will consider additional methods for assessing pain management in quality reporting programs and for incentivizing evidence-based multi-modal pain care in the Hospital IQR Program in the future.

Comment: One commenter recommended CMS consider proxy reporting as a subsequent change to the HCAHPS Survey measure. The commenter noted that by allowing proxy reporting, CMS would have more complete information on the experience of care for all patients, rather than just those who are healthy enough to complete the survey.

Response: Although we have never permitted proxy respondents, meaning permitting any person other than the patient who experienced the hospital

stay to respond to the HCAHPS Survey on behalf of the patient, we recently collected and are in the process of analyzing test data, in which proxies were permitted. These analyses will provide information about whether to proceed with potential future changes to the survey. Pending results of these analyses, we may consider allowing proxy reporting in the future.

Comment: One commenter urged CMS to carefully consider whether measures in general add value and improve overall patient care before including them in payment or public reporting programs.

Response: We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53510 through 53512) for a discussion of the considerations we use to expand and update quality measures under the Hospital IQR Program. With regard to the proposed refined Communication About Pain composite measure, and the HCAHPS Survey in general, we believe these improve overall patient care and add value to public reporting programs. Pain management is an important component of the quality of care provided at a hospital, and we believe public reporting of hospital rates on the HCAHPS Survey Pain Management questions provides patients with critical information for use in selecting a hospital setting for their care, ensures hospitals continue to appropriately manage patients' pain, and encourages hospitals to engage in quality improvement efforts addressing pain management and communication. We continue to believe pain control is a critical part of routine patient care that hospitals should manage and is an important concern for patients, their families, and their caregivers, and we continue to explore ways to ensure better measurement of patients' experiences with pain management.

Comment: One commenter recommended CMS distinguish between hospice care (which usually occurs in the last six months of a patient's life) and palliative care (which could occur at any time during a patient's life and could re-occur at any time as well).

Response: The HCAHPS Survey only asks about patient experience of care during a hospital stay. In addition, patients who are discharged to hospice care are not eligible to receive the HCAHPS Survey. We have implemented a separate survey for patient experience of care in hospices.

After consideration of the public comments we received we are finalizing our proposed refinements to the HCAHPS Survey measure pain management questions as proposed, with a modification regarding public display. Instead of publicly reporting results beginning with October of 2019 using CY 2018 data as proposed, we are delaying public reporting, such that hospital performance data on the refined Communication About Pain composite measure questions will not be publicly reported on the *Hospital Compare* Web site until October of CY 2020, using CY 2019 data. We will provide performance results, based on CY 2018 data on the refined Communication About Pain composite measure questions to hospitals in confidential preview reports, upon the availability of four quarters of data. We anticipate that these confidential preview reports would be available as early as July 2019.

b. Refinement of the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Ischemic Stroke Hospitalization Measure for the FY 2023 Payment Determination and Subsequent Years

(1) Background

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20039 through 20043), for the FY 2023 payment determination and subsequent years, we proposed a refinement of the CMS Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) following Acute Ischemic Stroke Hospitalization Measure (hereafter referred to as the Stroke 30-Day Mortality Rate measure) by changing the measure's risk adjustment to include stroke severity (Stroke 30-Day Mortality Rate with the refined risk adjustment) obtained from International Classification of Disease, Tenth Edition Clinical Modifier (ICD–10–CM) codes in the administrative claims. The current Stroke 30-Day Mortality Rate measure was finalized in the Hospital IQR Program in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50798). The previously adopted measure includes 42 risk variables, but does not include an assessment of stroke severity because, previously, it has not been available in claims data and was not routinely performed by all providers. For more details on the measure as currently adopted and implemented, we refer readers to its measure methodology report and measure risk-adjustment statistical model in the AMI, HF, PN, COPD, and Stroke Mortality Update zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57161), we considered potential inclusion of the National Institutes of Health (NIH) Stroke Scale for the Hospital 30-Day Mortality Following Acute Ischemic Stroke Hospitalization measure beginning as early as the FY 2022 payment determination. Commenters generally supported the inclusion of the NIH Stroke Scale score in the Stroke 30-Day Mortality Rate measure for future inclusion in the Hospital IQR Program. We refer readers to FY 2017 IPPS/LTCH PPS final rule (81 FR 57161 through 57163) for a complete discussion of the considered potential measure, public comments, and our responses.

Initial assessment of stroke severity, such as the NIH Stroke Scale score, is one of the strongest predictors of mortality in ischemic stroke patients,[129] [130] [131] and is part of the national guidelines on stroke care.[132]

This measure refinement was developed in collaboration with the American Heart Association (AHA) and American Stroke Association (ASA). We are seeking to update the current measure to include an assessment of stroke severity, because it has become feasible to do so due to both the increased use of the NIH Stroke Scale related to the AHA/ASA guidelines that recommend administering the NIH Stroke Scale on all stroke patients, as well as due to the recent ability to obtain the scores through claims data by incorporation into ICD–10. The proposed refinement would create a more parsimonious risk model by reducing the total number of risk adjustment variables from 42 to 20 and includes the NIH Stroke Scale [133] in the risk-adjustment model as a measure of stroke severity. These refinements result in a modestly higher c-statistic,[134] a measure of the ability to discriminate between patients at low and high risk of mortality following ischemic stroke,

[129] Fonarow GC, Saver JL, Smith EE, et al. Relationship of national institutes of health stroke scale to 30-day mortality in medicare beneficiaries with acute ischemic stroke. *J Am Heart Assoc.* Feb 2012;1(1):42–50.

[130] Nedeltchev K, Renz N, Karameshev A, et al. Predictors of early mortality after acute ischemic stroke. *Swiss Medical Weekly.* 2010;140(17–18):254–259.

[131] Smith EE, Shobha N, Dai D, et al. Risk score for in-hospital ischemic stroke mortality derived and validated within the Get With The Guidelines-Stroke Program. *Circulation.* Oct 12 2010;122(15):149615041496–1504.

[132] Jauch EC, Saver JL, Adams HP, Jr., et al. Guidelines for the early management of patients with acute ischemic stroke: A guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke.* Mar 2013;44(3):870–947.

[133] NIH Stroke Scale. Available at: *http://www.nihstrokescale.org/.*

[134] C-Statistic Definition available at: *http://www.statisticshowto.com/c-statistic/.*

compared with the risk-adjustment model in the current Stroke 30-Day Mortality Rate, which means the updated measure model differentiates the risk of mortality among patients better than the current model.

Mortality following stroke is an important adverse outcome which can be measured reliably and objectively and is influenced by both the severity of the stroke as well as the quality of care provided to patients during their initial hospitalization; therefore, mortality is an appropriate measure of quality of care following stroke hospitalization.[135] [136]

Specifically, post-stroke mortality rates have been shown to be influenced by critical aspects of care such as response to complications, speediness of delivery of care, organization of care, and appropriate imaging.[137] [138] [139] [140]

We proposed a refinement to the Stroke 30-Day Mortality Rate for several reasons. First, the proposed, refined measure would allow for more rigorous risk adjustment by incorporating the NIH Stroke Scale, discussed in more detail below, as an assessment of stroke severity.[141] Second, the inclusion of the NIH Stroke Scale is aligned with and supportive of clinical guidelines, as use of the NIH Stroke Scale to assess stroke severity when patients first present with acute ischemic stroke is Class I recommended in the AHA and ASA guidelines.[142]

Third, in October 2016, the ICD–10–CM codes for the NIH Stroke Scale were implemented. As of that date, hospitals can record the NIH Stroke Scale as a representation of stroke severity in Medicare claims by using ICD–10–CM codes, and we can use this information as a variable in the risk-adjustment model for the refined Stroke 30-Day Mortality Rate measure and other claims-based measures with minimal data collection burden for hospitals.[143]

Fourth, clinicians and stakeholders, including AHA, ASA, and other professional organizations, highlight the importance of including an assessment of stroke severity in risk-adjustment models of stroke mortality.[144] In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50798 through 50802), commenters emphasized that the medical literature and their own experience suggest that stroke severity is the dominant predictor of mortality in stroke patients; individuals and organizations expressed concern the measure might be misleading, limited, or inaccurate without adjustment for stroke severity, and four comments suggested risk adjusting using the NIH Stroke Scale or a similar index (78 FR 50800).

Members of the Technical Expert Panel convened by the measure developer also suggested risk-adjusting for stroke severity. In addition, during the 2012 Neurology Endorsement Maintenance Consensus Development Project, the NQF Neurology Steering Committee specifically identified the lack of the NIH Stroke Scale score in the risk-adjustment model as a concern (78 FR 50800). Therefore, the refined Stroke 30-Day Mortality Rate is responsive to public comments from a broad array of stakeholder groups, including clinical societies and clinical experts, and to feedback received from the Technical Expert Panel convened by the measure developer (81 FR 57162).

Fifth, in addition to a modestly higher c-statistic, which evaluates the measure's ability to differentiate between patients at varying risks of mortality following an acute ischemic stroke, the refined Stroke 30-Day Mortality Rate includes a more parsimonious risk model than the stroke mortality measure as previously adopted and specified, with a total of 20 risk adjustment variables including the NIH Stroke Scale, compared to the current use of 42 risk adjustment variables.

In compliance with section 1890A(a)(2) of the Act, the Stroke 30-Day Mortality Rate (MUC15–294) with the refined risk adjustment (using the NIH Stroke Scale) was included on a publicly available document entitled ''List of Measures under Consideration for December 1, 2015'' (available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*. Select ''2015 Measures Under Consideration List.''). The MAP reviewed and conditionally supported the Stroke 30-Day Mortality Rate (MUC15–294) with the refined risk adjustment pending NQF review and endorsement, and asked that we consider a phased approach in regards to implementation, to avoid multiple versions of the same measure.[145] The MAP also noted outcomes other than mortality may be more meaningful for stroke patients and to consider cognitive or functional outcomes such as impaired capacity. We considered the input and recommendations provided by the MAP and note the NIH Stroke Scale incorporates cognitive functions in assessing severity.

To avoid implementing multiple versions of the same measure, we intend for the Hospital IQR Program FY 2023 payment determination measure set either to include the 30-day stroke mortality measure as currently implemented or this modified version that includes the NIH stroke severity scale in the measures risk-adjustment model.

The Stroke 30-Day Mortality Rate with the refined risk adjustment was submitted to NQF for endorsement in the neurology project on January 15, 2016, but did not obtain endorsement. NQF endorsement was not granted primarily due to the inability to test the validity of NIH Stroke Scale data elements derived from Medicare claims prior to implementation of the new ICD–10–CM codes in October 2016.[146] The NQF Consensus Standards Advisory Committee (CSAC) supported the concern of the NQF committee regarding our inability to test the measure using ICD–10–CM codes since

[135] Weir NU, Sandercock PA, Lewis SC, Signorini DF, Warlow CP. Variations between countries in outcome after stroke in the International Stroke Trial (IST). *Stroke.* Jun 2001;32(6):1370–1377.

[136] DesHarnais SI, Chesney JD, Wroblewski RT, Fleming ST, McMahon LF, Jr. The Risk-Adjusted Mortality Index. A new measure of hospital performance. *Med Care.* Dec 1988;26(12):1129–1148.

[137] Hong KS, Kang DW, Koo JS, et al. Impact of neurological and medical complications on 3-month outcomes in acute ischaemic stroke. *European journal of neurology: The official journal of the European Federation of Neurological Societies.* Dec 2008;15(12):1324–1331.

[138] Lingsma HF, Dippel DW, Hoeks SE., et al. Variation between hospitals in patient outcome after stroke is only partly explained by differences in quality of care: Results from the Netherlands Stroke Survey. [Reprint in Ned Tijdschr Geneeskd. 2008 Sep 27;152(39):2126–32; PMID: 18856030]. *Journal of Neurology, Neurosurgery & Psychiatry.* 2008;79(8):888–894.

[139] Reeves MJ, Smith E, Fonarow G, Hernandez A, Pan W, Schwamm LH. Off-hour admission and in-hospital stroke case fatality in the get with the guidelines-stroke program. *Stroke.* Feb 2009;40(2):569–576.

[140] Smith MA, Liou JI, Frytak JR, Finch MD. 30-day survival and rehospitalization for stroke patients according to physician specialty. *Cerebrovascular diseases (Basel, Switzerland).* 2006;22(1):21–26.

[141] NIH Stroke Scale. Available at: *http://www.nihstrokescale.org/*.

[142] Jauch EC, Saver JL, Adams HP, Jr., et al. Guidelines for the early management of patients with acute ischemic stroke: A guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke.* Mar 2013;44(3):870–947.

[143] ICD–10–CM Official Guidelines for Coding and Reporting. Available at: *https://www.cdc.gov/nchs/data/icd/10cmguidelines_2017_final.pdf*.

[144] Jauch EC, Saver JL, Adams HP, Jr., et al. Guidelines for the early management of patients with acute ischemic stroke: A guideline for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. Mar 2013;44(3):870–947.

[145] 2016 Spreadsheet of Final Recommendations to HHS & CMS Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*.

[146] The memo regarding the CSAC's decision is available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=83217*.

the codes were not implemented until October 2016. While we provided risk-standardized mortality rates using data from Medicare administrative claims and data from the Get With The Guidelines (GWTG)-Stroke Registry, the Committee noted we could not validate the National Institutes of Health Stroke Scale (NIH Stroke Scale) against ICD–10–CM codes at the time the measure was considered for endorsement. The CSAC also acknowledged the primary reason for upholding the Committee's decision was based on the lack of testing of the measure using ICD–10–CM codes. This measure went through the same rigorous development process as the other publicly reported outcomes measures and involved extensive input by stakeholders and clinical experts. It follows the same scientific approach to evaluate hospital performance as other Hospital IQR Program outcome measures.

When the NQF committee considered the scientific acceptability of the Stroke 30-Day Mortality Rate measure, 19 of 22 members voted the measure met the NQF's evidence criterion, 19 members voted the measure met the high or moderate standard for the Performance Gap, 18 members voted the measure met high or moderate standard for reliability, 19 members voted the measure met the high or moderate standard for feasibility, and 18 members voted the measure met the moderate standard for Use and Usability.[147] We tested and validated the measure using NIH Stroke Scale data derived from medical record review done by the GWTG-Stroke registry data supplied by AHA/ASA. However, the NQF committee ultimately determined the validity testing was not sufficient for endorsement.[148]

We believe the inclusion of the NIH Stroke Scale score in the measure's risk-adjustment model improves upon the Stroke 30-Day Mortality Rate measure which is currently publicly reported on *Hospital Compare* and has been implemented in the Hospital IQR Program since FY 2016 (78 FR 50802). This is supported by the improved risk-adjustment model performance. For example, the c-statistic, which is a measure of the ability to discriminate between patients at low and high risk of mortality following ischemic stroke, associated with the new, modified risk-adjustment model was 0.81 in the measure development sample[149] and improved to a c-statistic of 0.75 in the most recent measurement period for the Stroke 30-Day Mortality Rate measure that is currently implemented in the Hospital IQR Program.[150]

The new refined Stroke 30-Day Mortality Rate measure also has increased face validity which is supported by the comments received from stakeholders. For example, we received comments that the more rigorous risk adjustment facilitated by the NIH Stroke Scale would help ensure the measure accurately risk adjusts for different hospital populations without unfairly penalizing high-performance providers, and the NIH Stroke Scale is well validated, highly reliable, widely used by providers caring for stroke patients, and a strong predictor of mortality and short- and long-term functional outcomes. However, we were not able to test the ICD–10 CM codes for NIH Stroke Scale score in claims during measure development because those codes were not available for hospitals to use in their claims until October 2016. Therefore, we proposed this measure now to inform hospitals they should begin to include the NIH stroke severity scale codes in the claims they submit for patients with a discharge diagnosis of ischemic stroke. Once hospitals have submitted these data, it will be possible for us to examine the completeness of these data in re-evaluation of the new refined Stroke 30-Day Mortality Rate measure before the proposed measure dry run and before the proposed implementation in the Hospital IQR Program. Once that testing is complete we will submit the retested measure to the NQF for endorsement prior to implementation.

Section 1886(b)(3)(B)(IX)(bb) of the Act provides that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Although the proposed measure and the existing Stroke 30-Day mortality measure are not currently NQF-endorsed, we considered other available measures which have been endorsed or adopted by the NQF, and we were unable to identify any other NQF-endorsed measures that assess stroke mortality with a standard period of follow-up. We also are not aware of any other 30-day stroke mortality measures that have been endorsed or adopted by a consensus organization.

We proposed this measure now because we believe the modifications to the measure's risk-adjustment model represent a substantial improvement over the Stroke 30-Day Mortality Rate measure that is currently publicly reported and implemented in the Hospital IQR Program and which does not include an assessment of stroke severity in the risk-adjustment model. In addition, by announcing our intention to include the Refined 30-Day Stroke Mortality Rate measure in the Hospital IQR Program in advance of implementation for FY 2023 payment determination and subsequent years, and by describing the proposed additional testing, dry run, and our intent to re-submit the measure to NQF once the NIH Stroke Scale data become available in claims, we are providing information that hospitals should begin to plan and alter their clinical workflows and billing processes in order to capture the NIH Stroke Scale score and include it in Medicare claims. Further, this notice will allow hospitals to complete collecting NIH Stroke Scale data over the three-year time period needed for measure calculation and implementation prior to any payment adjustment. The measure, as refined, is described in more detail below.

(2) Overview of Refined Measure

The measure cohort is aligned with the currently adopted Stroke 30-Day Mortality Rate measure. In addition, the data sources (Medicare fee-for-service (FFS) claims), three-year reporting period, inclusion and exclusion criteria, as well as the assessment of the outcome of mortality (assessed using Medicare enrollment data) would all align with the currently adopted measure (78 FR 50798). Only the measures' risk-adjustment models differ, as described in detail below. For the new refined Stroke 30-Day Mortality Rate measure, we proposed the first measurement period would include discharges between July 1, 2018 and June 30, 2021 for public reporting in FY 2022 and for the FY 2023 payment determination.

[147] The memo regarding the CSAC's decision is available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=83217*.

[148] Schwartz J, Wang Y, et al. *Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Ischemic Stroke Hospitalization with Claims-Based Risk Adjustment for Stroke Severity Technical Report.* 2016.

[149] Schwartz J, Wang Y, et al. *Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Ischemic Stroke Hospitalization with Claims-Based Risk Adjustment for Stroke Severity Technical Report.* 2016.

[150] 2017 Condition-Specific Mortality Measures Updates and Specifications Report. Available at: *www.qualitynet.org* > Hospitals—Inpatient > Claims-Based Measures > Mortality Measures > Measure Methodology.

(3) Risk Adjustment

The Stroke 30-Day Mortality Rate measure that is currently adopted in the Hospital IQR Program adjusts for differences in patients' level of risk for death in one hospital relative to patients receiving care in another hospital but not for stroke severity. For details about the risk-adjustment model for the currently adopted measure, we refer readers to the Technical Report (78 FR 50798).[151]

However, in developing the proposed, refined Stroke 30-Day Mortality Rate measure, we re-selected risk variables, resulting in a final model with 20 risk-adjustment variables, including the NIH Stroke Scale risk variable as an assessment of stroke severity. The NIH Stroke Scale is a 15-item neurologic examination stroke scale used to provide a quantitative measure of stroke-related neurologic deficit. The NIH Stroke Scale evaluates the effect of acute ischemic stroke on a patient's level of consciousness, language, neglect, visual-field loss, extra-ocular movement, motor strength, ataxia (the loss of full control of bodily movements), dysarthria (difficult or unclear articulation of speech), and sensory loss. The NIH Stroke Scale was designed to be a simple, valid, and reliable assessment tool that can be administered at the bedside consistently by neurologists, physicians, nurses, or therapists, and is Class I recommended in the AHA/ASA guidelines.[152] The NIH Stroke Scale is a publicly available standardized tool, the results of which should be assessed by a clinician when first examining a patient presenting to the hospital with a stroke and subsequently documented in the patient's medical record. Once this information has been documented by a clinician, it can then be recorded in the claim for that hospital admission using ICD–10–CM codes through the hospital's normal coding practices.

We sought to develop a risk-adjustment model that included the NIH Stroke Scale variable and other key variables which we believe are clinically relevant and demonstrate a strong statistical association with 30-day mortality. To select candidate variables, we considered those 42 risk-adjustment variables in the currently adopted measure, plus the NIH Stroke Scale as candidate variables. We then performed a bootstrapping simulation method for variable selection. This bootstrapping simulation method is a means of creating multiple samples to determine which risk variables are most important to include in a model. We selected the best model using the logistic regression model with the stepwise selection method based on 1,000 bootstrapping samples for each copy of the multiple imputed (MI) data. Variable selection rate for all the variables selected into the best model was calculated for each copy of the MI data, and variables were included into the final model if the minimum variable selection rate among the 5 copies of MI was 90 percent or more. This method resulted in 20 risk-adjustment variables that were included more than 90 percent of the time for all the copies of the imputed data were retained in the final model, including the NIH Stroke Scale. For more details on the risk-adjustment variable selection process, we refer readers to the measure methodology report and measure risk-adjustment statistical model in the AMI, HF, PN, COPD, and Stroke Mortality Update zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

Refining the risk adjustment model of the Stroke 30-Day Mortality Rate created a modestly higher c-statistic with fewer risk variables, meaning the proposed, refined measure's risk-adjustment model better distinguishes among patients with a low risk and high risk of mortality following ischemic stroke compared with the Stroke 30-Day Mortality Rate measure that is currently implemented in the Hospital IQR Program. Including the NIH Stroke Scale in the risk-adjustment model allows the measure to more accurately account for patients' status upon arrival at the hospital, which is responsive to clinical guidelines and feedback from the medical community and other stakeholders, as discussed above.

In order to use the NIH Stroke Scale data in the proposed, refined Stroke 30-Day Mortality Rate measure, many hospitals that have not routinely captured these data on patients with ischemic stroke will need to implement new workflows to ensure that their clinicians measure and record stroke severity. In addition, hospital coders will need to include the appropriate ICD–10 code for the clinician's documented NIH Stroke Scale score in the Medicare claim. By proposing this measure, we are providing hospitals the information and advanced notice that they would be required to submit this information in their Medicare claims for this proposed, refined Stroke 30-Day Mortality Rate measure.

(4) Effect of ICD–10

New ICD–10 codes for the NIH Stroke Scale were implemented on October 1, 2016; these codes were included so that hospitals could characterize the severity of their patients' strokes using a rigorously validated and standardized approach and include that information in claims and for quality measurement purposes.[153] However, because there were previously no ICD–9 or ICD–10 CM codes for the NIH Stroke Scale scores, hospitals have not previously included this information on claims they submit to CMS. In order to have information on the severity of patients' ischemic stroke included in the calculation Stroke 30-Day Mortality Rate, some hospitals that do not currently capture or record the NIH Stroke Scale would have to create workflows and processes to do this. This additional work, however, is consistent with current clinical guidelines for the care of ischemic stroke patients, and are consistent with the standard of care. Implementation of the proposed, refined Stroke 30-Day Mortality Rate with the refined risk adjustment would require hospitals to document in the medical record the first NIH Stroke Scale on every eligible patient who is admitted for treatment of acute ischemic stroke and provide that information among the ICD–10–CM code recorded on the claim. The new ICD–10–CM code representing the NIH Stroke Scale will be included in the risk adjustment model for the Stroke 30-Day Mortality Rate measure.

Because many hospitals would have to create new clinical workflows to assess and document the NIH Stroke Scale in patients' medical records as well as include the appropriate ICD–10–CM code for the documented NIH Stroke Scale score in the claim they submit, we would provide hospitals with dry run results of this proposed, refined measure in their confidential hospital-specific feedback reports prior to implementation of the proposed, refined measure for the FY 2023 payment determination. For example, we anticipate using claims data, which would include ICD–10–CM codes for the NIH Stroke Scale, for discharges occurring between October 1, 2017 through June 30, 2020, to calculate measure results for the dry run

[151] Bernheim S WC, Want Y, et al. *Hospital 30-Day Mortality Following Acute Ischemic Stroke Hospitalization Measure Methodology Report.* 2010.

[152] Jauch EC, Saver JL, Adams HP, Jr., et al. Guidelines for the early management of patients with acute ischemic stroke: A guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke.* Mar 2013;44(3):870–947.

[153] ICD–10–CM Official Guidelines for Coding and Reporting. Available at: *https://www.cdc.gov/nchs/data/icd/10cmguidelines_2017_final.pdf.*

anticipated in CY 2021.[154] The data in the confidential hospital-specific feedback reports would not be publicly reported.

We invited public comment on our proposal to adopt a refinement of the Stroke 30-Day Mortality Rate in the Hospital IQR Program for the FY 2023 payment determination and subsequent years as discussed above.

Comment: Many commenters supported the proposed refinement to the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate following Acute Ischemic Stroke Hospitalization (Stroke Mortality Measure) measure to include the NIH Stroke Scale as a measure of stroke severity beginning with the FY 2023 payment determination. One commenter believed the proposed refinements would provide an opportunity to better evaluate hospital performance and would not add additional reporting burden to providers. Another commenter believed the proposed refinements represent a significant improvement of the measure as it is currently reported because the more parsimonious and discriminating risk model would greatly enhance the accuracy of reporting and classifying the performance of hospitals.

Response: We thank the commenters for their support.

Comment: Some commenters acknowledged that while switching from ICD–9 to ICD–10 codes allowed for more robust coding, they were concerned about reliability and accuracy of ICD–10 coding, and comparability across sites. They requested CMS field test the measure using the new ICD–10 codes. Many commenters recommended that CMS fully test the refined measure using ICD–10 codes that included the NIH Stroke Scale and resubmit the measure for NQF-endorsement prior to implementation. Several commenters supported the proposed refinements to the Stroke Mortality measure, but asked that CMS not adopt this measure until it was endorsed by NQF.

Response: Regarding the commenters' concern about the reliability and accuracy of ICD–10 coding and the comparability across sites, the refined stroke measure which includes stroke severity was developed and tested exclusively with ICD–9-coded claims.

However, we note that we have completed extensive testing of the current stroke mortality measure specifications in ICD–10 coded claims and of measure performance in the 3-year measurement period, which includes a combination of ICD–9 and ICD–10 coded claims.[155] The measure cohort sizes and number of hospitals with publicly reported results are similar, and the national and hospital-level measure results as well as the performance of the risk-adjustment model are similar to the results observed when calculating the measure with only ICD–9 coded-claims in previous reporting years. Results of some of this testing are described in the publicly available 2017 Annual Updates and Specifications Report Hospital-Level 30-Day Risk-Standardized Mortality Measures.[156] In addition, consistent with the commenters' request, we do plan to further test the refined measure using ICD–10 codes. The ICD–10–CM codes for the NIH Stroke Scale were implemented in October 2016, so we were not able to test the ICD–10–CM codes for NIH Stroke Scale score during measure development. However, since the ICD–10–CM codes for the NIH Stroke Scale have been available since October 2016 for use in claims, it will be possible for us to examine these data under the refined Stroke 30-Day Mortality Rate measure before both the measure dry run and implementation in the Hospital IQR Program.

Similarly, because the ICD–10 code system was implemented in October 2015, there were insufficient claims coded with ICD–10 (and the NIH Stroke Scale) submitted by hospitals to provide any testing results to NQF during the endorsement process in 2016.

We will submit testing results in claims data coded using ICD–10 codes in future cycles of NQF endorsement, as discussed in our proposal above. We plan to re-submit this measure to NQF for endorsement once we have adequate NIH Stroke Scale data from hospitals, which we anticipate will be prior to the FY 2023 payment determination. In addition, we will continue to assess the measure, including risk adjustment and model performance, as part of annual re-evaluation as the three-year measurement period includes a greater proportion of ICD–10 coded data over time. However, we did not want to delay finalization of the refined measure beginning with the FY 2023 payment determination because this provides hospitals with additional time to prepare for the implementation, which is generally perceived as an improvement in the measure by the stakeholder community.

Furthermore, as discussed above in our proposal, we note that section 1886(b)(3)(B)(IX)(bb) of the Act provides that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Although the proposed refined measure and the existing Stroke 30-Day mortality measure are not currently NQF-endorsed, we considered other available measures which have been endorsed or adopted by the NQF, and we were unable to identify any other NQF-endorsed measures that assess stroke mortality with a standard period of follow-up.

Comment: Some commenters believed delaying implementation would allow hospitals time needed to implement new workflows to ensure that clinicians measure and record stroke severity, as many hospitals have not routinely captured the NIH Stroke Scale data.

Response: We acknowledge hospitals need time prior to implementation of this measure since they have not previously included the NIH Stroke Scale information on claims they submit to CMS, and many hospitals will have to create new clinical workflows to assess and document the NIH Stroke Scale in patients' medical records as well as include the appropriate ICD–10–CM code in their administrative claims. In an effort to provide hospitals with more time to prepare for the use of ICD–10 stroke severity codes, in FY 2017 IPPS/LTCH PPS final rule (81 FR 57161), we included a detailed discussion of the refined Stroke 30-Day Mortality Rate measure, which included the NIH Stroke Scale as a measure of stroke severity, as a measure for future consideration. In addition, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20043), we proposed the refined measure for the FY 2023 payment determination and subsequent years, affording hospitals multiple years to prepare. We also discussed conducting a dry run prior to implementation, in

[154] We note that we have made a correction to the date provided here. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20043), a typographical error resulted in the date of June 1, 2020; however, we have corrected the date within the preamble of this final rule to reflect the correct time period that will be used to calculate measure results for the dry run.

[155] Testing results found in the ''AMI, HF, PN, COPD and Stroke Mortality Update'' zip file, available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[156] 2017 Condition-Specific Mortality Measures Updates and Specifications Report. Available at: *www.qualitynet.org* > Hospitals—Inpatient > Claims-Based Measures > Mortality Measures > Measure Methodology.

which hospitals would receive dry run results in their confidential hospital-specific feedback reports a year prior to the measure being implemented and publicly reported in the Hospital IQR Program. For the dry run anticipated in CY 2021, we intend to calculate the measure by using discharges occurring between October 1, 2017 through June 30, 2020.

Comment: One commenter requested clarification on which NIH Stroke Scale assessment to use, since clinical personnel can record stroke scale scores at regular intervals on each patient should the NIH Stroke Scale be implemented.

Response: The intent of the risk adjustment for stroke severity is to account for patients' clinical status at the time they are admitted to the hospital. Therefore, the refined Stroke 30-Day Morality Rate measure would utilize only the initial NIH Stroke Scale score, which is administered upon admission. We refer readers to the current clinical guidelines describing the qualifications and appropriate administration of the NIH Stroke Scale.

Comment: One commenter was concerned that since registry data was used as a proxy for EHR data, CMS should test whether the measure captures valid data.

Response: We would like to clarify that while this measure was developed using data from Medicare administrative claims and GWTG-Stroke Registry, the Stroke 30-Day Mortality Rate measure uses the NIH Stroke Scale obtained from ICD–10 codes, and not from electronically submitted EHR data. In addition, we intend to conduct at least one dry run prior to the measure being implemented in order to ensure that enough hospitals are submitting data on stroke severity to be used in measure risk adjustment given that the original measure testing was done using registry data as a surrogate source of NIH Stroke Scale.

Comment: One commenter encouraged CMS to recognize the value of the NIH Stroke Scale in future measures for the Hospital IQR Program, including measures that promote the use of the tool throughout the stages of care of a patient. Another commenter suggested if a measure of stroke mortality is proposed for any other CMS program, CMS require use of the NIH Stroke Scale in that measure. One commenter recommended CMS consider this refined stroke mortality measure for the Hospital VBP Program.

Response: We thank the commenters for their suggestions. We will take these suggestions for future measures and other CMS programs into consideration in future rule-making.

Comment: Several commenters recommended that CMS consider moving up the proposed year of implementation for the refinement of the Stroke Mortality measure from the FY 2023 payment determination to the FY 2022 payment determination. The commenters believed that one year of preparation for hospitals to put the processes in place for documenting and coding for the NIH Stroke Scale is adequate. In addition, the commenters requested that CMS generate a parallel report that includes the NIH Stroke Scale for hospitals to track their progress on achieving completeness of documentation and coding beginning in FY 2018.

Response: We thank the commenters for their support, however, we want to allow hospitals sufficient time to adjust their clinical workflows to capture the NIH Stroke Scale and include it in their claims. We believe adopting the Stroke 30-Day Mortality Rate measure in the Hospital IQR Program beginning with the FY 2023 payment determination (using discharges occurring between July 1, 2018 through June 30, 2021) appropriately balances the need to implement this substantive improvement to the measure with allowing time for hospitals to prepare for the use of ICD–10 stroke severity codes if they are not already doing so.

With regards to a parallel report that includes the NIH Stroke Scale for hospitals to track their progress, we believe the confidential hospital-specific feedback reports will achieve this. The hospital-specific report (HSR) generally includes a hospital's results, summary results from other hospitals in the State and the nation, discharge-level data for all eligible discharges, and the prevalence of risk factors for a hospital's patients compared to State and national averages. In addition, we intend that the reports for the refined measure will include an enumeration of each hospital discharge with a principal diagnosis of ischemic stroke along with the NIH Stroke Scale code included in the Medicare claim sent to CMS, as well as each hospital discharge if no NIH Stroke Scale code is included. This will allow hospitals to explore processes and workflows involving capture and reporting of NIH Stroke Scale codes in their claims, and avoid having an additional, separate report run during the same time period specifically for the hospital's NIH Stroke Scale.

Comment: Several commenters requested the measure add risk adjustments for tPA (tissue plasminogen activator) administration or thrombectomy, and for socio-demographic (SDS) factors.

Response: We thank the commenters for their input. The measure seeks to adjust for case mix differences among hospitals based on the clinical status of the patient at the time of the index admission. We do not generally adjust the measures for actions taken by the hospital, such as administration of tPA, as such factors may be related to the quality of care rather than patient factors.

In addition, we understand social risk factors such as income, education, race and ethnicity, employment, disability, community resources, and social support (certain factors of which are also sometimes referred to as socioeconomic status (SES) factors or socio-demographic status (SDS) factors) play a major role in overall health. As noted in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57124), the NQF has undertaken a 2-year trial period in which new measures, measures undergoing maintenance review, and measures endorsed with the condition that they enter the trial period can be assessed to determine whether risk adjustment for selected social risk factors is appropriate for these measures. This trial entailed temporarily allowing inclusion of social risk factors in the risk-adjustment approach for these measures. This measure was considered for endorsement during the trial period. The results of the analyses presented to the committee demonstrated that the SES variables that could be feasibly incorporated into this model only have a small, though statistically significant, relationship with the outcome in multivariable modeling and that adding them in the risk model did not change hospitals' mortality rates.[157] Although the measure was not recommended for endorsement, the exclusion of social risk factors from the risk-adjustment model was not among the concerns raised by the committee.[158] We also refer readers to section IX.A.1.d. of the preamble of this final rule where SDS is discussed in more detail.

Comment: One commenter noted this measure excludes patients under age 65, which impacts its generalizability to all stroke patients.

Response: The measure only includes admissions of Medicare FFS beneficiaries aged 65 years or older who were discharged from an inpatient stay

[157] *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=80601.*

[158] *Ibid.*

at a short-term acute care hospital.[159] The measure does not include Medicare patients who are younger than 65 because these patients usually qualify for the program due to severe disability and, thus, are considered to be clinically distinct from Medicare patients 65 and over. Furthermore, this refined measure has not been tested on a population under 65. With respect to the generalizability of the measure to all stroke patients, we are unable to comment on the appropriateness of the use of the measure in data other than the Medicare data for which it was developed.

After consideration of the public comments we received, we are finalizing our proposal to refine the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate following Acute Ischemic Stroke Hospitalization (Stroke Mortality Measure) measure for the FY 2023 payment determination and subsequent years as proposed.

c. Summary of Previously Adopted and Finalized Hospital IQR Program Measures for the FY 2020 Payment Determination and Subsequent Years

The table below outlines the Hospital IQR Program measure set (including previously adopted measures and finalized refinements from this final rule) for the FY 2020 payment determination and subsequent years. The refined measures, as discussed above, are denoted with a superscript as defined in the legend below the table.

PREVIOUSLY ADOPTED HOSPITAL IQR PROGRAM MEASURES FOR THE FY 2020 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Short name	Measure name	NQF #
Healthcare-Associated Infection Measures		
CAUTI	National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.	1717
CLABSI	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI.	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
HCP	Influenza Vaccination Coverage Among Healthcare Personnel	0431
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	1716
Claims-Based Patient Safety Measures		
Hip/knee complications	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550
PSI 04	Death Rate among Surgical Inpatients with Serious Treatable Complications	0351
PSI 90	Patient Safety for Selected Indicators Composite Measure, Modified PSI 90 (Updated Title: Patient Safety and Adverse Events Composite).	0531
Claims-Based Mortality Outcome Measures		
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0230
MORT–30–CABG	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery.	2558
MORT–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1893
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization.	0229
MORT–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization.	0468
MORT–30–STK	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Ischemic Stroke*.	N/A
Claims-Based Coordination of Care Measures		
READM–30–AMI	Hospital 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0505
READM–30–CABG	Hospital 30-Day, All-Cause, Unplanned, Risk-Standardized Readmission Rate (RSRR) Following Coronary Artery Bypass Graft (CABG) Surgery.	2515
READM–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1891
READM–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Heart Failure (HF) Hospitalization.	0330
READM–30–HWR	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	1789
READM–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization.	0506
READM–30–STK	30-Day Risk-Standardized Readmission Rate Following Stroke Hospitalization	N/A

[159] Schwartz J, Wang Y, et al. *Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Ischemic Stroke Hospitalization with Claims-Based Risk Adjustment for Stroke Severity Technical Report.* 2016.

PREVIOUSLY ADOPTED HOSPITAL IQR PROGRAM MEASURES FOR THE FY 2020 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

Short name	Measure name	NQF #
READM–30–THA/TKA	Hospital-Level 30-Day, All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1551
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI).	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF).	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia.	2579
THA/TKA Payment	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty.	N/A
MSPB	Payment-Standardized Medicare Spending Per Beneficiary (MSPB)	2158
Cellulitis Payment	Cellulitis Clinical Episode-Based Payment Measure	N/A
GI Payment	Gastrointestinal Hemorrhage Clinical Episode-Based Payment Measure	N/A
Kidney/UTI Payment	Kidney/Urinary Tract Infection Clinical Episode-Based Payment Measure	N/A
AA Payment	Aortic Aneurysm Procedure Clinical Episode-Based Payment Measure	N/A
Chole and CDE Payment	Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment Measure.	N/A
SFusion Payment	Spinal Fusion Clinical Episode-Based Payment Measure	N/A
Chart-Abstracted Clinical Process of Care Measures		
ED–1 **	Median Time from ED Arrival to ED Departure for Admitted ED Patients	0495
ED–2 **	Admit Decision Time to ED Departure Time for Admitted Patients	0497
Imm–2	Influenza Immunization	1659
PC–01 **	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
VTE–6	Incidence of Potentially Preventable Venous Thromboembolism	(+)
EHR-Based Clinical Process of Care Measures (That is, Electronic Clinical Quality Measures (eCQMs))		
AMI–8a	Primary PCI Received Within 90 Minutes of Hospital Arrival	(+)
CAC–3	Home Management Plan of Care Document Given to Patient/Caregiver	(+)
ED–1**	Median Time from ED Arrival to ED Departure for Admitted ED Patients	0495
ED–2**	Admit Decision Time to ED Departure Time for Admitted Patients	0497
EHDI–1a	Hearing Screening Prior to Hospital Discharge	1354
PC–01**	Elective Delivery	0469
PC–05	Exclusive Breast Milk Feeding	0480
STK–02	Discharged on Antithrombotic Therapy	0435
STK–03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK–05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK–06	Discharged on Statin Medication	0439
STK–08	Stroke Education	(+)
STK–10	Assessed for Rehabilitation	0441
VTE–1	Venous Thromboembolism Prophylaxis	0371
VTE–2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Patient Experience of Care Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems *** (including Care Transition Measure (CTM-3) and Communication About Pain composite measure).	0166 (0228)
Structural Patient Safety Measures		
Patient Safety Culture	Hospital Survey on Patient Safety Culture	N/A
Safe Surgery Checklist	Safe Surgery Checklist Use	N/A

* Measure refinement of the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Ischemic Stroke, for the FY 2023 payment determination and for subsequent years, as described in section IX.A.6.b. of the preamble of this final rule.

** Measure listed twice, as both chart-abstracted and electronic clinical quality measure.

*** Measure refinement of the HCAHPS measure's Pain Management questions for the FY 2020 payment determination and for subsequent years, as described in section IX.A.6.a. of the preamble of this final rule.

(+) NQF endorsement has been removed.

7. Voluntary Hybrid Hospital-Wide Readmission Measure With Claims and Electronic Health Record Data (NQF #2879)

a. Background

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49698), we stated that we are considering the use of a set of core clinical data elements extracted from hospital EHRs for each hospitalized Medicare FFS beneficiary over the age of 65 years. The core clinical data elements are data which are routinely collected on hospitalized adults, extraction from hospital EHRs is feasible, and can be utilized as part of specific quality outcome measures. One way in which we envisioned using core clinical data elements in conjunction with other sources of data, such as administrative claims, is to calculate ''hybrid'' outcome measures, which are quality measures that utilize more than one source of data. For more detail about core clinical data elements, we refer readers to our discussion in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49698 through 49704). In addition, we note an important distinguishing factor about core clinical data elements and the hybrid measures: Hybrid measure results must be calculated by CMS to determine hospitals' risk-adjusted rates relative to national rates used in public reporting. With a hybrid measure, hospitals can submit data extracted from the EHR, and we can perform the measure calculations. This was the approach that was finalized for the calculation of the Hybrid Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (NQF #2473), which was incorporated into the Advancing Care Coordination Through Episode Payment Models as a voluntary measure for patients admitted for AMI in the AMI Model (82 FR 354 through 356).

In the FY 2016 IPPS/LTCH PPS final rule, we stated we developed two hybrid measures: (1) Hospital 30-Day Risk-Standardized Acute Myocardial Infarction (AMI) Mortality eMeasure (NQF #2473) (now called the Hybrid Hospital 30-Day All Cause Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) (NQF #2473)); and (2) a hybrid hospital-wide 30-day readmission measure now called the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (NQF #2879). Although the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (NQF #2879) (hereinafter referred to as Hybrid HWR measure) was not originally endorsed when the MAP considered the measure, the MAP encouraged further development (80 FR 49698),[160] and the measure has since been endorsed by the NQF.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49702), commenters noted either outright or conditional support for the development of hybrid measures, and for the collection of additional administrative linkage variables to merge data from EHRs with claims. A few commenters noted collection of the core clinical data elements would not impose additional burden on hospitals (80 FR 49702). A few commenters recommended the hybrid measures should go through NQF review or be endorsed by NQF prior to inclusion in a quality reporting program, which we have done, as the Hybrid HWR measure was endorsed by NQF on December 9, 2016. Other commenters recommended that before we require the submission of the core clinical data elements, we should conduct further testing and analysis to ensure the accuracy and completeness of the data being submitted; specifically, one commenter suggested a testing period (80 FR 49703). We conducted further testing, which is further described below. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49702 through 49704) for a full discussion of all public comments and our responses related to core clinical data elements.

Since the FY 2016 IPPS/LTCH PPS final rule, in keeping with our goal to move toward greater use of data from EHRs for quality measurement, and in response to stakeholder feedback to include clinical data in outcome measures (80 FR 49702 through 49703), we have further developed the proposed voluntary Hybrid HWR measure. This measure would incorporate a combination of claims data and EHR data submitted by hospitals, and because of these combined data sources, it is referred to as a hybrid measure. The Hybrid HWR measure cohort and outcome are identical to those in the Hospital-Wide All-Cause Unplanned Readmission measure (NQF #1789), which was adopted into the Hospital IQR Program for the FY 2015 payment determination and subsequent years (77 FR 53521).

The Hybrid HWR measure was presented on the List of Measures under Consideration for December 1, 2014. The MAP encouraged further development of the Hybrid HWR measure in December 2014.[161] The Hybrid HWR measure (NQF #2879) was endorsed by NQF on December 9, 2016. This measure aligns with the National Quality Strategy (NQS) priorities of making care safer by reducing harm caused in the delivery of care and promoting effective communication and coordination of care.

Measure development followed the same scientific approach and rigorous process as other Hospital IQR Program outcome measures. To align the core clinical data elements with other measures that utilize EHR data, we developed and tested a Measure Authoring Tool and identified value sets for extraction of the core clinical data elements. As stated in the FY 2016 IPPS/LTCH PPS final rule, the core clinical data elements use existing value sets where possible in an effort to harmonize with other measures and reporting requirements and we completed testing of the electronic specifications for the core clinical data elements used in the Hybrid HWR measure (80 FR 49703). The electronic specifications were tested in four separate health systems that used three separate EHR systems. During Hybrid HWR measure development and testing we demonstrated that the core clinical data elements were feasibly extracted from hospital EHRs for nearly all adult patients admitted. We also demonstrated that the use of the core clinical data elements to risk-adjust the Hybrid HWR measure improves the discrimination of the measure, or the ability to distinguish patients with a low risk of readmission from those at high risk of readmission, as assessed by the c-statistic.[162] [163] [164] In addition, inclusion of clinical information from patient EHRs is responsive to stakeholders who find it preferable to

[160] National Quality Forum. Measure Application Partnership, MAP Hospital Programmatic Deliverable—Final Report. Available at: *http://www.qualityforum.org/Publications/2015/02/MAP_Hospital_Programmatic_Deliverable_-_Final_Report.aspx*. Accessed on March 10, 2017.

[161] National Quality Forum. Measure Application Partnership, MAP Hospital Programmatic Deliverable—Final Report. Available at: *http://www.qualityforum.org/Publications/2015/02/MAP_Hospital_Programmatic_Deliverable_-_Final_Report.aspx*. Accessed on March 10, 2017.

[162] Hybrid 30-day Risk-standardized Acute Myocardial Infarction Mortality Measure with Electronic Health Record Extracted Risk Factors (Version 1.1). Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

[163] Hybrid Hospital-Wide Readmission Measure with Electronic Health Record Extracted Risk Factors (Version 1.1). Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

[164] 2013 Core Clinical Data Elements Technical Report (Version 1.1). Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

use clinical information that is available to the clinical care team at the time treatment is rendered to account for patients' severity of illness rather than relying solely on data from claims (80 FR 49702). The Hybrid HWR measure is now fully developed and tested and NQF-endorsed (NQF #2879).

b. Voluntary Reporting of Electronic Health Record Data for the Hybrid HWR Measure (NQF #2879)

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20045 through 20049), in accordance with, and to the extent permitted by, the HIPAA Privacy Rule and other applicable law, we proposed the Hybrid HWR measure as a voluntary measure for the reporting of data on discharges over a 6-month period in the first two quarters of CY 2018 (January 1, 2018 through June 30, 2018). A hospital's annual payment determination would not be affected by this voluntary measure. As we stated when we adopted the Hospital-Wide All-Cause Unplanned Readmission measure (NQF #1789) that is currently used in the Hospital IQR Program, a hospital's readmission rate is affected by complex and critical aspects of care such as communication between providers or between providers and patients; prevention of, and response to, complications; patient safety; and coordinated transitions to the outpatient environment, such that a hospital-wide, all-condition readmission measure could portray a broader sense of the quality of care in hospitals and promote hospital quality improvement (77 FR 53522). We believe this would also be the case with using the Hybrid HWR measure (NQF #2879) that we proposed for voluntary data collection in the proposed rule.

Hospitals that voluntarily submit data for this measure would receive confidential hospital-specific reports that detail submission results from the performance reporting period, as well as the Hybrid HWR measure results assessed from merged files created by our merging of the EHR data elements submitted by each participating hospital with claims data from the same set of index admission. We note that in the proposed rule (82 FR 20047), we stated we are only seeking to collect data for the Hybrid HWR measure that are in accordance with the measure's electronic specifications, available on the CMS Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. Hospitals that volunteer to submit data would also increase their familiarity with submitting data for hybrid quality measures from their EHR systems. Participating hospitals would receive information and instruction on the use of the electronic specifications for this measure, would have an opportunity to test extraction and submission of data to CMS, and would receive reports from CMS, downloadable from QualityNet, with details on the success of their submission, such as the completeness and accuracy of the data. This would allow us to refine this measure if necessary to provide meaningful information on outcomes for hospitalizations for Medicare FFS beneficiaries with the intent to propose this as a required measure in future rulemaking. For example, we would consider feedback from hospitals when making refinements to improve the utility of the measure specifications. In addition, we would examine the completeness and accuracy of the data received to determine its adequacy for calculation of the measure's risk adjustment model and measure results.

EHR data or measure results for this proposed voluntary Hybrid HWR measure would not be publicly reported. However, if we propose to require mandatory reporting of the Hybrid HWR measure in future rulemaking, such a proposal would include public reporting of the measure results. Consistent with estimates for previous voluntary measure reporting, such as the Hospital IQR Program eCQM voluntary reporting (79 FR 50346), we believe up to approximately 100 hospitals would voluntarily submit data for the Hybrid HWR measure. Details about the measure and our proposal for voluntarily reporting certain data elements for this measure are discussed below.

c. Data Sources

We proposed to use two sources of data for the calculation of the proposed voluntary Hybrid HWR measure: Medicare Part A claims and core clinical data elements for Medicare FFS beneficiaries who are 65 years or older, comprising the measure cohort. Claims data would be used to identify index admissions included in the measure cohort, to create a risk-adjustment model, and to assess the 30-day unplanned readmission outcome. This data would be merged with core clinical data elements from each participant hospital's EHRs collected at presentation (discussed in more detail below) and used for risk-adjustment of patients' severity of illness (for Medicare FFS beneficiaries who are 65 years or older), in addition to data from claims. Medicare enrollment data, from the Medicare Enrollment Database, are used to confirm Medicare enrollment for at least 30 days post hospital discharge for the unplanned readmission outcome assessment. For this proposed voluntary Hybrid HWR measure, in accordance with, and to the extent permitted by, the HIPAA Privacy Rule and other applicable law, the EHR data submission process would align as much as possible with existing electronic Clinical Quality Measure (eCQM) standards and data reporting procedures for hospitals, as further discussed below. We refer readers to section IX.A.10.e. of the preamble of this final rule for details on the Submission Form and Method for the Voluntary Hybrid Hospital-Wide Readmission Measure. The electronic specifications for the proposed voluntary Hybrid HWR measure, which include the electronic specifications for extraction of the core clinical data elements from hospital EHRs (the Measure Authoring Tool output and value sets) for all included data elements, are available on the CMS Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

d. Outcome

As stated above, the proposed voluntary Hybrid HWR measure outcome is aligned with the currently adopted, publicly reported, Hospital-Wide All-Cause Unplanned Readmission measure (NQF #1789), which was adopted into the Hospital IQR Program for the FY 2015 payment determination and subsequent years (77 FR 53521 through 53528). The proposed voluntary Hybrid HWR measure outcome assesses unplanned readmissions for any cause within 30 days of discharge from the index admission. It does not consider planned readmissions as part of the readmission outcome and identifies them by using the CMS Planned Readmission Algorithm, which is a set of criteria for classifying readmissions as planned using Medicare claims, and is currently used in the previously adopted, Hospital-Wide All-Cause Unplanned Readmission measure (77 FR 53521).[165] This algorithm identifies admissions that are typically planned and may occur within 30 days of discharge from the hospital.[166] The algorithm was most

[165] 2017 All-Cause Hospital-Wide Measure Updates and Specifications Report. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

[166] *Ibid.*

recently refined in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50211 through 50216) for the previously adopted, claims-based measure. The same algorithm is used for this proposed voluntary Hybrid HWR measure.[167] A complete description of the CMS Planned Readmission Algorithm, which includes lists of planned diagnoses and procedures, can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

e. Cohort

As noted above, the proposed voluntary Hybrid HWR measure cohort is aligned with the currently adopted, Hospital-Wide All-Cause Unplanned Readmission measure.[168] The measure cohort consists of Medicare FFS beneficiaries, aged 65 years or older, discharged from non-Federal acute care hospitals. Hospitals would only submit data for this cohort, and the measure would only be calculated for this cohort. The proposed voluntary Hybrid HWR measure includes admissions for nearly all Medicare FFS beneficiaries over the age of 65 years who are discharged alive from acute care non-Federal hospitals. However, during measure calculation, a small number of these admissions are excluded under the measure specifications. Excluded admissions include those for principal discharge diagnoses indicating some psychiatric disorders. These exclusions are only a small proportion of all index admissions and are identified during the measure calculation process.

f. Inclusion and Exclusion Criteria

The proposed voluntary Hybrid HWR measure inclusion and exclusion criteria are also aligned with the currently adopted Hospital-Wide All-Cause Unplanned Readmission measure.[169] For both measures, the index admission is the hospitalization to which the readmission outcome is attributed. Both the claims-based, Hospital-Wide All-Cause Unplanned Readmission measure and the proposed voluntary Hybrid HWR measure include the following index admissions for patients:

- Enrolled in Medicare FFS Part A for the 12 months prior to the date of admission and during the index admission.
- Aged 65 or older.
- Discharged alive from a non-Federal acute care hospital.
- Not transferred to another acute care facility.

This measure excludes the following index admissions for patients:

- Admitted to prospective payment system (PPS)-exempt cancer hospitals.
- Without at least 30 days of post-discharge enrollment in Medicare FFS.
- Discharged against medical advice.
- Admitted for primary psychiatric diagnoses.
- Admitted for rehabilitation.
- Admitted for medical treatment of cancer.

For both measures, each index admission is assigned to one of five mutually exclusive specialty cohort groups: medicine; surgery/gynecology; cardiorespiratory; cardiovascular; and neurology. The cohorts reflect how care for patients is organized within hospitals. To assign admissions to cohorts, admissions are first screened for the presence of an eligible Agency for Healthcare Research and Quality (AHRQ) Clinical Classifications Software (CCS) [170] surgical procedure category. Admissions with an eligible surgical procedure category are assigned to the surgical cohort, regardless of the principal discharge diagnosis code of the admission. All remaining admissions are assigned to cohorts based on the AHRQ CCS diagnosis category of the principal discharge diagnosis.

g. Risk-Adjustment

The proposed voluntary Hybrid HWR measure adjusts both for case mix differences (clinical status of the patient, accounted for by adjusting for age and comorbidities, and the core clinical data elements from patients' EHRs) and service-mix differences (the types of conditions and procedures cared for and procedures conducted by the hospital, accounted for by adjusting for the discharge condition category). Patient comorbidities are based on the index admission, the admission included in the measure cohort, and a full year of prior history. The core clinical data elements are derived from information captured in the EHR during the index admission only, and are listed below.

Data elements	Units of measurement	Time window for first captured values (hours)
Heart Rate	Beats per minute	0–2.
Systolic Blood Pressure	mmHg	0–2.
Respiratory Rate	Breath per minute	0–2.
Temperature	Degrees Fahrenheit	0–2.
Oxygen Saturation	Percent	0–2.
Weight	Pounds	0–24.
Hematocrit	% red blood cells	0–24.
White Blood Cell Count	Cells/mL	0–24.
Potassium	mEq/L	0–24.
Sodium	mEq/L	0–24.
Bicarbonate	mmol/L	0–24.
Creatinine	mg/dL	0–24.
Glucose	mg/dL	0–24.

[167] Hybrid Hospital-Wide Readmission Measure with Electronic Health Record Extracted Risk Factors (Version 1.1). Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

[168] 2017 All-Cause Hospital-Wide Measure Updates and Specifications Report. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

[169] 2017 All-Cause Hospital-Wide Measure Updates and Specifications Report. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

[170] Clinical Classifications Software (CCS) for ICD–9–CM Fact Sheet. Accessed at: *https://www.hcup-us.ahrq.gov/toolssoftware/ccs/ccsfactsheet.jsp*.

The risk-adjustment variables included in the development and testing of the proposed voluntary Hybrid HWR measure are derived from both claims and clinical EHR data. The variables are: (1) 13 Core clinical data elements derived from hospital EHRs; (2) the Clinical Classification Software (CCS) categories for the principal discharge diagnosis associated with each index admission derived from ICD–10 codes in administrative claims data; and (3) comorbid conditions of each patient identified from inpatient claims in the 12 months prior to and including the index admission derived from ICD–10 codes and grouped into the CMS condition categories (CC).

All 13 core clinical data elements were shown to be statistically significant predictors of readmission in one or more risk-adjustment models of the five specialty cohort groups used to calculate the proposed voluntary Hybrid HWR measure.[171] The proposed voluntary Hybrid HWR measure specialty cohort groups are further defined in section IX.A.7.e. of the preamble of this final rule, below. The testing results demonstrate that the core clinical data elements enhanced the discrimination (assessed using the c-statistic) when used in combination with administrative claims data.[172] For additional details regarding the risk-adjustment model, we refer readers to the proposed voluntary Hybrid HWR Measure technical report, which is posted on the CMS Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

We note this measure was developed using claims coded in ICD–9. However, we have identified and tested ICD–10 specifications for all information used in the measure derived from Medicare claims for both the claims-based, Hospital-Wide All-Cause Unplanned Readmission measure and for the proposed voluntary Hybrid HWR Measure. The ICD–10 specifications are identical for both measures. Only the use of the core clinical data elements in the risk-adjustment models differs between the two measures. Those data elements are not affected by ICD–10 implementation. For additional details regarding the measure specifications that accommodate ICD–10-coded claims, we refer readers to the 2017 All-Cause Hospital-Wide Measure Updates and Specifications Report, which is posted on the CMS Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

h. Calculating the Risk-Standardized Readmission Rate (RSRR)

The methods used for calculation of the proposed voluntary Hybrid HWR measure align with the methods used to calculate the currently adopted, Hospital-Wide All-Cause Unplanned Readmission measure. Index admissions are assigned to one of five mutually exclusive specialty cohort groups consisting of related conditions or procedures. The five specialty cohort groups are: Surgery/gynecology, general medicine, cardiorespiratory, cardiovascular, and neurology. For each specialty cohort group, the standardized readmission ratio (SRR) is calculated as the ratio of the number of ''predicted'' readmissions to the number of ''expected'' readmissions at a given hospital. For each hospital, the numerator of the ratio is the number of readmissions within 30 days predicted based on the hospital's performance with its observed case mix and service mix, and the denominator is the number of readmissions expected based on the nation's performance with that hospital's case mix and service mix. This approach is analogous to a ratio of ''observed'' to ''expected'' used in other types of statistical analyses.

The specialty cohort SRRs are then pooled for each hospital using a volume-weighted geometric mean to create a hospital-wide composite SRR. The composite SRR is multiplied by the national observed readmission rate to produce the RSRR. For additional details regarding the measure specifications to calculate the RSRR, we refer readers to the 2017 All-Cause Hospital-Wide Measure Updates and Specifications Report, which is posted on the CMS Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

i. Data Submission and Reporting Requirements

We proposed hospitals use QRDA I files for each Medicare FFS beneficiary who is 65 years and older. Submission of data using QRDA I files is the current EHR data and measure reporting standard adopted for electronic clinical quality measures (eCQMs) implemented in the Hospital IQR Program. This same standard would be used for reporting the core clinical data elements to the CMS data receiving system. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49706) where we have previously discussed QRDA I standards for use in the Hospital IQR Program. We also refer readers to section IX.A.10.e. of the preamble of this final rule for discussions of additional proposals related to data submission and reporting requirements for the Hybrid HWR measure.

We also proposed to use the following criteria to determine if a hospital has successfully submitted voluntary Hybrid HWR measure data:

- Submission of only the first-captured values, which are data collected routinely on each Medicare FFS beneficiary who is 65 years or older upon presentation to the hospital, for each of the 13 core clinical data elements used in risk adjustment to assess the patient's severity of illness.
- Hospitals would be expected to successfully submit data values from hospital EHRs for vital signs (heart rate, respiratory rate, temperature, systolic blood pressure, oxygen saturation, weight), and six linking variables required to merge with the CMS claims data (CCN, HIC Number or Medicare Beneficiary Identifier, date of birth, sex, admission date, and discharge date). When we tested the electronic specifications for extraction of the core clinical data elements in hospital systems, we also tested the use of these linking variables to merge data from claims and from hospitals' EHRs from several health systems, and achieved match rates over 90 percent accounting for missing or erroneous data. In order to calculate results for the Hybrid HWR measure, hospitals would need to submit these data on more than 95 percent of on all Medicare FFS patients who are 65 years and older discharged from the hospital.
- Participating hospitals would be requested to submit values for laboratory test results (hematocrit, white blood cell count, sodium, potassium, bicarbonate, creatinine, and glucose) for Medicare FFS beneficiaries, 65 years or older, included in the measure cohort. In order to calculate measure results for the Hybrid HWR measure, hospitals would need to submit these data elements on more than 80 percent of these beneficiaries. However, for the proposed voluntary measure for the CY 2018 reporting period (January 1, 2018 through June 30, 2018) we would request the data elements on at least 50

[171] Hybrid Hospital-Wide Readmission Measure with Electronic Health Record Extracted Risk Factors (Version 1.1). Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

[172] Hybrid Hospital-Wide Readmission Measure with Electronic Health Record Extracted Risk Factors (Version 1.1). Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

percent of these patients discharged over the same time period. Data submission to the CMS data receiving system would occur in the fall of 2018.

• The measurement period would include discharges occurring over a 6-month period in the first two quarters of CY 2018 (January 1, 2018 through June 30, 2018). However, for hospitals that choose to report this measure, we would request submission of these data elements on at least 50 percent of these patients. As we noted above, in our proposal for voluntary data collection of the Hybrid HWR measure, we are only seeking to collect data for this measure on applicable Medicare FFS beneficiaries in accordance with the measure's electronic specifications, available on the CMS Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

j. Confidential Hospital-Specific Reports

Hospitals that voluntarily submit data for this measure would receive confidential hospital-specific reports that detail submission results from the reporting period, including detailed information about the completeness and accuracy of the EHR data they submit, as well as the Hybrid HWR measure results assessed from merged files created by our merging of the EHR data elements submitted by each participating hospital with claims data from the same set of index admission. We would calculate and provide each participating hospital with their risk-standardized readmission rate for the voluntary Hybrid HWR measure. This would provide each hospital with an indication of their performance relative to the other hospitals that participate in the voluntary measure. In addition, we would create a hospital-specific report for each participating hospital which would include detailed information about their Medicare FFS beneficiaries who are 65 and older who had an unplanned readmission within 30-days of hospital discharge, including the patients' clinical risk factors from claims and EHR data. This information would allow hospitals to identify the factors that increase patients' risk of readmission and would inform quality improvement strategies to reduce unplanned readmissions. In addition, the reports would include the match rate between the hospital's submitted EHR data and corresponding claims data, as well as the proportion of patient data submitted relative to all qualifying admissions for each of the 13 core clinical data elements.

We note that we are considering proposing the Hybrid HWR (NQF #2879) measure as a required measure as early as the FY 2023 payment determination and requiring hospitals to submit the core clinical data elements and linking variables used in the measure as early as CY 2020 to support a dry run of the measure during which hospitals would receive a confidential preview of their results in 2021. Any requirement for mandatory reporting on this measure would be proposed through future rulemaking. We invited public comment on our proposal to adopt the Hybrid HWR measure (NQF #2879) for the Hospital IQR Program as a voluntary measure for the CY 2018 reporting period as described above.

Comment: A few commenters expressed that they would support the proposed voluntary reporting of the Hybrid HWR measure should it obtain NQF endorsement.

Response: We thank the commenters for their support. As stated in the proposed rule (82 FR 20046) and above, the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (NQF #2879) was endorsed by NQF on December 9, 2016.

Comment: Many commenters recommended that CMS focus efforts on using data elements from EHRs to risk-adjust condition specific measures that are currently being used in the Medicare performance or penalty programs. Specifically, commenters urged CMS to take steps to test the feasibility of using non-clinical EHR-derived elements, such as education, location, and other factors, to develop appropriate socio-demographic adjustments.

Response: We understand the important role that socio-demographic factors play in the care of patients, however, we believe the Hybrid HWR measure's risk-adjustment methodology is appropriate and reliable. The measure already incorporates a risk-adjustment methodology that accounts for age and comorbidities, as well as vital signs and laboratory values at the start of the inpatient encounter. We will take under consideration potential future inclusion of additional non-clinical EHR-derived elements, such as education, location, and other socio-demographic factors, however, we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of diverse socio-demographic factors because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. In addition, as discussed in section V.J.3. of the preamble of this final rule, the Hybrid HWR measure recently underwent successful NQF endorsement during the NQF's trial period for socio-demographic factors. We refer readers to section IX.A.1.d. of the preamble of this final rule for more details on accounting for social risk factors in the Hospital IQR Program. The NQF trial period considered the analyses and interpretations as well as performance scores with and without socio-demographic factors in the risk-adjustment model for this measure. In accordance with the NQF's trial criteria, NQF's evaluation indicated that SDS adjustment was not necessary for this measure.[173] We routinely monitor the impact of socio-demographic status on hospitals' results on our measures and will assess the appropriateness of further risk adjustment in the future, as well as the availability and feasibility of collecting social risk factor data elements from EHRs. We will also continue to consider using data elements from EHRs to risk-adjust condition specific measures, the claims-based versions of which are currently being used in the Medicare pay for performance programs (sometimes referred to as penalty programs).

Comment: Two commenters encouraged CMS to incentivize both hospitals and vendors to participate in voluntary reporting either through recognition or reduction in other requirements to offset the resources required to fully participate.

Response: We thank the commenter for their suggestion. We will continue to consider ways to reduce burden on hospitals as well as to incentivize participation in the voluntary reporting of this measure.

Comment: One commenter expressed concern about the proposed voluntary reporting of the Hybrid HWR measure, because merging clinical data derived from electronic health records (EHRs) with claims data is especially difficult and extremely complex.

Response: We will merge the EHR data submitted by hospitals as outlined in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20049) with the claims files and calculate the measure results. To clarify, participating hospitals or vendors are not expected to merge these data files themselves. We have successfully tested this process using EHR data and claims data submitted by three separate hospital systems during measure development. The additional experience we gain through voluntary data collection on

[173] NQF All-Cause Admissions and Readmissions 2015–2017 Technical Report: *http://www.qualityforum.org/Publications/2017/04/All-Cause_Admissions_and_Readmissions_2015-2017_Technical_Report.aspx*.

this measure will allow us to refine the data merging process as necessary without affecting payment or public reporting, since this voluntary measure will not be publicly reported. For hospitals that participate in the voluntary reporting of the Hybrid HWR measure, we will provide each hospital with a confidential hospital specific report that details submission results, as well as a description of the merged data set with both EHR and claims data included for the measure reporting period.

After consideration of the public comments we received, we are finalizing our proposal to adopt the Hybrid HWR measure (NQF #2879) as a voluntary measure for the CY 2018 reporting period, as proposed.

8. Changes to Policies on Reporting of eCQMs

a. Background

For a discussion of our previously finalized eCQMs and policies, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50807 through 50810; 50811 through 50819), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50241 through 50253; 50256 through 50259; and 50273 through 50276), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49692 through 49698; and 49704 through 49709), and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57150 through 57161; and 57169 through 57172). In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57172), we finalized that hospitals must submit eCQM data by the end of two months following the close of the calendar year for the CY 2017 reporting period/FY 2019 payment determination and subsequent years.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20049 through 20051), we proposed two modifications to our finalized eCQM reporting policies for the CY 2017 reporting period/FY 2019 payment determination and the CY 2018 reporting period/FY 2020 payment determination. Specifically, we proposed to: (1) Decrease the number of eCQMs for which hospitals must submit data; and (2) decrease the number of calendar quarters for which hospitals are required to submit data, as further detailed below. These proposals were made in conjunction with our proposals discussed in sections IX.E.2.b. of the preamble of this final rule to align requirements for the Hospital IQR Program and the Medicare and Medicaid EHR Incentive Programs for hospitals and CAHs.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57150 through 57159), we finalized a policy to require hospitals to submit one full calendar year of data (consisting of four quarterly data reporting periods) for 8 self-selected eCQMs out of the available eCQMs for both the CY 2017 reporting period/FY 2019 payment determination and the CY 2018 reporting period/FY 2020 payment determination.

Since the conclusion of the public comment period for the FY 2017 IPPS/LTCH PPS final rule, we have continued to receive frequent feedback (via email, webinar questions, help desk questions, and conference call discussions) from hospitals and EHR vendors about ongoing challenges of implementing eCQM reporting. A summary of the main concerns identified by these data submitters are as follows:

- The timing of the transition to a new EHR system during 2017 (or system upgrades or new EHR vendor) affects hospitals' ability to report on an increased number of measures in a timely manner;
- There is a need for at least one year between new EHR requirements due to the varying 6- to 24-month cycles needed for vendors to code new measures, test and institute measure updates, train hospital staff, and rollout other upgraded features;
- Hospitals have had difficulty identifying applicable measures that reflect their patient population, given the reduction in the number of available eCQMs (from 28 to 15) for CY 2017 reporting;
- Hospitals have had challenges with data mapping (aligning the information available in an electronic health record (EHR), particularly if the information is not located in a structured field (for example, PDF attachment, free text section) to the required fields in a QRDA Category I (QRDA I) file), and workflow (the process of extrapolating the pertinent patient data from an EHR, transferring that data to a QRDA I file, and submission of the QRDA I file to CMS) because hospitals still need to collect CY 2017 data while reporting CY 2016 data; and
- Hospitals have identified challenges in implementing annual updates and new editions of certified health IT because of significant impacts on workflow, staffing, and connected technology systems. (We note that this information was inadvertently omitted in the proposed rule at 82 FR 20050.)

In response to these issues, we proposed to modify the eCQM reporting requirements for both the CY 2017 reporting period/FY 2019 payment determination and the CY 2018 reporting period/FY 2020 payment determination as discussed in more detail below.

b. Modifications to the eCQM Reporting Requirements for the Hospital IQR Program for the CY 2017 Reporting Period/FY 2019 Payment Determination

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20050), for the CY 2017 reporting period/FY 2019 payment determination, we proposed to modify eCQM reporting requirements, such that hospitals: (1) Report on at least 6 of the available eCQMs, instead of 8 as previously finalized; and (2) submit two, self-selected quarters of data, instead of one full calendar year of data as previously finalized.

We stated in the proposed rule that although the publication of the FY 2018 IPPS/LTCH PPS final rule will not occur until on or about August 1, 2017, the data submission deadline for the CY 2017 reporting period/FY 2019 payment determination is not until February 28, 2018 which should provide hospitals with ample time to adjust to these modified policies. Hospitals that were prepared to submit one full calendar year of data for 8 eCQMs in accordance with the previously finalized CY 2017 eCQM reporting requirements should be able to submit two, self-selected quarters of data for 6 eCQMs in accordance with the modified CY 2017 reporting requirements. Reducing the number of data reporting periods to two quarters, rather than four, and allowing hospitals to self-select which two quarters of CY 2017 to report also offers greater reporting flexibility and allows hospitals and their vendors more time to plan for reporting and to account for and schedule hospital-specific scenarios, such as EHR upgrades or system transitions.

We believe these modified reporting requirements directly address stakeholder concerns while remaining consistent with our goal to incrementally transition to electronic reporting (80 FR 49694).

We note we proposed similar policies in the EHR Incentive Program and refer readers to section IX.E.2.b. of the preamble of this final rule. Our policies to modify the CY 2017 eCQM reporting requirements in the Hospital IQR Program continue to align with the requirements of the CQM electronic reporting requirements in the Medicare and Medicaid EHR Incentive Programs for eligible hospitals and CAHs to reduce confusion and reporting burden. In addition, in the proposed rule (82 FR 20050), we did not propose any changes to the February 28, 2018 submission deadline for CY 2017 reporting (81 FR 57172) to ensure that APU determinations for FY 2019 are not affected and to maintain the established

alignment with the Medicare EHR Incentive Program's submission deadline (81 FR 57255).

We invited public comment on our proposals to modify the eCQM reporting requirements for the CY 2017 reporting period/FY 2019 payment determination for the Hospital IQR Program as described above.

Comment: Several commenters supported the proposed policies for the CY 2017 reporting period/FY 2019 payment determination that reduce the reporting period from one full calendar year of data to two, self-selected quarters of data and the number of eCQMs required to report from 8 to 6, but recommended that CMS further reduce the CY 2017 reporting requirements by retaining the previously finalized CY 2016 policies that required the reporting of 4 eCQMs for one quarter of data. The commenters indicated that maintaining the CY 2016 eCQM reporting requirements would provide certified health IT vendors and CMS additional time to work on measure specification and, data validation, while giving hospitals more time to focus on incorporating system upgrades, data mapping, staff training, and planning for data processing for CMS reporting. In addition, some commenters expressed concern regarding the increase in eCQM reporting requirements impacting the ability of hospitals to effectively execute current eCQM reporting requirements and prepare for potential future increases in eCQM reporting requirements, thus placing an additional burden on hospitals by limiting available time for testing prior to production file submission. These commenters indicated that recent updates to measure specifications have required labor-intensive updates to complete terminology mapping, which has reduced hospitals' ability to expand eCQM reporting to additional eCQMs. The commenters noted that implementation of eCQM reporting is a multi-year process that requires significant capital and operating expenditures and requires close collaboration with clinical and other operations staff. The commenters encouraged CMS to continue to take into account the operational implications of eCQM data submission requirements for smaller hospitals that have resource limitations. One commenter indicated that even if facilities were already collecting data on 8 eCQMs, the reduction in the number of eCQMs required to report and the decreased reporting period would give facilities that have limited resources or difficulties reporting for an entire calendar year the opportunity to be more successful.

Response: We appreciate commenters expressing their concerns and providing more details regarding their challenges associated with eCQM reporting. Based on commenter feedback, we are finalizing a modification to our proposals for eCQM reporting requirements for the CY 2017 reporting period/FY 2019 payment determination. Instead of requiring submission of one calendar year of data, for 8 eCQMs, as previously finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57150 through 57159), or submission of two, self-select calendar quarters of data, for 6 eCQMs, as proposed in the FY 2018 IPPS proposed rule (82 FR 20050), we are finalizing a modification of our proposal to further reduce the eCQM reporting requirements, such that hospitals are required to submit only one, self-selected calendar quarter of data for 4 eCQMs. This retains reporting requirements similar to the CY 2016 reporting period/FY 2018 payment determination (80 FR 49698) with one change, such that hospitals will be able to submit data for any one of the 4 quarters for the CY 2017 reporting period/FY 2019 payment determination, whereas hospitals were only able to submit data for either Q3 or Q4 for the CY 2016 reporting period/FY 2018 payment determination.

In determining the modified number of eCQMs to report for the CY 2017 reporting period, we decided to continue the CY 2016 reporting period/FY 2018 payment determination requirements to give hospitals more time to gain experience reporting eCQMs. While we believe many hospitals are ready to successfully report on at least 6 eCQMs beginning with the CY 2017 reporting period/FY 2019 payment determination, as proposed, we also want to be responsive to feedback that many hospitals, especially small, rural, and IHS and tribal hospitals, as well as hospitals with fewer financial resources, need additional time and flexibility to successfully implement all of the eCQM reporting requirements. We intend to review the results of the first year of required eCQM data collection prior to increasing requirements for subsequent years.

We believe these modified, reduced reporting requirements directly address stakeholder concerns while remaining consistent with our goal to gradually transition toward more robust electronic quality measure reporting. Further, we believe reducing the number of eCQMs required to be reported and reducing the quarters of data to be reported eases the burden on data submitters, allowing them to shift resources to support system upgrades, data mapping, and staff training related to eCQMs. Successful reporting in CY 2016 should streamline CY 2017 reporting because hospitals can re-use the same measures submitted to satisfy the CY 2016 reporting requirements. In addition, we believe that these modified, reduced reporting requirements will provide hospitals and health IT vendors more time to report quality data to CMS, including more time to submit test QRDA files before submitting production QRDA files for program credit. We also believe the reduction in the number of required eCQMs lessens the burden of identifying new measures to report; under the modified policy, hospitals are not required to identify any additional measures between CY 2016 and CY 2017. We will continue to assess the progress of hospitals in implementing eCQM reporting requirements and engage in discussions with hospitals and health IT vendors regarding their experiences as we consider eCQM policies in future rulemaking.

Although we are not finalizing our original proposal to require reporting on 6 eCQMs, we encourage hospitals to continue refining their electronic reporting implementation activities to successfully achieve electronic data capture and reporting. In addition, we encourage early testing and the use of pre-submission testing tools to reduce errors and inaccurate data submissions in eCQM reporting. Over time, we anticipate hospitals will continue to build and refine their EHR systems and gain more familiarity with reporting eCQM data, resulting in more accurate data submissions with fewer errors.

We note that we made similar proposals in the Medicare and Medicaid EHR Incentive Programs and refer readers to section IX.E.2.b. of the preamble of this final rule, where we also are finalizing a modification to our proposals. Our policies to modify and reduce the CY 2017 reporting period/FY 2019 payment determination eCQM reporting requirements in the Hospital IQR Program will continue to align with requirements in the Medicare and Medicaid EHR Incentive Programs. We also refer readers to section IX.A.10.d. of the preamble of this final rule for our eCQM submission policies.

Comment: A majority of commenters supported the proposed reduction from 8 required eCQMs to 6 eCQMs and the reduction from one full calendar year of data to two, self-selected quarters of data for the CY 2017 reporting/FY 2019 payment determination. The

commenters noted that as proposed, the requirements align with the CY 2017 Joint Commission reporting standards. A few commenters requested CMS finalize the proposed requirements as soon as possible in order for hospitals to prepare and educate appropriate staff.

Several commenters indicated that the modified reporting period from one full year to two quarters of data would provide hospitals with sufficient time to adequately transition their EHR systems and allow them to avoid a reporting period that overlaps with the quarter in which they transition EHR systems.

Response: We thank the commenters for their support. At this time, we believe that continuing the CY 2016 reporting requirements for hospitals to report one, self-selected calendar quarter of data for 4 eCQMs, as discussed above, balances stakeholder concerns while remaining consistent with our goal to gradually transition toward more robust electronic quality measure reporting. As previously stated, we believe the electronic collection and reporting of quality data using health IT will ultimately simplify and streamline reporting for various CMS quality reporting programs and hospitals will experience decreased financial and administrative burden as we continue to align program reporting requirements and adopt a more streamlined set of clinical quality measures with electronic specifications.

Comment: One commenter believed the current methodology of collecting information for more eCQMs, over a greater period of time, relies too heavily upon the entry of ''hardcoded'' documentation by physicians and nurses within certain timing constraints.

Response: We interpret the commenter's concern about eCQMs relying too heavily upon entry of ''hardcoded'' documentation to mean that the commenter believes clinical staff may have difficulty inputting patient information in ''real time'' into the appropriate structured fields during the patient encounter due to competing clinical demands. The EHR may allow the clinician to update the patient information at a later time in the event that clinical staff need to provide crisis care and cannot record patient information at the time of the encounter without compromising patient care or in the case that additional information needs to be added to the medical record after the patient encounter. We recommend hospitals and their EHR vendors work together to implement EHR functionalities that will successfully support clinical activities, documentation, and quality measure reporting that are also consistent with each hospital's policies and procedures. We believe that recording patient information in structured fields for the purpose of reporting eCQMs is more accurate, less prone to errors because it relies less on interpretation, and ultimately reduces burden on hospitals because it does not require manual abstraction, as compared with conventional chart-abstracted data reporting.

Comment: One commenter did not support the proposal to reduce the eCQM submission requirements and recommended that the number of measures and the reporting window be kept the same, if not increased. The commenter indicated that capturing and exporting the data for a QRDA I file is part of the ONC EHR certification program, and if a hospital is not capturing data in such a way that a QRDA I file can be generated, then this implies that either the EHR is violating its certification or the hospital is not using its EHR appropriately. Rather than modifying the Hospital IQR Program eCQM reporting requirements to make it acceptable for EHRs to violate their certification, the commenter suggested that the existing regulations be enforced and penalties be applied to these health IT vendors.

In addition, the commenter suggested measure specifications could be published in advance to enable hospitals to view them before the reporting period begins; this does not require the total number of measures to be reduced. The commenter recognized the challenges some hospitals are having, but argued that these issues should be addressed directly with individual hospitals instead of through indirect mechanisms like changing the number of measures for all hospitals. The commenter expressed support for the creation of new eCQMs as a more appropriate approach to addressing concerns regarding the lack of measures rather than simply reducing the requirements.

Response: We thank the commenter for their support of the eCQM reporting requirements for the CY 2017 reporting period/FY 2019 payment determination as previously finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57150 through 57161; and 57169 through 57172). We note that hospitals have reported data electronically for several years to both the Medicare and Medicaid EHR Incentive Programs and the Hospital IQR Program (3 prior years of pilot reporting and 3 prior years of voluntary reporting), and thus we believe most hospitals are able to successfully meet our previously finalized eCQM reporting requirements to report on additional measures for the CY 2017 reporting period/FY 2019 payment determination. However, as discussed above, we also want to be sensitive and responsive to feedback that a number of hospitals, especially small, rural, and IHS and tribal hospitals as well as hospitals with fewer financial resources, need additional time and flexibility to successfully implement all of the eCQM reporting requirements. At this time, we believe that continuing the CY 2016 reporting requirements for hospitals to report one, self-selected calendar quarter of data for 4 eCQMs, as discussed above, better balances stakeholder concerns while remaining consistent with our goal to gradually transition toward more robust electronic quality measure reporting.

We appreciate the commenter's suggestion that measure specifications could be published further in advance to enable hospitals to view them before the reporting period begins as well as the suggestion to find and develop better measures. We will take these suggestions into consideration. We note that, generally, each year we issue a call for new measures, including eCQMs and other types of electronic measures, to be considered for adoption in the Hospital IQR Program. We also refer readers to section IX.A.9. of the preamble of this final rule for discussion of future potential eCQMs under consideration for the Hospital IQR and Medicare and Medicaid EHR Incentive Programs. Interested stewards and/or developers may submit measures for consideration by NQF. Submission guidance for eCQMs are available at: *www.qualityforum.org/Electronic_Quality_Measures.aspx*.

Comment: A few commenters recommended that CMS clarify the definitions used for the terms ''workflow'' and ''data submission,'' in the context of electronic measure reporting. Specifically, the commenters suggested that while ''workflow'' is related to technical challenges, the term is not appropriate in defining the process of data extraction and QRDA I submission.

Response: We thank the commenters for their suggestion. Our references to the terms ''data submission'' and ''workflow'' depend on the context in which the terms are used, which party is providing data to which party, and for what purpose. In the context of eCQM reporting, hospitals may experience challenges modifying workflow in regards to clinical care, corresponding documentation, and data capture, such that clinical staff enter patient information into the appropriate fields of the EHR at the time of the patient

encounter. Sometimes the clinician, medical assistant, scribe, or other staff member entering data into the EHR may find it easier or more expeditious to enter patient information in the ''free text'' section of the EHR, even though specific fields exist in the EHR where that data should be recorded so that it maps appropriately when the eCQMs pull data from the EHRs. To clarify, when we suggested that hospitals need to make changes to workflow, we meant hospitals should focus additional time and effort on training the appropriate staff to effectively capture patient data within the EHR. We further encourage hospitals to innovate and design workflows that fit their unique needs to make the best use of both clinical and non-clinical staff resources to maintain patient health information in the EHR.

In addition, when the staff enter patient information in the ''free text'' section of the EHR, it is also sometimes the case that staff or hospital administrators go back after the patient encounter has completed and manually enter that information into the appropriate fields. This also could be considered part of the ''workflow'' under the definition provided by the commenter. Data submission in the context of eCQM reporting would refer to the sending and subsequent receiving of that documented clinical data corresponding to eCQM specifications through the QualityNet Secure Portal for purposes of the Hospital IQR Program eCQM submissions.

Comment: One commenter urged CMS to begin allowing hospitals to select eCQMs as their official Hospital IQR Program performance metric and opt out of the manual submission of the same quality metric; the commenter noted that it would encourage organizations to begin the transition towards eCQMs by relieving the burden of dual abstraction when the organization is comfortable with the accuracy of its eCQM data.

Response: We thank the commenter for their suggestion to allow hospitals to elect to report eCQMs as their official Hospital IQR Program performance metric and opt out of manual submission for chart-abstracted measures, and will take the suggestion under consideration for future policies on quality measure reporting for the Hospital IQR Program. At this time, as we are planning to validate eCQM data starting with CY 2017 data and not publicly displaying the eCQM data, we believe it is important for chart-abstracted measure data to continue to be collected and publicly displayed to provide important information to consumers and providers.

Comment: One commenter urged CMS to suspend all regulatory requirements that mandate submission of eCQMs given that hospitals have spent significant time and resources to revise certified EHRs to meet eCQM requirements for the CY 2016 reporting period/FY 2018 payment determination, with no benefit for patient care.

Response: We thank the commenter for their recommendations, but disagree that eCQM reporting does not benefit patients. While we recognize the current burden associated with implementing the necessary infrastructure and EHR technology as well as training and refinement of work flows for transitioning to electronic quality reporting and understand that there are operational shortcomings that need to be further reconciled to streamline the process, we do not believe that suspending all eCQM reporting would be the best way to advance the Hospital IQR Program's goals of improving the quality of care and transparency through quality measurement while also reducing the associated operational, administrative, and financial burdens associated with manual chart-abstraction. In addition, suspending all eCQM reporting in the Hospital IQR Program would result in misalignment with the EHR Incentive Program's CQM reporting policies.

We believe electronic reporting furthers CMS and HHS policy goals to promote quality through performance measurement and, in the long-term, will both improve the accuracy of the data and reduce reporting burden for providers. Moreover, we believe it is appropriate to require reporting and validation of eCQM data given that measures available now and those being developed for the future are based increasingly on electronic standards (80 FR 49696).

We encourage hospitals to work closely with health IT vendors to ensure that a contract is in place that supports the hospital's quality reporting requirements and the annual update of quality measures. We understand that hospitals have spent resources to update certified EHRs to meet eCQM requirements, but we believe eCQMs will promote better quality of care as hospitals and health IT vendors continue to refine EHR systems to appropriately structure them commensurate with the clinical work flow. Further, we believe these updates will lead to improved accuracy, reliability, and completeness of the eCQM data, which will promote higher quality outcomes and lower costs while ultimately decreasing reporting burden on hospitals as compared with chart-abstraction of quality measure data. We will continue to monitor the progress of hospitals implementing eCQM reporting requirements and encourage hospitals to share their experiences in preparing for and meeting reporting requirements. In addition, we will evaluate the eCQMs available to report as part of routine measure maintenance as well as consider new electronic measures as they become available for potential use in the Hospital IQR and Medicare and Medicaid EHR Incentive Programs.

After consideration of the public comments we received, we are finalizing a modification of our proposal. Instead of reporting two, self-selected quarters of data for 6 eCQMs as proposed, we are further reducing requirements, such that hospitals are required to report only one, self-selected calendar quarter of data for 4 self-selected eCQMs for the CY 2017 reporting period/FY 2019 payment determination. We refer readers to section IX.E.2.b. of the preamble of this final rule where we are finalizing a similar modified policy under the Medicare and Medicaid EHR Incentive Programs.

c. Modifications to the eCQM Reporting Requirements for the Hospital IQR Program for the CY 2018 Reporting Period/FY 2020 Payment Determination

As stated above, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57150 through 57159), we finalized a policy requiring submission of 8 self-selected eCQMs out of the available eCQMs in the Hospital IQR Program for both the CY 2017 reporting period/FY 2019 payment determination and CY 2018 reporting period/FY 2020 payment determination. In addition, for the CY 2018 reporting period/FY 2020 payment determination, hospitals are required to submit the data by February 28, 2019 (the end of two months following the close of the calendar year, as set out in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57172)). For the same reasons as discussed above, we proposed similar modifications for the CY 2018 reporting period/FY 2020 payment determination in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20050 through 20051). Specifically, we proposed to require hospitals to report on at least six of the available eCQMs for the CY 2018 reporting period/FY 2020 payment determination, instead of eight as previously finalized. These six eCQMs may be the same or a different set of six eCQMs a hospital reports for the CY 2017 reporting period. In addition, we proposed to decrease the number of required reporting periods, from four quarters as previously finalized, to the

first three quarters of the CY 2018 reporting period (that is, Q1, Q2, and Q3 of CY 2018). We noted that this differs from our proposal for the CY 2017 reporting period as discussed above, which would only require two self-selected quarters of data.

In crafting this proposal, we considered several alternatives. Specifically, we considered aligning the CY 2018 reporting period requirements with the proposed CY 2017 reporting period requirements, such that hospitals would report on at least six of the available eCQMs and submit two self-selected quarters of data for both years. We also considered retaining the reporting requirements finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57150 through 57159), such that hospitals would submit one full calendar year of data for 8 self-selected eCQMs for the CY 2018 reporting period/FY 2020 payment determination. Ultimately, we believe that our proposals as stated above balance our goal to progressively shift towards electronic reporting of quality measure data with hospitals' concerns of the burden this increase may cause. In addition, hospitals will have had several years to report data electronically for the Hospital IQR and Medicare and Medicaid EHR Incentive Programs. Therefore, we believe that hospitals will be better prepared to submit an additional quarter of data for the CY 2018 reporting period compared to the number of quarterly reporting periods we are proposing for the CY 2017 reporting period. We also believe that hospitals will be better prepared to submit additional eCQMs in the future, since hospitals will have had a sufficient number of cycles of eCQM reporting.

Our proposals for the CY 2018 reporting period/FY 2020 payment determination were made in conjunction with proposals discussed in section IX.E.3. of the preamble of the proposed rule that fully align requirements for the Hospital IQR Program with the requirements for the CQM electronic reporting option in the Medicare EHR Incentive Program for eligible hospitals and CAHs. We noted that the deadline for submission would be the same as previously finalized, two months following the end of the reporting period calendar year, specifically February 28, 2019 (81 FR 57172).

We invited public comment on our proposals to modify the CY 2018 reporting period/FY 2020 payment determination eCQM reporting requirements for the Hospital IQR Program as described above.

Comment: Several commenters supported the proposed policies for the CY 2018 reporting period/FY 2020 payment determination that would reduce the reporting period from one full calendar year of data to the first three quarters of data and the number of eCQMs required to report from 8 to 6, for the CY 2018 reporting period/FY 2020 payment determination as a step in the right direction, but recommended that CMS further reduce the requirements by continuing the CY 2016 eCQM reporting requirement of one, self-selected calendar quarter of data for 4 eCQMs. The commenters indicated that maintaining the CY 2016 eCQM reporting requirements would provide certified health IT vendors and CMS additional time to work on measure specification and data validation, while giving hospitals more time to focus on incorporating system upgrades, data mapping, staff training, and planning for data processing for CMS reporting.

Some commenters remained concerned with the pace of the expansion of eCQM reporting requirements impacting the ability of hospitals to effectively execute current eCQM reporting requirements and prepare for potential future increases in eCQM reporting requirements, thus placing an additional burden on hospitals by limiting available time for testing prior to production file submission. These commenters indicated that recent updates to measure specifications have required labor-intensive updates to complete terminology mapping, which has hindered hospitals' ability to expand reporting to additional eCQMs. The commenters noted that implementation of eCQM reporting is a multi-year process that requires significant capital and operating expenditures and requires close collaboration with clinical and other operations staff.

A few commenters expressed concern about the considerable burden required to map the necessary data elements from the EHR to the appropriate QRDA file format given that some vendors are not properly equipped to collect and transmit such data through the CMS QualityNet Secure Portal. The commenters stated that until these issues are sufficiently addressed, CMS should not increase the required eCQM reporting requirements for the Hospital IQR Program.

Response: We appreciate commenters expressing their concerns and providing more detail regarding their challenges associated with eCQM reporting. Based on commenter feedback we are finalizing a modification to our proposals for eCQM reporting requirements for the CY 2018 reporting period/FY 2020 payment determination. Instead of requiring submission of one calendar year (four quarters) of data, for 8 eCQMs, as previously finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57150 through 57159), or submission of two, self-selected calendar quarters of data, for 6 eCQMs, as proposed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20050), we are modifying our proposal to further reduce the eCQM reporting requirements, such that hospitals are required to submit only one, self-selected calendar quarter of data for 4 eCQMs. This continues reporting requirements similar to the CY 2016 reporting period/FY 2018 payment determination (80 FR 49698) with one change, such that hospitals will be able to submit data for any one of the 4 quarters for the CY 2018 reporting period/FY 2020 payment determination, whereas hospitals are only able to submit data for either Q3 or Q4 for the CY 2016 reporting period/FY 2018 payment determination.

We believe reducing the number of eCQMs required to be reported and reducing the quarters of data to be reported offers greater reporting flexibility and eases the burden on data submitters, allowing them to shift resources to support system upgrades, data mapping, and staff training related to eCQM documentation and reporting. In addition, we believe that these modified reporting requirements will provide hospitals and health IT vendors more time to report quality data to CMS, including more time to submit test QRDA files before submitting production QRDA files for program credit. We note we are aligning the requirement for hospitals to submit data on one, self-selected calendar quarter of data for 4 eCQMs between the Hospital IQR Program and the Medicare and Medicaid EHR Incentive Programs in order to streamline the electronic submission of quality data for hospitals.

Further, successful reporting in CY 2016 and CY 2017 should streamline CY 2018 reporting because hospitals can re-use the same measures with which they already have gained familiarity. Once hospitals have become comfortable submitting data for 4 eCQMs in CY 2016 and CY 2017, the requirements we are finalizing will also allow greater flexibility if hospitals wish to select different eCQMs from those they submitted for CY 2016 or CY 2017 reporting. In addition, hospitals will have flexibility to select which quarter of data to report data based upon their individual quality improvement needs and electronic reporting capabilities.

Our decision to finalize the same requirements for both the CY 2017 and CY 2018 reporting periods is in an effort to be responsive to the feedback we have received about the challenges of eCQM reporting and recommendations to allow more time to become familiar with and improve upon electronic reporting capabilities. While we believe most hospitals will be ready to successfully report on at least 6 eCQMs beginning with the CY 2018 reporting period/FY 2020 payment determination, we also want to be responsive to feedback that a number of hospitals, especially small, rural, and IHS and tribal hospitals as well as hospitals with fewer financial resources, need additional time and flexibility to successfully implement all of the eCQM reporting requirements. We intend to review the results of the first year of required eCQM data collection prior to increasing requirements for subsequent years. We believe these modified, reduced reporting requirements directly address stakeholder concerns while remaining consistent with our goal to gradually transition to more robust electronic quality measure reporting. In addition, we believe that these modified, reduced reporting requirements will provide hospitals more time and flexibility to address measure specification updates, data validation, technology readiness, system issues, and future requirements generally. We will continue to assess the progress of hospitals implementing eCQM reporting requirements and engage in discussions with hospitals regarding their experiences as we consider eCQM policies in future rulemaking. We intend to determine requirements for the CY 2019 reporting period/FY 2021 payment determination and subsequent years in future rulemaking.

Although we are not finalizing our original proposal to require reporting on 6 eCQMs, we encourage hospitals to continue refining their electronic reporting implementation activities to successfully achieve electronic data capture and reporting. In addition, we encourage early testing and the use of pre-submission testing tools to reduce errors and inaccurate data submissions in eCQM reporting. Over time, we anticipate hospitals will continue to build and refine their EHR systems and gain more familiarity with reporting eCQM data, resulting in more accurate data submissions with fewer errors. We note that we made similar proposals in the Medicare and Medicaid EHR Incentive Programs and refer readers to section IX.E.2.b. of the preamble of this final rule where we also are finalizing the same modification of our proposal and is a continuation of our policy to align the eCQM reporting requirements of the Hospital IQR Program with the CQM electronic reporting requirements in the Medicare and Medicaid EHR Incentive Programs in order to reduce confusion and reporting burden for all hospitals. We also refer readers to section IX.10.d. of the preamble of this final rule for our eCQM submission policies for the Hospital IQR Program.

In arriving at this modified finalized policy, we considered several alternatives. Specifically, we considered aligning the CY 2018 reporting period requirements with the proposed CY 2017 reporting period requirements, such that hospitals would report on at least 6 of the available eCQMs and submit two, self-selected quarters of data. We also considered retaining the reporting requirements finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57150 through 57159), such that hospitals would submit one full calendar year of data for 8 self-selected eCQMs for the CY 2018 reporting period/FY 2020 payment determination. Ultimately, based on commenter feedback and for the reasons articulated above, we have decided to modify our policy to further reduce the eCQM reporting requirements for the CY 2018 reporting period/FY 2020 payment determination, such that hospitals are required to submit one, self-selected calendar quarter of data for 4 eCQMs. Our decision to keep the same eCQM reporting requirements for the CY 2017 reporting period/FY 2019 payment determination and the CY 2018 reporting period/FY 2020 payment determination was also based on commenter feedback recommending additional time and flexibility to successfully implement electronic reporting capabilities. As previously stated, we believe the electronic collection and reporting of quality data using health IT will ultimately simplify and streamline reporting for various CMS quality reporting programs and hospitals will experience decreased financial and administrative burden as we continue to align program reporting requirements and adopt a more streamlined set of clinical quality measures with electronic specifications.

Comment: Many commenters supported the proposed reduction from 8 required eCQMs to 6 required eCQMs and the reduction from one full calendar year of data to the first three calendar quarters of data for the CY 2018 reporting period/FY 2020 payment determination. A few commenters suggested CMS maintain the requirement to report 6 eCQMs beyond the CY 2018 reporting period, while increasing the performance period to one year and then gradually increasing the number of required eCQMs in future years.

The commenters believed this approach would allow hospitals to adapt to more robust eCQM requirements. Other commenters supported the proposed reduction from 8 required eCQMs to 6 for the CY 2018 reporting period/FY 2020 payment determination, but suggested that CMS retain the proposed CY 2017 reporting period/FY 2019 payment determination requirement, such that hospitals are required to report two, self-selected quarters of data for the CY 2018 reporting period/FY 2020 payment determination. Some commenters noted smaller hospitals, with fewer resources, require more time to become proficient in all of the parameters (mapping, new work flows, staff education, etc.) associated with electronic reporting.

A few commenters indicated that if hospitals were allowed to self-select two quarters of data (instead of three or four quarters of data) for the CY 2018 reporting period/FY 2020 payment determination, it would provide the necessary time for quality, health IT, and clinical teams to more effectively utilize change management processes to improve scores until such time as alternative and more advanced techniques are more commonplace and tested without significantly impairing CMS' ability to review and analyze data generated by eCQMs.

Response: We thank the commenters for their support. While we believe that most hospitals would be ready to successfully report on at least 6 eCQMs for the CY 2018 reporting period/FY 2020 payment determination, we also want to be responsive to feedback that a number of hospitals, especially small, rural, and IHS and tribal hospitals as well as hospitals with fewer financial resources, need additional time and flexibility to successfully implement all of the eCQM reporting requirements. Therefore, at this time, we believe finalizing the modified, reduced requirements for hospitals to report one, self-selected calendar quarter of data for 4 eCQMs, as discussed above, better balances stakeholder concerns while remaining consistent with our goal to gradually transition toward more robust electronic quality measure reporting.

Although we are not finalizing our original proposal to require reporting on the first three calendar quarters of data for 6 eCQMs, we encourage hospitals to continue refining their electronic reporting implementation activities to

successfully achieve electronic data capture and reporting. In addition, we encourage early testing and the use of pre-submission testing tools such as the PSVA to reduce errors and inaccurate data submissions in eCQM reporting. As time passes, we anticipate that hospitals will continue to build and refine their EHR systems and gain more familiarity with reporting eCQM data, resulting in more accurate data submissions with fewer errors.

Comment: Several commenters supported the proposed reduction from 8 required eCQMs to 6 for the CY 2018 reporting period/FY 2020 payment determination, but suggested that CMS allow hospitals to self-select the three quarters for which they provide data. The commenters noted that the comprehensive process at the start of the calendar year is still very time consuming and cumbersome with changing/updating eCQM logic definitions, vendor relations, schemas for running reports, and XML files occurring at the same time. Some commenters indicated that they would support reporting data from the first quarter performance period when this year-end process is more established and predictable.

Response: We refer readers to our reduced requirements as discussed above. We acknowledge the burden associated with eCQM logic definitions, implementation of report schemas and reconciliation of XML files, which is why we have further reduced the reporting requirements for both the CY 2017 and CY 2018 reporting periods. In addition, we refer readers to section IX.A.10.d.(2)(b)(ii) of the preamble of this final rule, in which we discuss our policy to require EHRs to be certified to all available eCQMs. We believe that satisfying this requirement will offset the burden associated with health IT vendor relations, as hospitals will not have to certify individual electronic measures at the time electronic reporting is increased. Furthermore, we will take these comments into consideration for future policies. We believe that with time, as hospitals continue to gain more experience with eCQM reporting, the challenges hospitals encounter at the beginning of each calendar year will be reduced.

Comment: One commenter supported the reduction in the number of required eCQMs from 8 to 6 for the CY 2018 reporting period/FY 2020 payment determination, but suggested that CMS retain the requirement to report one full calendar year of data. Further, the commenter suggested gradually increasing the number of required eCQMs in future years. The commenter believed that this approach would allow hospitals to adapt to more robust eCQM requirements.

Response: We thank the commenter for their support. We refer readers to our modified policies as discussed above. For future years, we will consider requiring hospitals to report more quarters of data and gradually increase the electronic reporting of quality measure data in the Hospital IQR Program. In the meantime, we will continue to assess the progress of implementing eCQM reporting capabilities and engage in discussions with hospitals regarding their experiences as we consider the establishment of eCQM policies in future rulemaking.

Comment: One commenter sought clarification on whether or not the CY 2018 eCQM data would be publicly reported.

Response: In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50815 through 50818), we adopted a policy under which we would only publicly report eCQM data in the Hospital IQR Program if we deem that the data are accurate enough to be publicly reported (78 FR 50816). As described in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57176), we will not conduct the first validation of eCQM data until spring of 2018 to validate data from the CY 2017 reporting period. Validation of CY 2017 data during spring of 2018 affects the FY 2020 payment determination (81 FR 57177).

We believe it is important to confirm the validity of quality performance data before it is publicly reported on the *Hospital Compare* Web site. A number of commenters have expressed concerns about the accuracy of eCQM data or the comparability of eCQM data to non-electronic CQMs, and a full validation of the CY 2017 data will allow us to assess the merit of these concerns. Once we have analyzed the first year of eCQM data validation results, we will determine whether the data should be publicly reported the *Hospital Compare* Web site.

After consideration of the public comments we received, we are finalizing a modification of our proposal, such that instead of requiring submission of 6 eCQMs for the first three calendar quarters (Q1–Q3) of CY 2018, we are further reducing requirements, such that hospitals are required to report only one, self-selected calendar quarter of data for 4 eCQMs for the CY 2018 reporting period/FY 2020 payment determination. We also refer readers to section IX.E.2.b. of the preamble of this final rule where we are finalizing the same modified policy for CQM electronic reporting requirements under the Medicare and Medicaid EHR Incentive Programs.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20051), we stated that the proposals related to the CY 2017 reporting period/FY 2019 payment determination and CY 2018 reporting period/FY 2020 payment determination, if finalized, would also have implications for eCQM validation in the Hospital IQR Program. Validation of eCQM data under the Hospital IQR Program is set to begin using CY 2017 reported data for the FY 2020 payment determination, as finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57153 through 57181). We refer readers to section IX.A.11. of the preamble of this final rule where we discuss our finalized validation policies.

9. Possible New Quality Measures and Measure Topics for Future Years

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53510 through 53512), we outlined considerations to guide us in selecting new quality measures to adopt into the Hospital IQR Program. Specifically, we seek to adopt measures for the Hospital IQR Program that would: (1) Promote better, safer, more efficient care; (2) expand the pool of measures to include measures that aim to improve patient safety; (3) support the NQS' three-part aim of better health care for individuals, better health for populations, and lower costs for health care by creating transparency around the quality of care at inpatient hospitals to support patient decision-making and quality improvement; (4) collect data in a manner that balances the need for information related to the full spectrum of quality performance and the need to minimize the burden of data collection and reporting; (5) weigh the relevance and utility of the measures compared to the burden on hospitals in submitting data under the Hospital IQR Program; (6) to the extent practicable, consider measures that have been nationally endorsed by a multi-stakeholder organization, developed with the input of providers, purchasers/payers, and other stakeholders, and aligned with best practices among other payers and the needs of the end users of the measures; (7) in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed, give due consideration to measures that have been endorsed or adopted by a consensus organization identified by the Secretary; (8) give priority to measures that assess performance on conditions that result in the greatest mortality and morbidity in

the Medicare population, are high volume and high cost for the Medicare program, and for which wide cost and treatment variations in the Medicare population have been reported across populations or geographic areas despite established clinical guidelines; (9) focus on selecting measures that will also meet the Hospital VBP Program measure inclusion criteria and advance the goals of the Hospital VBP Program by targeting hospitals' ability to improve patient care and patient outcomes; and (10) align with the HHS Strategic Plan and Initiatives [174] and the CMS Strategic Plan.[175]

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20051 through 20064), in keeping with these considerations, we invited public comment on the potential future inclusion of the following seven measures in the Hospital IQR Program (one measure related to the quality of informed consent documents, four measures that evaluate end-of-life processes and outcomes for cancer patients, and two measures that evaluate nursing skill mix):

- Quality of Informed Consent Documents for Hospital-Performed, Elective Procedures measure;
- Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life measure (NQF #0210);
- Proportion of Patients Who Died from Cancer Not Admitted to Hospice measure (NQF #0215);
- Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life measure (NQF #0213);
- Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days measure (NQF #0216);
- Skill Mix (Registered Nurse [RN], Licensed Vocational/Practical Nurse [LVN/LPN], Unlicensed Assistive Personnel [UAP], and contract) (Nursing Skill Mix) Measure (NQF #0204); and
- Nursing Hours per Patient Day Measure (NQF #0205).

We also are considering newly specified eCQMs for possible inclusion in future years of the Hospital IQR and Medicare and Medicaid EHR Incentive Programs. These measures are listed and these topics are further discussed below.

- Safe Use of Opioids—Concurrent Prescribing;
- Completion of a Malnutrition Screening within 24 Hours of Admission;
- Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition within 24 Hours of a Malnutrition Screening;
- Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment;
- Appropriate Documentation of a Malnutrition Diagnosis;
- Tobacco Use Screening (TOB–1);
- Tobacco Use Treatment Provided or Offered (TOB–2)/Tobacco Use Treatment (TOB–2a);
- Tobacco Use Treatment Provided or Offered at Discharge (TOB–3)/Tobacco Use Treatment at Discharge (TOB–3a);
- Alcohol Use Screening (SUB–1);
- Alcohol Use Brief Intervention Provided or Offered (SUB–2)/Alcohol Use Brief Intervention (SUB–2a); and
- Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge (SUB–3)/Alcohol & Other Drug Use Disorder Treatment at Discharge (SUB–3a).

a. Potential Inclusion of the Quality of Informed Consent Documents for Hospital-Performed, Elective Procedures Measure

(1) Background

The process and documentation of informed consent for surgical procedures is an ethical obligation and legal mandate intended to uphold patient autonomy. It is also a standard part of clinical practice performed prior to most procedures and therapies with material risks. This process provides information to patients about the associated risks and benefits, alternative treatment options, and what to expect during and after the procedure. As described in the literature and reported by patients, comprehensive informed consent documents can improve patient comprehension and satisfaction, and support patients in making decisions that are aligned with their expectations, preferences, and goals.[176 177 178 179 180 181 182]

Despite their importance, and our regulations in the Conditions for Participation Guidelines,[183] informed consent documents are frequently generic, lack information that is relevant to the procedure, and include illegible, hand-written information. Moreover, patients are often given and asked to sign the informed consent document minutes before the start of a procedure when they are most vulnerable and least likely to ask questions.

Therefore, we developed the Measure of Quality of Informed Consent Documents for Hospital-Performed, Elective Procedures (hereinafter referred to as, Quality of Informed Consent Documents measure). This measure was developed in conjunction with feedback from patients and patient advocates convened by the measure developers, all of whom affirmed the measure captured the most salient elements of informed consent documents, and represented a minimum, though significant, standard all hospitals should meet. We recognize the Quality of Informed Consent Documents measure does not capture all aspects of the informed consent process or all aspects of quality related to patient engagement in shared decision making. However, we view the Quality of Informed Consent Documents measure as a critical first step to incentivize hospitals to improve the informed consent process and to ensure patients receive basic information in a written format which is understandable, legible and presented with sufficient time allowed for questions and deliberation. The members of the patient workgroup involved in measure development also agreed with this determination and supported the measure.

[174] HHS Strategic Plan, available at: *https://www.hhs.gov/about/strategic-plan/*.

[175] CMS Strategy: The Road Forward 2013–2017, available at: *https://www.cms.gov/About-CMS/Agency-Information/CMS-Strategy/Downloads/CMS-Strategy.pdf*.

[176] Arnold SV, Decker C, Ahmad H, et al. Converting the informed consent from a perfunctory process to an evidence-based foundation for patient decision making. Circ Cardiovasc Qual Outcomes. 2008;1(1):21–28.

[177] Zuckerman MJ, Shen B, Harrison ME, et al. Informed consent for GI endoscopy. Gastrointestinal endoscopy. 2007;66(2):213–218.

[178] Wu HW, Nishimi RY, Page-Lopez CM, Kizer KW. Improving Patient Safety Through Informed Consent for Patients with Limited Health Literacy. An implementation report. National Quality Forum; 2005. Available at: *http://www.qualityforum.org/Publications/2005/09/Improving_Patient_Safety_Through_Informed_Consent_for_Patients_with_Limited_Health_Literacy.aspx*. Accessed: July 5, 2016.

[179] Schenker Y, Fernandez A, Sudore R, Schillinger D. Interventions to improve patient comprehension in informed consent for medical and surgical procedures: a systematic review. Medical decision making: an international journal of the Society for Medical Decision Making. 2011;31(1):151–173.

[180] Tait AR, Voepel-Lewis T, Malviya S, Philipson SJ. Improving the readability and processability of a pediatric informed consent document: effects on parents' understanding. Archives of pediatrics & adolescent medicine. 2005;159(4):347–352.

[181] Kinnersley P, Phillips K, Savage K, et al. Interventions to promote informed consent for patients undergoing surgical and other invasive healthcare procedures. The Cochrane database of systematic reviews. 2013;7:Cd009445.

[182] Lorenzen B, Melby CE, Earles B. Using principles of health literacy to enhance the informed consent process. AORN journal. 2008;88(1):23–29.

[183] Electronic Code of Federal Regulations, available at: Part 482—Conditions of Participation for Hospitals, § 482.24, § 482.51, § 482.90, § 482.98, § 482.102. *http://www.ecfr.gov/cgi-bin/text-idx?SID=faac625d3284209cb805fb0b44c941fa&mc=true&node=pt42.5.482&rgn=div5#se42.5.482_124*.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20052 through 20055), we stated that we are considering including the Quality of Informed Consent Documents measure in the Hospital IQR Program in future rulemaking.

(2) Overview of Measure

Improving the quality of informed consent documents is a fundamental step for advancing patient-centered decision making.[184 185 186 187 188 189] The written quality of informed consent documents is a critical component of the informed consent process, and hospitals have a role in ensuring their patients have the information they need in a readable form and with time to consider their options. We expect the Quality of Informed Consent Documents measure will help to pave the way for future measures which evaluate other components of the informed consent process, including shared decision-making.

The measure focuses on the quality of informed consent documents for elective procedures. Further, with a focus on ensuring that each person and family is engaged as partners in their care, this measure addresses the NQS priority of promoting effective communication and coordination of care. Elective procedures were chosen as the focus of the measure because all elective procedures have informed consent documents as standard practice. In addition, we believe patients undergoing elective, rather than emergent surgery, will benefit from a measure aimed at optimizing communications about the risk, benefits, and purpose of the procedure because there are typically reasonable alternatives to elective procedures and different patients may choose different options depending on their preferences, values, and goals. Further, elective procedures usually allow ample decision time and do not require expedited explanations and decisions due to life threatening situations.

The measure would require hospitals to evaluate a sample of their informed consent documents from elective procedures performed among Medicare FFS patients aged 18 years and older hospitalized at acute care hospitals. The measure uses administrative claims to select a stratified random sample of elective procedures across specialties that are performed in hospitals. The informed consent documents associated with these procedures are reviewed and abstracted by trained personnel using a validated Abstraction Tool. Abstractors are trained using standard instructions, videos, and test documents with audit review we have developed. For additional information about the training materials and procedures, see the measure methodology report on our Web site available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.* After completing this training, we estimate the abstraction time is approximately four minutes per document and the inter-rater reliability is high. The tool captures 10 items which are fundamental to informed consent document quality. Documents are scored on a scale of 0 to 20, with 20 representing a better quality document. Document scores are then aggregated to calculate hospital-level performance on the measure. The measure is not risk adjusted because patient characteristics should not impact informed consent document quality. We invited public comment on how the measure would be reported and implemented.

We developed the Quality of Informed Consent Documents measure in 8 hospitals, and demonstrated the measure to be valid, reliable, feasible and of minimal hospital burden. We then tested the measure among a sample of 25 additional hospitals, which also showed feasibility and low burden on hospitals. In both the development and testing samples, we observed overall low performance on the measure, with intra-hospital and inter-hospital variation in the quality of consent documents. The Quality of Informed Consent Documents measure aligns with our goal to increase opportunities for shared decision making with patients and the NQS priorities of: (1) Ensuring person- and family-centered care; and (2) promoting effective communication and coordination of care. For details on development and testing, we refer readers to the measure methodology report on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

(3) Data Sources

The measure uses two sources of data to calculate the Quality of Informed Consent Documents measure: Medicare Part A administrative claims, specified below, to generate a random sample of qualified elective procedures performed at each hospital; and a sample of each hospital's informed consent documents and the first page of the procedure/operative report for those elective procedures. Basing the sample selection on administrative data to identify medical records of elective procedures ensures a diversity of informed consent documents on a range of procedures will be reviewed, and minimizes selection bias.

(4) Outcome

The outcome for the Quality of Informed Consent Documents measure is a quality score which is calculated by aggregating the scores for individual informed consent documents from each hospital assessed with the Abstraction Tool. The items selected for inclusion in the Abstraction Tool were important to patients, supported by evidence in the literature and published standards and guidelines, applicable to the cohort of elective procedures, easily abstracted from medical records without undue burden on patients and hospitals, and feasibly and reliably measured. These elements are also meaningful components of informed consent document quality from the patient perspective. Further, we received consistent feedback from all participating hospitals during testing of this measure that this information was useful for hospitals' efforts to improve their informed consent documents and processes by identifying important gaps in existing documentation. Quality scores on each informed consent document will be aggregated to derive a hospital-level performance score.

The measure outcome does not overlap with our current regulations holding hospitals accountable for informed consent pursuant to our Conditions of Participation or The Joint Commission 2009 Requirements Related to the Provision of Culturally Competent Patient-Centered Care Hospital

[184] Spatz ES, Krumholz HM, Moulton BW. The new era of informed consent: Getting to a reasonable-patient standard through shared decision making. *JAMA.* 2016;315(19):2063–2064.

[185] Kinnersley P, Phillips K, Savage K, et al. Interventions to promote informed consent for patients undergoing surgical and other invasive healthcare procedures. *The Cochrane database of systematic reviews.* 2013;7:Cd009445.

[186] Robb WJ, Carroll C, Kuo C. Orthopaedic Surgical Consent: The First Step in Safety. *American Academy of Orthopaedic Surgeons (AAOS) Now.* 2015;9(9).

[187] Arnold SV, Decker C, Ahmad H, et al. Converting the informed consent from a perfunctory process to an evidence-based foundation for patient decision making. *Circ Cardiovasc Qual Outcomes.* 2008;1(1):21–28.

[188] The Joint Commission. Quick Safety: An advisory on safety and quality issues. Informed consent: More than getting a signature. February 2016. Available at: *https://www.jointcommission.org/assets/1/23/Quick_Safety_Issue_Twenty-One_February_2016.pdf.* Accessed: July 5, 2016.

[189] Krumholz HM. Informed consent to promote patient-centered care. *JAMA.* 2010;303(12):1190–1191.

Accreditation Program (HAP),[190] and fully aligns with State laws within the few States which have more specified informed consent rules. Current Conditions of Participation regulations focus on whether informed consent occurred and emphasize informed consent documents should include the name of the hospital, procedure, and practitioner performing the procedure along with a statement certifying the procedure, anticipated benefits, material risks, and alternative treatment options were explained to the patient or the patient's legal representative.[191] The Joint Commission offers additional guidance for best practices.[192] However, there are no regulations to ensure hospitals provide patients with adequate written information about the procedure. We believe the use of this measure would supplement and augment existing standards by incentivizing hospitals to provide a minimum set of critical information about an elective procedure to the patient within a reasonable time before the patient undergoes the procedure and to enable the patient to receive and process the information prior to signing and providing informed consent.

(5) Cohort

The cohort for the Quality of Informed Consent Documents measure includes informed consent documents for a randomly selected sample of qualifying elective surgical procedures performed within non-federal acute care hospitals performed on Medicare FFS beneficiaries, aged 18 years and over who are enrolled in Part A at the time of the procedure. The list of qualifying elective procedures includes procedures for which informed consent is standard practice. The list of qualifying procedures is broad, capturing 10 specialties and various levels of invasiveness. For example, electively-performed knee replacements and coronary artery bypass surgeries are both included. For more information about the list of qualifying procedures, we refer readers to the measure methodology report on our Web site available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospital QualityInits/Measure-Methodology.html*.

(6) Inclusion and Exclusion Criteria

Qualifying electively-performed procedures were identified using the AHRQ Clinical Classification Software (CCS) codes [193] from the list of potentially planned procedures and the list of acute discharge diagnosis AHRQ CCS codes in the CMS Planned Readmission Algorithm. The Planned Readmission Algorithm used for existing CMS readmission measures was refined in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50211 through 50216). A complete description of the CMS Planned Readmission Algorithm, which includes lists of potentially planned procedures and acute discharge diagnoses, can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospital QualityInits/Measure-Methodology.html*.

The CMS Planned Readmission Algorithm identifies a list of potentially planned procedures and a list of acute discharge diagnosis codes. Admissions that have a potentially planned procedure without an acute discharge diagnosis code are considered planned according to the CMS Planned Readmission Algorithm. The Quality of Informed Consent Documents measure does not use the Planned Readmission Algorithm to identify planned versus unplanned readmissions. The measure builds upon the established approach of the Planned Readmission Algorithm to identify only electively-performed procedures because planned procedures are also commonly electively-performed. We used clinical expert review to further narrow the list of potentially planned procedures from the Planned Readmission Algorithm to those which are consistently elective-performed and likely to have informed consent obtained prior to every procedure.

The measure excludes highly specialized procedures, such as organ transplantation because they typically use unique informed consent processes; non-invasive radiographic diagnostic tests because informed consent standards may be different than standards for invasive procedures and surgeries; and procedures that are conducted over several encounters since informed consent is likely only conducted prior to the first procedure. For more information about the list of qualifying procedures and excluded procedures, we refer readers to the measure methodology report on our Web site available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

(7) Abstraction Tool

The Abstraction Tool is an instrument used to evaluate the quality of a hospitals' informed consent documents based on a score of 0–20; a higher score indicates better quality. The Abstraction Tool is a checklist evaluating the presence of the following items in the consent document: A description of the procedure; how the procedure will be performed; the rationale for why the procedure will be performed; and the risks, benefits, and alternatives to the procedure. The Abstraction Tool also includes an item to assess whether patients received the document at least one calendar day in advance of the procedure date. Inclusion of the timing item ensures informed consent documents are not shared for the first time with patients on the day of the procedure. The Abstraction Tool provides an option for hospitals to note if a patient chose to opt out of signing their informed consent document 24 or more hours before surgery, enabling full credit to be given to the hospital for this item in that scenario. In addition, the tool gives credit for sharing the document prior to the day of the procedure, even if the patient does not sign the document until the day of the procedure. These aspects were raised with the patient and patient advocate workgroup and deemed to be more flexible to a range of scenarios and contexts, and therefore more patient-sensitive. To assess the reliability of the Abstraction Tool, we examined the inter-rater reliability (the degree of agreement among abstractors) of each item on the Abstraction Tool as well as the document scores produced by the Abstraction Tool for 80 of the 800 documents tested from the pilot project hospitals. For additional information about testing refer to our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

Abstractors enter responses for each item evaluated in each informed consent document. We would provide

[190] The Joint Commission. Quick Safety: An advisory on safety and quality issues. Informed consent: More than getting a signature. February 2016. Available at: *https://www.jointcommission.org/assets/1/23/Quick_Safety_Issue_Twenty-One_February_2016.pdf*. Accessed: July 5, 2016.

[191] Department of Health & Human Services. Centers for Medicare & Medicaid Services (CMS). *CMS Manual System. Regulations and Interpretive Guidelines for Hospitals—Condition of Participation: Medical Record Services.* Sections 482.13(b), 482.24(b), 482.51(b)(2). 2008. Available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R37SOMA.pdf*. Accessed: July 5, 2016.

[192] *https://www.jointcommission.org/assets/1/23/Quick_Safety_Issue_Twenty-One_February_2016.pdf*.

[193] Clinical Classifications Software (CCS) for ICD–9–CM Fact Sheet. Accessed at: *https://www.hcup-us.ahrq.gov/toolssoftware/ccs/ccsfactsheet.jsp*.

comprehensive standardized training materials including an instruction manual with guidance and examples of what meets criteria for each item in the Abstraction Tool, a training video, and sample test documents. This process has previously been piloted and found to be effective and efficient. For more information about the Abstraction Tool and instructions manual, we refer readers to our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

(8) Calculating the Measure Score

The measure will be calculated by aggregating the scores of the sample of hospitals' informed consent documents, as assessed using the Abstraction Tool. Based on input from stakeholders during the measure development stage, including the Technical Expert Panel convened by the measure developer, and feedback from patients and patient advocates, we are considering reporting the proportion of a hospital's sampled informed consent documents that achieve a pre-specified threshold score. For example, the proportion of a hospital's sampled informed consent documents which meet a minimum, patient-centered standard. We are considering setting the threshold score at 10 (out of 20 total points), and increasing the threshold over time. The stakeholders we sought input from during the measure development process agreed with incrementally increasing the threshold score over time. This would establish an initial target that hospitals could feasibly meet in a short period of time, and allow for further informed consent improvement. Ultimately, we envision this measure would either evolve to include additional components or could complement a measure of shared decision making when an appropriate measure becomes available for potential use in the Hospital IQR Program.

Using this scoring approach, performance scores among the 25 hospitals in the testing sample were poor. The median hospital level score, based on evaluation of 100 informed consent documents, ranged from 0 (95 percent CI: 0–5) to 12 (95 percent CI: 10–12) out of a total of 20 points. The proportion of documents achieving a threshold score of at least 10 (out of 20 points) per hospital, ranged from 0 percent to 70 percent, demonstrating that the quality of informed consent documents varies both within and between hospitals.

(9) Implementation

We are considering two implementation approaches. One approach implements the measure in a centralized fashion where hospitals send their sample of informed consent documents directly to CMS or to an entity contracted by us for central abstraction and measure score calculation. Another approach is local; hospitals abstract their own informed consent documents and transmit the abstraction results to CMS for measure calculation.

During measure development, we worked closely with hospitals to evaluate the burden associated with each approach. The greatest burden was associated with copying and electronically sending informed consent documents, making centralized abstraction a more burdensome option for hospitals. Using a brief formal training process and materials to prepare abstractors, we found hospital abstractors can reliably abstract documents at a rate of 15–20 documents per hour or 3–4 minutes per document. The final sample size required for measure reporting has not been determined but will not exceed 100 documents per hospital and may be substantially fewer than 100 documents per hospital.

Implementation would entail identifying a hospital's elective procedures which meet eligibility for the Quality of Informed Consent Documents measure using administrative claims data. We would then provide hospitals with a list of procedures and encounter dates selected from a hospital's eligible elective procedures, along with the HIC number and date of birth of the patient who had the procedure in order to identify the medical record, the qualifying procedure, and the corresponding informed consent document and operative report. Hospitals would then locally evaluate the informed consent documents for these procedures using the Abstraction Tool and transmit the results of the abstraction through a secure data file transfer or similar process, such as the QualityNet Secure Portal or the External File Online Tool. We would then calculate and report the results as the proportion of a hospital's sampled informed consent documents achieving the threshold score of 10 out of 20. Hospitals could submit data on the prior year's informed consent documents on an annual basis or more frequently, such as quarterly or every six months, allowing for more rapid cycle improvements in measure performance. If we were to pursue a local abstraction approach, we would also consider expanding the data validation process in the Hospital IQR Program to ensure hospitals' abstraction work was accurate, requiring hospitals to submit select informed consent documents to us or an entity contracted by us via a secure mechanism for review and validation.

The Quality of Informed Consent Documents for Hospital-Performed, Elective Procedures (MUC16–262) measure is included in a publicly available document entitled ''2016–2017 Spreadsheet of Final Recommendations to HHS and CMS,'' which is available on the NQF Web site.[194] The MAP did not support this measure, indicating concern about the lack of evidence that implementation will affect hospital practices and the complexity of existing guidelines, regulations and State laws related to informed consent. Further, the MAP noted that this measure captures the quality of informed consent documents rather than the quality of communication between patients and their providers.[195] However, the MAP noted that this measure concept is critical for shared decision making, and recommended that future measures on informed consent be patient-centered. In addition, the MAP noted that this measure should demonstrate reliability and validity, at the facility level, in the hospital setting, prior to being suitable for inclusion in the Hospital IQR Program measure set. Lastly, the MAP recommended the measure be submitted to NQF for review and endorsement.[196]

We invited public comment on multiple aspects of the measure. Specifically, we sought public comment on the potential scoring approach described above, reporting the proportion of a hospital's sampled informed consent documents, and setting a threshold score of 10 out of 20. In addition, we sought input on how the measure should be implemented, either through local abstraction where hospitals provide us with the results of their own abstraction work or by transmitting informed consent documents to us for centralized abstraction. We also sought public comment on the frequency of measure reporting for this measure, whether annually, quarterly, or at some other interval. More frequent reporting updates would require hospitals to abstract documents and submit the

[194] ''2016–2017 Spreadsheet of Final Recommendations to HHS and CMS, available at: *http://www.qualityforum.org/map/*.

[195] ''2017 Considerations for Implementing Measures Hospitals-Final Report,'' available at: *http://www.qualityforum.org/map/*.

[196] *Ibid.*

results more often than less frequent reporting. Finally, we sought input on a potential validation process for the Quality of Informed Consent Documents measure.

Comment: Many commenters supported the future inclusion of the ''Quality of Informed Consent Measure.'' The commenters noted that this measure is critical to patient care because it would establish standards for informed consent that would help to alleviate confusion patients have about their care (by awarding credit for the use of lay terms on the consent document) and provide opportunities for patients to ask questions (because the consent documents that are shared with patients in advance of a procedure are given credit). The commenters also stated that the more patients are empowered to be proactive and educated in their own care, the more the care provided will align with their preferences and goals. In addition, the commenters noted that measurement of informed consent documents is important because communication about care is essential to patients and their families since written information, when provided in advance, can be reviewed and shared. Further, the commenters suggested that implementing this measure would instate new standard operating procedures that could improve the patient experience. To that end, the commenters recommended that the consent forms be tailored to patient-centered care by indicating diagnosis, procedure, and alternative methods of treatment. Lastly, the commenters suggested that the document also include any/all known harmful drug and/or procedural side effects so patients are fully informed of what to expect.

Response: We thank the commenters for their support. The current version of the Abstraction Tool evaluates the informed consent document for the presence, readability, and legibility of the procedure name and a description of how the procedure is performed. It also assesses whether the document includes the rationale for the procedure (including the diagnosis), a quantitative and qualitative description of the risks associated with the procedure, patient-oriented benefits of the procedure (in other words, the physical impact of the procedure on patients), and alternatives to the procedure. The Tool also assesses whether the document was shared with the patient at least one calendar day prior to the procedure. These elements of informed consent documents were selected and developed for the measure in close partnership with a patient workgroup; they represent priority quality standards that are feasible to abstract reliably. The Tool gives credit for each item, and gives a score of 0 to 20; as such, the measure would demonstrate variation in quality between informed consent documents within a single hospital, and would illuminate overall quality differences between hospitals. In addition to illuminating quality, the measure is intended to incentivize hospitals to produce more patient-centered informed consent documents that meet, at a minimum, the standards set forth in this tool.

Comment: Many commenters supported the future inclusion of the ''Quality of Informed Consent'' measure in the Hospital IQR Program measure set, but provided several recommendations for CMS to consider. Specifically, the commenters suggested being more prescriptive about the content and form of the description of alternative treatments, noting that this content should contain comparative benefits versus risks and a disclosure of any financial incentives in place. In addition, the commenters noted that the provided scoring standard is limited in the number of elements that are essential for an informed consent document. Commenters noted that facilities could develop a standardized consent form that meets the criteria of all elements that are specified in the measure.

Response: We thank the commenters for their support and will consider these recommendations in planning for any potential future proposal of this measure. We acknowledge that although the Abstraction Tool captures many aspects of informed consent documents which commenters noted were important, it does not currently require a description of the comparative benefits versus risks associated with different treatment options or a disclosure of any financial incentives in place. While we believe the current Abstraction Tool effectively and concisely captures key elements of informed consent document quality that represent a minimum standard for informed consent documents that are meaningful to patients, we will continue to collect and evaluate feedback from stakeholders and consider commenters' suggestions to refine the Abstraction Tool during ongoing measure re-evaluation work. The measure is intended to evaluate quality and illuminate deficiencies in the current informed consent process. We hope this measure would lead hospitals to produce more patient-centered informed consent documents that meet, at a minimum, the standards set forth in this measure.

Comment: Other commenters encouraged CMS to require shared decision making for its hospital elective procedures and for all conditions that it has identified under its *Beneficiary Engagement* models. Many commenters suggested that informed consent should be a shared process when the patient has a partner or spouse. Other commenters also recommended that the measure developer consider incorporating the American College of Surgeons (ACS) principles in the development of the informed consent document and capture the informed consent discussion, not simply the timing of when the legal document is shared. Other commenters were concerned that this measure focused on documentation rather than the actual communication process.

Response: This measure evaluates one aspect of the quality of informed consent and is not intended to be a comprehensive measure of the informed consent process or shared decision-making. It is intended as an initial step toward improving the informed consent process and represents a minimum requirement for optimal informed consent and shared decision-making. The measure assesses basic elements of the informed consent document and captures when the document is shared with the patient, a signal of when an informed consent discussion took place. We did not consider the elements of the *Beneficiary Engagement* models, as they pertain to shared-decision making and not specifically to the informed consent document. Additional information about *Beneficiary Engagement* models can be found on the CMS Innovation Center Web site at: *https://innovation.cms.gov/initiatives/Beneficiary-Engagement/*. Regarding commenters' concern that the focus of the measure is on documentation rather than the actual communication process, there are significant challenges in both the methods and feasibility of assessing whether shared decision-making occurred prior to a broad range of elective procedures. While we acknowledge that this measure of informed consent does not assess all aspects of decision-making quality, we believe the informed consent document is a critical part of the informed consent process. Patients and families have observed and experienced that many informed consent documents are of poor quality and in need of improvement. They have encouraged policymakers to work towards a more patient-centered standard. We have worked closely with patients, patient advocates, and families

to develop this measure, which provides a mechanism for assessing the quality of informed consent documents and the timing in relation to the procedure in which they are shared, as two aspects of the communication needed for informed decision-making. We received broad stakeholder support for the concept of measuring the quality of informed consent documents, and we believe this measure represents an important first step forward in improving high-quality decision-making. The measure would fill a significant gap in evaluating the quality of current informed consent documents. We will consider incorporating the American College of Surgeons (ACS) principles [197] and other aspects of shared decision-making in future versions of the measure.

Comment: A few commenters urged CMS to require that patient decision aids are certified pursuant to the certification criteria adopted by the NQF.

Response: We recognize commenters' desire to capture the use of patient decision aids, which are tools designed for patients who have certain conditions to help them think about what is important to them when discussing with their clinician the options for health management. While standards exist for what defines a decision aid, pamphlets about a procedure and patient instructions are frequently labeled as decision aids [198] despite not meeting the standards. As such, without the certification of decision aids, there is a risk of incentivizing the use of low-quality tools. While certification may be feasible in the future, at the current time, no national certification program exists. The NQF has put forth criteria for certifying decision aids, though the process for doing so has yet to be defined. We refer readers to the NQF Web site for more information regarding the decision aids project at: *http://www.qualityforum.org/Decision_Aids.aspx*. We will continue to evaluate the inclusion of decision aids as well as other elements of high-quality informed consent documents, as suggested above.

Comment: Several commenters expressed concerns about the Quality of Informed Consent measure's lack of NQF endorsement.

Response: Although the Quality of Informed Consent measure has yet to undergo NQF endorsement review, the measure was developed according to and adhering to the guidelines and standards from NQF. NQF provides measure evaluation criteria on its Web site at: *http://www.qualityforum.org/Measuring_Performance/Submitting_Standards/Measure_Evaluation_Criteria.aspx*. We plan to submit the measure for NQF endorsement during the next appropriate call for measures.

Comment: Several commenters expressed concern the Quality of Informed Consent measure fails to account for patient variables, such as health literacy and additional education.

Response: We recognize that patients of different levels of English language proficiency and health literacy may require tailored informed consent documents. The current measure assesses lay language in English. Future measure development efforts may consider adapting the Abstraction Tool used to evaluate the quality of informed consent documents in non-English languages and the technical capacity for literacy support (for example, text readers, large print, health coaches, etc.).

Comment: Several commenters stated that if hospitals are not communicating information necessary to achieve informed consent, the issue should be addressed through existing processes as opposed to layering on a new quality metric.

Response: We believe the Quality of Informed Consent measure would fill a gap in existing processes, which may not be sufficient to ensure high quality informed consent documentation. Guidelines do not specify which details should be included in the written informed consent document, despite the documents' design to support patient- and procedure-specific information. Research has shown there is no standardization of informed consent documents and often the most important information about the procedure is missing, illegible, or incomprehensible.[199] The Quality of Informed Consent measure is designed to set a basic standard for the quality of informed consent documents administered by hospitals and, as such, is an important quality improvement tool.

Comment: Several commenters indicated they did not believe this measure would lead to improved patient engagement. The commenters encouraged CMS to work with hospitals, patient advocates, Congress, and States to streamline the amount of paperwork that patients, patient advocates, and their families are required to sign prior to or upon admission.

Response: We collaborated closely with patients in developing this measure in order to identify the essential elements of informed consent documents. We designed the measure to illuminate deficiencies with informed consent and to incentivize improved, patient-centered informed consent documents that are shared with patients ahead of the procedure, which we and our patient collaborators believe would lead to improved patient engagement and more meaningful informed consent documents. The measure is a first step towards increasing the attention and effort that hospitals dedicate to providing high-quality informed consent, a critical aspect of patient-centered decision making.

We appreciate the commenters' concerns about the burden of paperwork on patients. This measure assesses a practice that is already in place; informed consent documents are signed and scanned into patients' medical charts as routine medical care making them feasible to review without the need for further data collection.

Comment: Some commenters expressed concern about the future inclusion of the Quality of Informed Consent measure in the Hospital IQR Program. Specifically, the commenters were concerned about the administrative burden of abstraction or transmission of informed consent documents to CMS for centralized abstraction in order to report the Quality of Informed Consent measure, especially for large academic medical hospitals. The commenters requested that CMS allow hospitals ample time to review and implement each abstracted element prior to the data collection period. Further, the commenters stated that additional testing should be performed and workable solutions identified prior to implementation. In addition, the commenters believed the collective administrative burden of reporting this measure would be immense, costly, and would not commensurately improve value for the patient. Several commenters did not support the future inclusion of the Quality of Informed Consent measure, indicating that the measure does not assess quality of care and is significantly burdensome.

Response: We have performed testing across a diverse spectrum of hospitals and those findings indicate the measure would not be significantly burdensome. In developing this measure, we have worked with 33 hospitals to assess the feasibility of the abstraction process and

[197] American College of Surgeons Principles and Practice 7th Edition, available at: *http://booksmedicos.org/acs-surgery-principles-and-practice-7th-edition/*.

[198] Herrin J, Harris K, K K, Hines M, Frosch D. Patient and family engagement: a survey of US hospital practices. BMJ Qual Saf. 2016;25:182–9.

[199] Shahu A, Schwartz J, Perez M, Bernheim SM, Krumholz HM, Spatz ES. Discerning quality: an analysis of informed consent documents for common cardiovascular procedures. *BMJ Qual Saf.* 2016.

have determined it presents a low burden to hospitals. While abstraction was conducted centrally for the development and testing of the measure, we would recommend local abstraction of informed consent documents by hospital personnel, eliminating the transfer of documents. We have developed training materials and a process for easily identifying the informed consent document in the medical record and for rating the quality of informed consent documents. Among our test hospitals, experienced abstractors required less than 1 hour of training to be able to abstract documents accurately, with high inter-rater reliability, at a rate of approximately 3 minutes per document. We will continue to consider this feedback and would inform stakeholders about the abstraction process if we decide to move forward with proposing to adopt the Quality of Informed Consent measure in the Hospital IQR Program through future rulemaking. With regard to the comment that the Quality of Informed Consent measure does not assess quality of care, we have received positive feedback from patients, patient advocates, and patient' families, both during measure development and during this public comment period in support of this measure as a meaningful metric of quality of care.

Comment: Some commenters expressed concern with the scoring standard used for determining a high-quality informed consent document, noting that the current threshold score is too low, and recommended that CMS raise the threshold to ensure overall form improvement via the inclusion of information on the suggested items of alternative treatments and comparative benefits versus risks. These commenters strongly recommended that CMS raise the minimum passing score of 10 out of 20 points substantially, to 18 out of 20 points. The commenters noted that changing a singular document at multiple intervals to improve the score requires unnecessary, repeated corporate and legal review and may also confuse providers as well as patients. Setting the threshold at a higher level from the beginning better serves both patients and hospitals. Lastly, some commenters noted that all the scores are solely based on a ''Yes'' or ''No'' checklist completed by a healthcare provider, and suggested that those response options are insufficient to adequately represent the patient experience.

Response: The threshold approach sets an external standard for quality. The threshold score we sought comment on (that is, the percentage of documents scoring at least 10 out of 20 points) was supported by the patient working group and TEP which was convened by a contractor during measure development. The patient working group and TEP felt that an intermediate threshold would reward hospitals in their efforts to improve documents. While this standard would need to be set by consensus, the standard could increase as hospitals gain more experience with the measure, which would also decrease the initial burden of training.

We do not believe that increasing the threshold score over time would lead to repeated corporate or legal review, or be confusing to clinicians or patients, because hospitals could work to revise the content included in their informed consent document at one time and then focus on improving their score though efforts to share the documents at least one calendar day prior at a future time. These efforts may take longer, as they require changes in process and in some cases, the use of technology, but not necessarily corporate or legal review.

While we agree the ''Yes'' or ''No'' checklist does not capture the spectrum of informed consent document quality, we developed definitions and criteria for what qualifies as ''passing'' based on iterative review of consent forms from 33 hospitals, considering a range of elective procedures and using feedback from the patient workgroup. Thus, we believe that the ''Yes'' or ''No'' approach is a meaningful indicator of quality. Nonetheless, we recognize that quality exists on a spectrum, and we will take into consideration the commenters' feedback in future development of the measure. We also will continue to collect and evaluate feedback from stakeholders and consider commenters' suggestions to refine the threshold used for initial measure implementation during ongoing measure re-evaluation work. We will inform stakeholders of any changes to the Abstraction Tool and/or minimum threshold in future rulemaking, should we move forward with proposing to adopt the Quality of Informed Consent Document measure for the Hospital IQR Program.

Comment: Several commenters also recommended that the manual abstraction process defined in the Quality of Informed Consent measure be converted to electronic extraction. Several commenters recommended that this be a voluntary measure in at least the first year of reporting to determine feasibility of being able to electronically capture the data. Other commenters suggested that manual abstraction should remain an option for those organizations that are not early adopters. One commenter encouraged the use of Health Information Technology (HIT) to facilitate the informed consent process and suggested the inclusion of the Advancing Care Information requirements complementary to certified HIT standards (already in the 2015 Edition) that support patient specific education and clinical decision support selection for use in the selection of patient-specific informed consent, and the patient's response incorporated into the HIT using the existing clinical content document (CCD–CCDA) standards.

Response: The measure currently utilizes a manual abstraction process, but we agree electronic extraction could potentially improve efficiency and decrease reporting burden in the future. Specifically, we appreciate the suggestion that this measure might be appropriate for the Advancing Care Information performance category under the Merit-based Incentive Payment System (MIPS), which is part of the Quality Payment Program established under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).[200] We also recognize that some hospitals already have in place technology to assist with providing informed consent documents to patients. The purpose of the Quality of Informed Consent measure is to improve the quality of informed consent documents rather than assessing the methods by which hospitals choose to provide their informed consent documents to patients. We encourage innovation in informed consent development and delivery to patients. This measure captures hospital quality by assigning higher ratings to informed consent documents that are patient- and procedure-specific and that are shared with patients ahead of their procedures. We will consider additional abstraction options prior to proposing to adopt this measure for the Hospital IQR Program in the future.

We thank the commenters and we will consider their views as we develop future policy regarding the use of a Quality of Informed Consent Documents for Hospital-Performed, Elective Procedures measure in the Hospital IQR Program.

b. Potential Inclusion of Four End-of-Life (EOL) Measures for Cancer Patients

(1) Background

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20055 through 20056), we discussed the potential use of palliative and end-of-life care measures in the Hospital IQR Program.

[200] *https://qpp.cms.gov/mips/advancing-care-information.*

The quality of palliative and end-of-life care has been identified as a measurement gap in the Hospital IQR Program.[201] End-of-life care may be defined as ''comprehensive care that addresses medical, emotional, spiritual, and social needs during the last stages of a person's terminal illness.'' [202] While end-of-life care may include palliative care, palliative care is generally defined as multi-faceted, holistic care that anticipates, prevents, and alleviates suffering.[203] Both palliative and end-of-life care can be provided when a patient is receiving hospice services, but it is not necessary for a patient to be admitted to hospice to receive such care. Hospitals are encouraged to counsel patients about palliative and end-of-life care; however, the National Academy of Medicine (NAM) of the National Academies has noted that ''too few patients and families receive this help [palliative and end-of life care] in a timely manner,'' [204] despite evidence that this care improves patient quality of life. In the same report, the NAM proposed a number of core components of quality palliative and end-of-life care. These proposals included offering a referral to hospice if a patient ''has a prognosis of 6 months or less'' and regular revision of a patient's care plan to address the patient's changing needs, as well as the changing needs of the patient's caregivers.[205] The four palliative and end-of-life measures described below seek to improve the quality of care for cancer patients.

(2) Overview of Measures

All four of these end-of-life measures seek to assess the quality of end-of-life care for patients who died of cancer in order to improve the quality of end-of-life care for future cancer patients. As such, the four palliative and end-of-life measures all address the NQS priority of communication and care coordination. The Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (EOL-Chemo) (NQF #0210) measure evaluates the proportion of patients who died from cancer who received chemotherapy in the last 14 days of life. This measure was finalized for CY 2017 for the MIPS (81 FR 77672). The Proportion of Patients Who Died from Cancer Not Admitted to Hospice (EOL-Hospice) (NQF #0215) measure assesses the proportion of patients who died from cancer who were not admitted to hospice and evaluates whether or not patients were admitted to hospice. The Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days (EOL–3DH) (NQF #0216) measure evaluates whether patients who were admitted to hospice were admitted to hospice late in the course of their illness, defined as within three days of their death. The Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life (EOL–ICU) (NQF #0213) measure assesses whether cancer patients were admitted to the ICU in the last 30 days of their lives.

These measures were reviewed by the MAP in December of 2016 for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program (MUC16–271, MUC16–273, MUC16–274, and MUC16–275).[206] The MAP Hospital Workgroup supported the inclusion of these measures in the PCHQR Program. Specifically, the MAP stressed the importance of end-of-life care as an area of cancer care that needs improvement and noted that these measures could help improve the patient and caregiver experience. The MAP also noted these measures could help encourage the use of hospice care and help avoid aggressive treatment in the last days of life, as unnecessary treatment at the end of life has been found to negatively impact a person's quality of life.[207] We note that prior to implementation in the Hospital IQR Program, these measures would require a subsequent review from the MAP to assess appropriateness for programmatic inclusion.

With additional testing to assess the appropriateness of these measure in the acute care setting, we believe that these measures may be suitable for the Hospital IQR Program because they provide insight on the quality of end-of-life care for cancer patients provided in inpatient settings other than at PPS-exempt cancer hospitals. Currently, the Hospital IQR Program measure set does not contain any measure that assesses end-of-life care. As such, the future inclusion of these measures could promote the expansion of the Hospital IQR Program measure set to include a more robust set of measures that evaluate end-of-life care and address the NQS priority of improving person and family engagement. In addition, because these measures are specific to cancer patients, future inclusion would promote programmatic alignment between the Hospital IQR and PCHQR Programs should these measures be finalized as discussed in section IX.B.4.b. of the preamble of the final rule for inclusion in the PCHQR Program.

Additional information on these measures is available at: *http://www.qualityforum.org/Publications/2016/12/Palliative_and_End-of-Life_Care_2015-2016.aspx*.

We invited public comment on the possible future inclusion of one or more of these end-of-life measures in the Hospital IQR Program.

Comment: Many commenters supported the proposed future inclusion of the End of Life Cancer measure set. The commenters believed that these measures represent a good start to ensuring that patients with cancer, who are at the end of life, receive appropriate care that serves to protect quality of life. The commenters indicated that the data from these measures would be useful in evaluating the impact of the use or lack of use of hospice services, and influential in improving the care of those with advanced illness. The commenters also stated there is a pressing need to establish additional quality measures that support evidence-based care for individuals with advanced illness and recommended CMS consider expanding measures to include additional illnesses, provider types, and use in additional care settings. In addition, commenters encouraged CMS to pair these utilization measures with measures of shared care planning, such as an assessment of how closely care received aligns with patient preferences and goals. Lastly, commenters noted these measures have been thoroughly tested and are NQF-endorsed. Some commenters suggested that CMS consider adding additional measures (''Advance Care Plan'' (NQF #0326) and ''Patients Admitted to the ICU Who Have Care Preferences Documented'' (NQF #1626)) to the Hospital IQR Program. The commenters stated these two measures would help fill a gap in the Program by ensuring that hospitals have documented patients' care preferences and make efforts to revisit and update these preferences as conditions change and critical care is needed.

Response: We thank the commenters for their support. We will consider the

[201] National Quality Forum, Final Report. Palliative and End-of-Life Care 2015–2016, available at: *http://www.qualityforum.org/Palliative_and_End-of-Life_Care_Project_2015-2016.aspx*.

[202] *Ibid.*

[203] *Ibid.*

[204] Committee on Approaching Death: Addressing Key End of Life Issues, Institute of Medicine: Dying in America: Improving Quality and Honoring Individual Preferences Near the End of Life. Washington, DC, National Academies Press, 2015.

[205] *Ibid.*

[206] 2016–2017 Spreadsheet of Final Recommendations to HHS and CMS, Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*.

[207] ''2017 Considerations for Implementing Measures Hospitals-Final Report,'' available at: *http://www.qualityforum.org/map/*.

possibility of pairing these measures with measures of shared care planning if we move forward with proposing one or more these measures for future adoption in the Hospital IQR Program. Further, we will assess the suitability of the suggested measures (''Advance Care Plan'' (NQF #0326) and ''Patients Admitted to the ICU Who Have Care Preferences Documented'' (NQF #1626)), and any other measures that address patients with advance illness, as we consider future measures the Hospital IQR Program measure set. We recognize that in order for these measures to be considered for inclusion in the Hospital IQR Program measure set they would have to be re-specified for the inpatient setting. If the measure steward expands these end-of-life measures to include additional illnesses and provider types, we will examine how these additional variables affect their reliability and validity as we consider whether to propose to adopt these measures in the Hospital IQR Program in the future.

Comment: Some commenters did not support the proposed future inclusion of the End of Life cancer measures in the Hospital IQR Program. These commenters expressed concern that these measures are not adjusted to exclude patients from the numerator and denominator who have stated a desire to pursue aggressive treatment through the end of life.

Response: We acknowledge the commenters' concerns that these measures are not adjusted to exclude patients from the numerator and denominator who have stated a desire to pursue aggressive treatment through the end of life. We note that prior to proposing to adopt the End of Life cancer measures in the Hospital IQR Program, these measures would require a subsequent review by the MAP to assess appropriateness for programmatic inclusion, which would include feedback on the appropriateness of numerator and denominator exclusion criteria. Should we decide to move forward with proposing to adopt these measures for the Hospital IQR Program in the future, we may consult the measure steward to determine whether patients who have undergone aggressive treatment through the end of life should be excluded from the measurement cohort.

Comment: Some commenters expressed concerns about the future inclusion of the End of Life cancer measure set in the Hospital IQR Program, noting that the proposed measures should remain only in the PCHQR Program, where they are more appropriate. The commenters expressed that patient mix and cancer stage at time of diagnosis can greatly impact the measures. In addition, the commenters suggested that, although these are inpatient measures, they are highly dependent on access to ambulatory services (for example, hospice, palliative care, and supportive services), which is in limited supply in many geographic areas. Other commenters stated that because measure performance is predicated on the physician, who is responsible for the patient's care, in instances where the hospital does not employ the oncologist (or primary care physician), the ability to drive performance improvement is limited. Further, these measures would disadvantage community hospitals that don't employ the oncologists in their community. Some commenters recommended CMS test the measures for use in both cancer hospitals and IPPS acute hospitals and the measures be reviewed for NQF endorsement in those settings prior to proposing to implement the measures in a public quality reporting program. Other commenters suggested these measures be tested in facilities with cancer patients and that CMS should adjust the specifications as needed prior to implementation.

Response: We acknowledge the commenters' concerns. We note that prior to proposing to adopt the End of Life cancer measures for the Hospital IQR Program, these measures would require testing in acute care hospitals by the measure steward, which would provide insight on the burden associated with data collection in these settings. Through testing the measure steward could be able to better assess the impact of factors such as patient mix and cancer stage at time of diagnosis, and determine if they should be a part of numerator and/or denominator exclusion criteria. Further, testing could help determine the impact of factors such as access to ambulatory services (as the commenter described) and the impact on quality of hospitals that have an oncologist on staff versus hospitals that do not. In addition, these measures would be subject to review by the MAP to assess appropriateness for Hospital IQR Program inclusion, which would include feedback on the appropriateness of risk adjustment, and the degree of specificity required in the measures' components (for example, title, numerator description, denominator description, etc.) and to ensure no unintended consequences result, such as dis-incentivizing physicians to refer terminally ill patients to appropriate palliative care. We reiterate when the MAP reviewed these measures for the PCHQR Program, it noted these measures could help encourage the use of hospice care and help avoid aggressive treatment in the last days of life, as unnecessary treatment at the end of life has been found to negatively impact a person's quality of life.[208] Further, we believe these measures may be suitable for the Hospital IQR Program as well, because they could provide insight on the quality of end-of-life care for cancer patients provided in inpatient settings other than at PPS-exempt cancer hospitals.

Comment: Some commenters also expressed concerns about manual data collection for these items affecting data quality and reliability, and about unintended consequences, such as providers refraining from offering treatment of potential value in the face of prognostic uncertainty. The commenters suggested since not all cancer patients are terminal, at minimum, CMS should add the word ''terminal'' before the word ''cancer'' in each of the measures' titles, which would avoid undesired penalties and incentivize physicians to refer terminally ill patients to appropriate palliative care. The commenters also recommended CMS consider the NQF palliative care measure for Documentation of Preferences for Patients Admitted to the ICU (NQF #1626) instead.

Response: We acknowledge the concerns about manual data collection for these items affecting data quality and reliability and about unintended consequences. As we noted above, prior to proposing to adopt the End of Life Cancer measures for the Hospital IQR Program in the future, these measures would require testing in the inpatient setting, which would provide insight on the burden associated with data collection in that setting. In addition, testing could provide the measure steward with data to be able to assess potential unintended consequences.

We thank the commenter for their suggested revision to the name of the measure, and will consider this, as well as the impact of terminally ill patients being a part of the measurement cohort, should we decide to move forward with proposing to adopt these measures for the Hospital IQR Program. We will consider the suggested measure (for Documentation of Preferences for Patients Admitted to the ICU (NQF #1626)) and any other measures that

[208] 2017 Considerations for Implementing Measures Final Report—Hospitals, available at: *http://www.qualityforum.org/Publications/2017/02/2017_Considerations_for_Implementing_Measures_Final_Report_-_Hospitals.aspx.*

evaluate the quality of end-of-life care for cancer patients if we move forward with proposing adoption of these types of measures for the Hospital IQR Program in the future.

Comment: One commenter recommended CMS consider a more comprehensive approach to measurement for end of life care and advance care planning that is consistent with the Institute of Medicine's (IOM) recommendations and sensitive to patient preferences.

Response: We thank the commenter for their suggestion and will consider the National Academy of Medicine (NAM's) (formerly, the IOM) recommendations [209] and the impact of patient preferences should we move forward with proposing to adopt the End of Life cancer measures in the Hospital IQR Program in the future.

We thank the commenters and we will consider their views as we develop future policy regarding the use of one or more of these end-of-life measures in the Hospital IQR Program.

c. Potential Inclusion of Two Nurse Staffing Measures

(1) Background

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20056 through 20059), we discussed the potential inclusion of two nurse staffing measures in the Hospital IQR Program. Nursing care is a core service of hospitals, and accordingly, hospital nurse staffing practices are increasingly recognized as a tool to improve the quality and value of patient care.[210] Studies have shown there is a link between appropriate nurse staffing and care quality and patient outcomes. For example, the AHRQ conducted a systematic review and meta-analysis examining the relationship between nurse staffing and patient outcomes. The review of 96 studies, published between 1990 and 2006, found that increased nurse staffing is associated with a reduction in hospital-related mortality and adverse patient events, such as respiratory failure, cardiac arrest, and hospital-acquired conditions.[211] A review of studies examining the impact of nurse staffing on hospital costs and patient length of stay found that an increased level of registered nurse (RN) staffing may result in reduced patient length of stay and hospital costs.[212] Furthermore, recent literature has demonstrated appropriate nursing skill mix (including licensure level and area of training for specialty) and increased RN nursing hours are associated with decreased rates of patient falls, pressure ulcers, urinary tract infections, and bloodstream infections.[213] [214] [215]

We believe there is an opportunity for hospitals to develop nurse staffing strategies to improve quality and the value of care. The inclusion of nurse staffing measures in the Hospital IQR Program would allow hospitals to assess how their nurse staffing and skill mix compare to similar hospitals and State and national levels, as well as encourage hospitals to develop optimal nurse staffing plans that meet the needs of their patients and improve quality of care. Because of the important role of nursing in providing high value care, we sought public comment on including two nurse staffing measures in the Hospital IQR Program: (1) Skill Mix (Registered Nurse [RN], Licensed Vocational/Practical Nurse [LVN/LPN], Unlicensed Assistive Personnel [UAP], and Contract) (Nursing Skill Mix) Measure (NQF #0204); and (2) Nursing Hours per Patient Day Measure (NQF #0205).

These two measures (Skill Mix (Registered Nurse [RN], Licensed Vocational/Practical Nurse [LVN/LPN], Unlicensed Assistive Personnel [UAP], and Contract) (Nursing Skill Mix) Measure (NQF #0204) (MUCE0204) and Nursing Hours per Patient Day Measure (NQF #0205) (MUCEO205)), are included in a publicly available document entitled ''Spreadsheet of MAP 2015 Final Recommendations,'' which is available on the NQF Web site.[216] These measures address the NQS priority of effective prevention and treatment, and were reviewed by the MAP in 2014. The MAP noted the need for resolution of data issues, specifically that hospitals participating in the National Database of Nursing Quality Indicators® (NDNQI®) program can have their data directly shared with CMS while those that do not currently participate in that program have the opportunity to send their data directly to CMS. In addition, the MAP noted that, at the time, there was no gold standard for these measures, and thus it is difficult to access relative performance on these measures.[217] The final recommendation from that review was to conditionally support the inclusion of these measures, contingent upon review and endorsement by the NQF. We note these measures initially obtained NQF endorsement on August 5, 2009, and after subsequent review by the NQF for aggregation at the hospital level, the measures retained their endorsement as of December 10, 2015.[218] Further, we note approximately 2,000 hospitals are already reporting this information to the NDNQI®,[219] founded by the American Nurses Association (ANA).[220] NDNQI® data are not publicly reported.

We received a number of comments applicable to both measures and will respond to those first. A more detailed discussion of each of the two measures, along with comments and responses, follows further below.

Comment: An overwhelming number of commenters supported the proposed future inclusion of the Nurse Staffing measure set in the Hospital IQR Program. The commenters stated that nurses are critical to patient safety in hospital settings and that inadequate staffing is associated with increased mortality and adverse events. The commenters indicated that proper use of support personnel improves workflow and hospitals that invest in appropriate

[209] National Academy of Medicine Key Findings and Recommendations available at: *http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2014/EOL/Key%20Findings%20and%20Recommendations.pdf.*

[210] Institute of Medicine. (2011). The future of nursing: Leading change, advancing health. Washington, DC: National Academies Press.

[211] Kane, R.L., Shamliyan, T.A., Mueller, C., Duval, S., & Wilt, T.J. (2007). The association of registered nurse staffing levels and patient outcomes: systematic review and meta-analysis. Medical Care, 45(12), 1195–1204.

[212] Thungiaroenjul, P., Cummings, G.G., Embleton, A. (2007). The impact of nurse staffing on hospital costs and patient length of stay: A systematic review. Nursing Economics, 25(5).

[213] Tzeng, H.-M., Titler, M.G., Ronis, D.L., & Yin, C.-Y. (2012). The contribution of staff call light response time to fall and injurious fall rates: an exploratory study in four US hospitals using archived hospital data. BMC Health Services Research, 12, 84. Available at: *http://doi.org/10.1186/1472-6963-12-84.*

[214] Esparza, S.J., Zoller, J.S., White, A.W., & Highfield, M.E.F. (2012). Nurse staffing and skill mix patterns: Are there differences in outcomes? Journal of Healthcare Risk Management: The Journal of the American Society for Healthcare Risk Management, 31(3), 14–23. Available at: *http://doi.org/10.1002/jhrm.20092.*

[215] Yang, P.-H., Hung, C.-H., Chen, Y.-M., Hu, C.-Y., & Shieh, S.-L. (2012). The impact of different nursing skill mix models on patient outcomes in a respiratory care center. Worldviews on Evidence-Based Nursing/Sigma Theta Tau International, Honor Society of Nursing, 9(4), 227–233. Available at: *http://doi.org/10.1111/j.1741-6787.2012.00246.x.*

[216] Spreadsheet of MAP 2015 Final Recommendations, available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367.*

[217] MAP 2014–2015 Preliminary Recommendations, available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367.*

[218] NQF Measures Database, ''Quality Positioning System,'' available at: *http://www.qualityforum.org/QPS/204* and *http://www.qualityforum.org/QPS/0205.*

[219] NDNQI® database is one of the nation's largest repositories of data on nurse-sensitive quality and safety measure. Approximately 2000 hospitals participate in the program.

[220] Press Ganey Nursing Quality (NDNQI), available at: *http://www.pressganey.com/solutions/clinical-quality/nursing-quality.*

nurse staffing and skill mix to meet the needs of their patients will receive higher ratings. The commenters also noted that reporting these data is not burdensome to hospitals, nurses, or other clinicians because the information is not being newly collected but rather, newly reported. Further, the electronic data collected for these measures is already included in hospital databases, as more than 2,000 hospitals in the U.S. have already adopted these measures. Finally, the commenters indicated the measures are endorsed by the American Nurses Association and the NQF, which strengthens the argument for their implementation in the Hospital IQR Program.

Response: We thank the commenters for their support. We are pleased to learn that electronic data collection of these measures is already widely in effect, as increased electronic reporting is an ongoing measurement goal for CMS.

Comment: In addition to the support received from stakeholders who provided form letters, several additional commenters supported the proposed future inclusion of the nursing measure set. These commenters noted that these measures have been NQF-endorsed, which is a positive testament to the thoroughness of their reliability and validity. The commenters stated that skill mix is part of the formula for appropriate staffing and that proper use of support personnel improves nurses' workflow, permitting nurses to fully apply their professional knowledge and skill. The commenters also noted that better staffing results in better patient care and that patients and their families should have access to this data as tools to make educated and informed care decisions when selecting from comparable hospitals. Further, commenters noted that these measures promote transparency, which empowers patients.

Response: We thank the commenters for their support. We recognize the importance of transparency and nurse staffing in the inpatient setting as it relates to patient engagement and quality of care.

Comment: A few commenters particularly supported the provisions that establish public reporting of the two nurse staffing quality measures. Currently, patients and their families compare hospitals on several factors on the *Hospital Compare* Web site, but they are unable to access information on how many nurses are staffing the unit to which they may be admitted or the staff skill mix, both of which ultimately impact patient outcomes. The commenters noted that public reporting would provide patients with information on how prepared comparable hospitals are to provide high quality and safe care, because there is a direct correlation between nurse staffing, patient satisfaction, readmissions, and adverse events. The commenters urged CMS to consider adding nurse staffing measures to the *Hospital Compare* Web site to provide greater transparency for patients and their families.

Response: We thank the commenters for their support, and share the commenters' opinion that public reporting of these measures could better equip patients to make more informed decisions when selecting from comparable hospitals. Transparency is a facet of patient care that is often overlooked and we will consider the future inclusion of these nurse staffing measures on the *Hospital Compare* Web site, should we move forward with proposing to adopt the nurse staffing measures in the Hospital IQR Program in the future.

Comment: One commenter supported the future inclusion of the nursing measures in the Hospital IQR Program if the definitions continue to align with National Database of Nursing Quality Indicators.[221] However, the commenter noted the measures fail to reflect the complexity of the patient population and any staffing challenges in the local environment (rural, labor supply, urban, etc.). The commenter recommended these measures not be linked to payment (through the Hospital VBP Program, for example) and that any publication of these measures be accompanied by explanations which clarify for the reader that these are not quality-of-care measures.

Response: We thank the commenter for their support, and appreciate their acknowledgement of other integral components that help in the evaluation of nursing care (that is patient population complexity and staffing challenges). These components are elements that we will consider as we continue to solicit feedback on clinical quality measures that assess nurse staffing practices. We disagree that these are not quality of care measures. We believe the potential future inclusion of nurse staffing measures in the Hospital IQR Program would allow hospitals to assess how their nurse staffing and skill mix compare to similar hospitals at the State and national level, as well as encourage hospitals to develop optimal nurse staffing plans that meet the needs of their patients and improve quality of care. As such, there would be no need to footnote publications of these measures, as suggested by the commenter. Should we move forward with proposing to adopt these measures for the Hospital IQR Program in the future, we will consider the potential benefit of linking these quality measures to cost measures and/or linking them to payment (via the Hospital VBP Program, for example).

Comment: Some commenters expressed concerns regarding the nurse staffing measures. Specifically, the commenters noted that the generalist ideology expected by hospital administration for its nursing staff, when specialty care nursing is often best for patient care, could be problematic. Further, staffing should not only encompass proper numbers but should also encompass nursing proficiency, education, and work environment. The commenters suggested that CMS conduct additional testing to ensure there are not unintended consequences associated with making information on the nurse staffing measures available to consumers. The commenters also suggested that CMS should develop a simple metric that can be understood by consumers and is associated with care outcomes. Lastly, other commenters suggested CMS explore simpler metrics that are meaningful to consumers.

Response: We acknowledge the commenters' concerns. In our continued efforts to solicit clinical quality measures that assess nurse staffing practices, we will consider additional factors (that is nurse education and work environment) that influence an appropriate nurse staffing plan as we continue to review these measures for future use in the Hospital IQR Program. While we understand the importance of developing a metric that is easily understood by consumers, we want to ensure that such a metric would adequately convey the impact of the varying facets that contribute to the quality of patient care, in the context of nurse staffing. We believe that to provide comprehensive quality nursing care, and to avoid unintended consequences, there should be multiple metrics that assess nurse staffing in the Hospital IQR Program. Accordingly, we will continue to consider additional factors that the measure steward may determine to be appropriate to include in this measure and be vigilant about potential unintended consequences associated with sharing nursing staffing information with consumers.

Comment: Some commenters did not support future inclusion of the nurse staffing measures in the Hospital IQR

[221] National Database of Nurse Quality Indicators, available at: *http://www.pressganey.com/solutions/clinical-quality/nursing-quality.*

Program, indicating these measures are already collected and used locally for quality improvement, thus, there would be no added value to reporting these measures on a national level. In addition, commenters stated that manual web-based submission causes undue burden in the form of labor resources to enter the data, as hospitals are duplicating the effort by submitting to NDNQI and CMS. Further, the commenters suggested that the administrative burden of frequent reporting far exceeds its value, as quarterly reporting warrants susceptibility to inaccurate data. The commenters also expressed disapproval of the American Nurses Association's dismissal of LPNs and LVNs as members of the nursing staff. The commenters recommended considering inclusion of this subset of nurses as a way of using all available resources in provision and delivery of patient care.

Response: We appreciate the commenters sharing their concerns. We believe there is an opportunity for hospitals to develop nurse staffing strategies to improve quality and the value of care, and that future inclusion of nurse staffing measures in the Hospital IQR Program would allow hospitals to assess how their nurse staffing and skill mix compare to similar hospitals at the State and national level, as well as encourage hospitals to develop optimal nurse staffing plans that meet the needs of their patients and improve quality of care. We also note numerous studies have demonstrated that increased nurse staffing is associated with a reduction in hospital-related mortality and adverse patient events.[222] We recognize that adding new measures to for the Hospital IQR Program could increase administrative and reporting burden for hospitals; however, as with any potential new measure, we would weigh the benefits of the measure with the burden. We note according to the public comments received, there are already over 2,000 hospitals nationwide that are reporting these measures. We also note that the Skill Mix measure includes LPNs and LVNs as members of the nursing staff. This measure acknowledges the contributions of all members of the nursing team, but notes that differing levels of education and skill need to be considered when making staffing decisions for individual units.

We thank the commenters, and we will consider their views as we develop future policy regarding use of the nurse staffing measures in the Hospital IQR Program.

(2) Skill Mix (Registered Nurse [RN], Licensed Vocational/Practical Nurse [LVN/LPN], Unlicensed Assistive Personnel [UAP], and Contract) (Nursing Skill Mix) Measure (NQF #0204)

(a) Overview of Measure

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20057 through 20058), we discussed the potential use of the Skill Mix (Registered Nurse [RN], Licensed Vocational/Practical Nurse [LVN/LPN], Unlicensed Assistive Personnel [UAP], and Contract) (Nursing Skill Mix) Measure (NQF #0204) in the Hospital IQR Program. The NQF-endorsed Nursing Skill Mix measure assesses the percentage of productive nursing care hours worked by nursing staff with direct patient care responsibilities for each nursing licensure category (RN, LPN/LVN, and UAP) and staff employment status (contract/agency versus hospital employee), by eligible hospital unit. The intent of this measure is to enable hospitals to track and assess their nursing skill mix, given that research demonstrates a relationship between skill mix and certain quality outcomes.[223]

The measure focuses on the structure of care quality and includes the skill mix for adult and pediatric medical-surgical hospital units. Medical-surgical hospital units include hospitals areas for the evaluation of patients with medical and/or surgical conditions. Eligible adult and pediatric medical-surgical units can be mapped to the CDC's National Healthcare Safety Network (NHSN) Healthcare Service locations codes as defined in the NHSN Patient Safety Component Manual.[224] Additional unit types, such as adult and pediatric critical-care, step-down, medical, and surgical units could be included in the future. At this time, we believe limiting the measure to adult and pediatric medical-surgical units would allow hospitals to become accustomed to collecting and reporting staffing data while also providing important staffing information to consumers. However, we sought public comment on how many inpatient units to include and which units should be prioritized.

Productive nursing care hours are defined as the hours worked by nursing staff (RN, LPN/LVN, and UAP) with direct patient care responsibilities, including unbudgeted overtime or scheduled hours. Direct patient care responsibilities are nursing activities performed by unit-based staff in the presence of the patients and activities that occur away from the patient that are patient related, such as the following:

- Medication administration
- Nursing treatments
- Nursing rounds
- Admission, transfer, and discharge activities
- Patient education
- Patient communication
- Coordination of patient care
- Documentation time
- Treatment planning
- Patient screening and assessment

Unlicensed assistive personnel (UAP) are defined as individuals trained to function in an assistive role to nursing in the provision of patient care, as delegated by and under the supervision of a registered nurse. UAPs include nursing assistants, patient care technicians/assistants, and graduate nurses not yet licensed who have completed orientations.

The measure includes: All nursing staff employed by the hospital; temporary staff who are not employed by the hospital (contract or agency); and float staff who are hospital employees temporarily assigned to provide direct patient care on an eligible unit other than their usual unit of employment.

(b) Data Source

Data collection for this structural measure would occur quarterly for each eligible unit from January 1 through December 31 of each calendar year, with data submission occurring 4.5 months after the end of each reporting quarter. An eligible unit must be open, with patients present, at least one month during the reporting period to be included. These data would be collected via a web-based tool available on the QualityNet Web site.

(c) Measure Calculation

For staff with direct patient care responsibilities, the measure assesses the percentage of total productive nursing hours worked by either employee or contract RNs, LPN/LVNs, and UAPs, as well as at the percentage of total productive nursing hours worked for contract or agency staff. Accordingly, four rates (percentages) are determined for each eligible hospital

[222] Safe Staffing Literature Review from the American Nurses Association. March 2017. Available at: *http://www.nursingworld.org/SafeStaffing-LiteratureReview.*

[223] Kane, R.L., Shamliyan, T.A., Mueller, C., Duval, S., & Wilt, T.J. (2007). The association of registered nurse staffing levels and patient outcomes: systematic review and meta-analysis. Medical Care, 45(12), 1195–1204.

[224] NHSN Patient Safety Component Manual *https://www.cdc.gov/nhsn/about-nhsn/index.html* [under ''Related Links''].

unit, one for each type of nursing staff, and one for contract and agency nursing staff. The four separate rates are as follows: (1) RN hours—Productive nursing care hours worked by RNs (employee and contract) with direct patient care responsibilities for each eligible inpatient unit/the total number of productive hours worked by employee or contract nursing staff with direct patient care responsibilities (RN, LPN/LVN, and UAP) for each eligible inpatient unit; (2) LPN/LVN hours—Productive nursing care hours worked by LPNs/LVNs (employee and contract) with direct patient care responsibilities for each eligible inpatient unit/the total number of productive hours worked by hospital employee or contract nursing staff with direct patient care responsibilities (RN, LPN/LVN, and UAP) for each eligible inpatient unit; (3) UAP hours—Productive nursing care hours worked by UAP (employee and contract) with direct patient care responsibilities for each eligible inpatient unit/the total number of productive hours worked by hospital employee or contract nursing staff with direct patient care responsibilities (RN, LPN/LVN, and UAP) for each eligible inpatient unit; and (4) Contract or agency hours—Productive nursing care hours worked by contract or agency staff nursing staff (RN, LPN/LVN, and UAP) with direct patient care responsibilities for each eligible inpatient unit/the total number of productive hours worked by employee or contract nursing staff with direct patient care responsibilities (RN, LPN/LVN, and UAP) for each eligible inpatient unit. The data collected and the rates calculated are aggregate nursing care hours worked by each licensure category, by unit type. Hospital rates are weighted for patient volume (patient days) to account for differences in unit sizes.

(d) Cohort

Hospital employee, contract, or agency RNs, LPN/LVNs, and UAPs with direct patient care responsibilities are included in the numerator and denominator statements. The measure numerator and denominator include nursing staff assigned to the eligible unit who have direct patient care responsibilities for greater than 50 percent of their shift who are counted in an eligible unit's staffing matrix, are replaced if they call in sick, and whose work hours are charged to the unit's cost center. The measure numerator and denominator exclude the following: Nursing staff with no direct patient care responsibilities whose primary responsibility is administrative in nature; specialty teams (for example, wound care), patient educators, or case managers who are not assigned to a specific unit; unit clerks, monitor technicians, and secretaries with no direct patient care responsibilities; sitters not providing routine UAP activities; therapy assistants; student nurses fulfilling educational requirements; and nursing staff undergoing orientation who are not included in the eligible units staffing matrix. For more information regarding the Nursing Skill Mix measure, we refer readers to the NQF measure information page available at: *http://www.qualityforum.org/QPS/0204*.

We invited public comment on the future inclusion of the Skill Mix (Registered Nurse [RN], Licensed Vocational/Practical Nurse [LVN/LPN], Unlicensed Assistive Personnel [UAP], and Contract) (Nursing Skill Mix) measure for the Hospital IQR Program. Specifically, we sought public comments on narrowing the number of hospital units included in the measures' calculation, which units we should consider for inclusion, and the burden of data collection on hospitals.

Comment: One commenter requested that CMS evaluate the Nursing Skill Mix measure against the ever-increasing pressure of reimbursement reductions from CMS and other payers who follow the CMS example. The commenter noted that the metric of two events seems counterproductive and that increased skill mix and staffing ratios will increase costs to the organization at the same time reductions in reimbursements will not allow for additional funds to support this need. As such, the commenter suggested that where facilities can meet/exceed the best practice measure, an incentive be provided so that funding could continue to support this measure as opposed to negatively impacting organizations trying to meet the needs of the patients through increased skill mix and staffing levels.

Response: We acknowledge the commenter's concern about costs associated with increased skill mix and staffing ratios and will take that under consideration; however, existing research shows improved patient outcomes when the nursing skill mix and number of RN hours are appropriate for the level of care on the individual unit.[225] We appreciate the need to balance long-term and short-term considerations with respect to nurse staffing decisions. We note the potential long-term benefits of the improved outcomes and reduction in adverse events may outweigh the potential short term goal of decreasing the immediate costs of appropriate staffing ratios and skill mix.

We thank the commenter, and we will consider their views as we develop future policy regarding the future inclusion of the Skill Mix (Registered Nurse [RN], Licensed Vocational/Practical Nurse [LVN/LPN], Unlicensed Assistive Personnel [UAP], and Contract) (Nursing Skill Mix) measure in the Hospital IQR Program.

(3) Nursing Hours per Patient Day Measure (NQF #0205)

(a) Overview of Measure

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20058 through 20059), we discussed the potential use of the Nursing Hours per Patient Day Measure (NQF #0205) in the Hospital IQR Program. The NQF-endorsed Nursing Hours per Patient Day measure assesses the number of productive hours worked by both RNs and all nursing staff (RN, LPN/LVN, and UAP) with direct patient care responsibilities per patient day, by eligible hospital inpatient unit. The intent of this measure is to enable hospitals to track and assess the ratio of hours worked by nursing staff per patient day, given that research demonstrates a relationship between increased nursing hours and certain quality outcomes.

The measure focuses on the structure of care quality and includes Nursing Hours per Patient Day for eligible adult and pediatric medical-surgical inpatient hospital units. Medical-surgical hospital units include hospitals areas for the evaluation of patients with medical and/or surgical conditions. Eligible adult and pediatric medical-surgical units can be mapped to the CDC's National Healthcare Safety Network (NHSN) Healthcare Service locations codes as defined in the NHSN Patient Safety Component Manual. Similar to the Nursing Skill Mix Measure, additional unit types, such as adult and pediatric critical-care, step-down, medical, and surgical units could be included, but at this time, we believe limiting the measure to adult and pediatric medical-surgical units would allow hospitals to become accustomed to collecting and reporting staffing data while also providing important staffing information to consumers. However, we sought comment on how many inpatient units to include and which units should be prioritized.

Productive hours are defined as the hours worked by nursing staff (RN,

[225] Safe Staffing Literature Review from the American Nurses Association. March 2017. Available at: *http://www.nursingworld.org/SafeStaffing-LiteratureReview*.

LPN/LVN, and UAP) with direct patient care responsibilities, including overtime, not budgeted, or scheduled hours. Direct patient care responsibilities are nursing activities performed by unit-based staff in the presence of the patients and activities that occur away from the patient that are patient related, such as the following:

- Medication administration
- Nursing treatments
- Nursing rounds
- Admission, transfer, and discharge activities
- Patient education
- Patient communication
- Coordination of patient care
- Documentation time
- Treatment planning
- Patient screening and assessment

UAP are individuals trained to function in an assistive role to nursing staff in the provision of patient care, as delegated by and under the supervision of a registered nurse. UAPs include nursing assistants, patient care technicians/assistants, and graduate nurses not yet licensed who have completed orientations.

The measure includes all nursing staff employed by the hospital; temporary staff who are not employed by the hospital (contract or agency); and float staff who are hospital employees temporarily assigned to provide direct patient care on an eligible unit other than their usual unit of employment.

(b) Data Source

Data collection for this structural measure for hospitals occurs quarterly, for each eligible unit, from January 1 through December 31 of each calendar year, with data submission occurring 4.5 months after the end of each reporting quarter. These data would be collected via a web-based tool available on the QualityNet Web site.

(c) Measure Calculation

For staff with direct patient care responsibilities, the measure assesses the number of productive hours per patient day worked by both RNs and by total nursing staff (RNs, LPN/LVNs, and UAPs). Accordingly, two rates are determined for each eligible hospital unit. The two separate rates are as follows: (1) RN hours per patient day—Total number of productive hours worked by RN nursing staff (contract and hospital employee) with direct patient care responsibilities for each eligible inpatient unit/total number of patient days for each eligible inpatient unit; and (2) Total nursing care hours per patient day—Total number of productive hours worked by RN, LPN/LVN, and UAP nursing staff (contract and employee) with direct patient care responsibilities for each eligible inpatient unit/total number of patient days for each eligible inpatient unit. Patient days must be from the same unit in which nursing care hours are reported. The data collected and the rates calculated are aggregate nursing hours per patient day, by unit type. Hospital rates are weighted for patient volume (patient days) to account for differences in unit sizes.

(d) Cohort

RNs, LPN/LVNs, and UAPs with direct patient care responsibilities are included in the numerator and denominator statement. The measure numerator includes nursing staff assigned to the eligible inpatient unit who have direct patient care responsibilities for greater than 50 percent of their shift, who are counted in an eligible unit's staffing matrix, are replaced if they call in sick, and work hours are charted to the unit's cost center. The numerator excludes the following: Nursing staff with no direct patient care responsibilities whose primary responsibility is administrative in nature; specialty teams (for example, wound care), patient educators, or case managers who are not assigned to a specific unit; unit clerks, monitor technicians, and secretaries with no direct patient care responsibilities; sitters not providing routine UAP activities; therapy assistants; student nurses fulfilling educational requirements; and nursing staff undergoing orientation who are not included in the eligible units staffing matrix. The measure denominator excludes patient days from ineligible units. For more information regarding the Nursing Hours Per Day measure, we refer readers to the National Quality Forum measure information page available at: *http://www.qualityforum.org/QPS/0205*.

We invited public comment on the possible future inclusion of the Nursing Hours per Patient Day measure for the Hospital IQR Program. Specifically, we sought comments on narrowing the number of hospital units included in the measures' calculation, which units we should consider for inclusion, and the burden of data collection on hospitals.

Comment: One commenter cautioned CMS that the complexity involved in determining the hours and staffing for the Nursing Hours Per Patient Days measure could be burdensome for the organizations. Further, the commenter stated that if the intent is to evaluate the impact of increased staffing in areas with respect to quality outcomes, it would seem more appropriate for an organization to provide the total number of patient days for a given unit (denominator) divided into the total hours (as categorized by the 4 groups noted) of staffing on that unit. The commenter suggested that this may be a simpler, less burdensome approach that would provide a better indication of the total number of hours that are dedicated to patient care in a given unit. In addition, another commenter stated that the management and oversight of the reporting has an element of burden and time commitment that is not easily supported in today's health care environment in which resources should be focused on the care of the patient.

Response: We appreciate the commenter's feedback, and will consider the suggested approach on how to calculate nursing hours per patient day. It is our intent to promote improved quality of care in the least burdensome manner possible. This measure is not meant to simply increase RN staffing in the areas evaluated in the measure, but also to evaluate the number of hours provided to patients by RNs as related to patient care requirements and whether the current staffing mix is appropriate. Studies have demonstrated improved outcomes especially in complex patients when the nursing provider is an RN versus an LPN/LVN or UAP.[226]

Comment: One commenter did not support the future inclusion of the Nursing Hours per Patient Day measure in the Hospital IQR Program, citing a concern that nurse staffing levels are influenced by a variety of factors that, in varying combinations, could influence patient care outcomes and may or may not be reflected in RN Hours Per Patient Day (RN HPPD). The commenter noted when nurse staffing is examined in the nursing research literature, no evidence exists that identifies a nurse staffing configuration or a process to use when making staffing decisions. The commenter believed that staffing decisions that influence RN HPPD need to be based on evidence, including patient need, the education and skill level of staff, the geography and size of units, the availability of technology and support staff, and multiple other factors. The commenter noted their belief that one of the most effective ways to attain superior patient outcomes and enhance nurse satisfaction is for nurse leaders and nursing staff to openly and continually communicate, assess, plan, execute, and evaluate strategies used in the provision of patient care.

[226] *Ibid.*

Response: We acknowledge the commenter's concerns. We recognize the importance of having an evidence base, rooted in empirical data, to support any clinical quality measure implemented in the Hospital IQR Program. We also understand that there are numerous factors that contribute to the overall quality of nursing care. At this time, we are interested in the impact and effects of skill mix and nursing hours per patient on quality of nursing care, and we will consider additional quality metrics that examine nursing care using different factors in the future. We agree that attaining superior patient outcomes and enhanced nurse satisfaction could be achieved through enhanced communication and the execution of ''best practice'' strategies in the provision of patient care; however, we are also concerned about the limitations placed on nurse managers and nursing staff when the hospital administration does not provide the available resources to adjust the staffing mix as appropriate for optimal patient care and positive outcomes. We refer readers to the American Nurses Association's literature review [227] of evidence to identify the proper nurse staffing configuration and/or process to use when making staffing decisions.

Comment: One commenter noted that publicly reported RN HPPD to the lay person or a regulating body does not facilitate comparisons that are relevant and meaningful.

Response: We believe that publicly reporting RN hours per patient day, coupled with the existing evidence that shows improvement in patient and nurse outcomes, based on workplace environment [228] could be useful for the lay person and regulating bodies to make meaningful and relevant hospital comparisons.

We thank the commenters and we will take these comments into consideration if we propose to adopt the Nursing Hours per Patient Day Measure (NQF #0205) in the future.

d. Potential Inclusion of Additional Electronic Clinical Quality Measures (eCQMs) in the Hospital IQR and Medicare and Medicaid EHR Incentive Programs

As we previously indicated in the FY 2013 IPPS/LTCH PPS final rule, EHR technology continues to evolve and additional infrastructure is being put in place to afford us the capacity to accept enhanced electronic reporting of many of the clinical chart-abstracted measures that are currently part of the Hospital IQR Program (77 FR 53534). We continue to believe that electronic reporting of quality measure data derived from the EHR will, in the long run, reduce the burden on hospitals to collect and submit data for the Hospital IQR Program.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20059 through 20064), in keeping with this goal, we solicited feedback on the potential inclusion of additional eCQMs in the Hospital IQR and Medicare and Medicaid EHR Incentive Programs. These measures assess opioid prescribing practices, malnutrition, tobacco use, and substance use among the adult, inpatient population. As we continue to advance electronic reporting, we want to ensure that we provide hospitals with a robust selection of eCQMs. As we state in section IX.A.8. of the preamble of this final rule, hospitals have expressed concerns with identifying applicable measures that reflect their patient population; thus, we believe that the addition of new eCQMs in the future will offer more clinically relevant eCQMs with meaningful data that will help drive quality improvement.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57116 through 57120), we removed 13 eCQMs from the Hospital IQR Program measure set, beginning with the CY 2017 reporting period/FY 2019 payment determination, in order to enable hospitals to focus on a smaller, more specific subset of eCQMs. In that same rule, we indicated that we are considering behavioral health measures for inclusion in the Hospital IQR Program to address an important gap in understanding the quality of care given to inpatient psychiatric patients treated in the acute care hospital setting rather than a distinct psychiatric unit or IPF (81 FR 57166 through 51767). The future inclusion of measures assessing opioid prescribing practices, tobacco use, and substance use will help to inform how we can improve the quality of care in these clinical domains, and help to fill this identified gap area. The table below lists the eCQMs being considered for future inclusion in the Hospital IQR and Medicare and Medicaid EHR Incentive Programs and for which we sought public feedback.

ELECTRONIC CLINICAL QUALITY MEASURES (eCQMs) FOR FUTURE CONSIDERATION IN THE HOSPITAL IQR AND MEDICARE AND MEDICAID EHR INCENTIVE PROGRAMS

Measure name	NQF #
Safe Use of Opioids—Concurrent Prescribing	N/A
Completion of a Malnutrition Screening within 24 Hours of Admission	N/A
Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition within 24 Hours of a Malnutrition Screening	N/A
Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment	N/A
Appropriate Documentation of a Malnutrition Diagnosis	N/A
Tobacco Use Screening (TOB–1)	N/A
Tobacco Use Treatment Provided or Offered (TOB–2)/Tobacco Use Treatment (TOB–2a)	N/A
Tobacco Use Treatment Provided or Offered at Discharge (TOB–3)/Tobacco Use Treatment at Discharge (TOB–3a)	N/A
Alcohol Use Screening (SUB–1)	N/A
Alcohol Use Brief Intervention Provided or Offered (SUB–2)/Alcohol Use Brief Intervention (SUB–2a)	N/A
Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge (SUB–3)/Alcohol & Other Drug Use Disorder Treatment at Discharge (SUB–3a)	N/A

[227] *Ibid.*

[228] *Ibid.*

(1) Safe Use of Opioids-Concurrent Prescribing Measure

(a) Background

Unintended opioid overdose fatalities have reached epidemic proportions in the last 20 years and are a major public health concern in the United States.[229] Reducing the number of unintended opioid overdoses has become a priority for numerous HHS agencies. Concurrent prescriptions of opioids or opioids and benzodiazepines put patients at greater risk of unintended opioid overdose due to increased risk of respiratory depression.[230] [231] Despite this risk, studies of multiple claims and prescription databases have shown that between 5 to 15 percent of patients receive concurrent opioid prescriptions, and 5 to 20 percent of patients receive concurrent opioid and benzodiazepine prescriptions across various settings.[232] [233] [234] In addition, an analysis of more than 1 million hospital admissions in the United States found that over 43 percent of all patients with nonsurgical admissions were exposed to multiple opioids during their hospitalization.[235]

(b) Overview of Measure

The Safe Use of Opioids—Concurrent Prescribing (MUC16–167) measure assesses patients (excluding cancer patients or patients receiving palliative care), ages 18 years and older with active, concurrent prescriptions for opioids, or opioids and benzodiazepines, at discharge.[236] This measure addresses the following NQS priorities: (1) Making care safer by reducing harm caused in the delivery of care; (2) promoting effective communication and coordination of care; and (3) promoting the most effective prevention and treatment practices for the leading causes of mortality, starting with cardiovascular disease.

This measure was reviewed by the MAP in December 2016 and received the recommendation to refine and resubmit for consideration for programmatic inclusion. MAP stakeholders acknowledged the significant health risks associated with concurrent prescribing of opioids, and opioids and benzodiazepines, but expressed concern with the measure specifications, indicating the need for a stronger evidence base for clinical guidelines and refinement of the measure exclusions to reduce the risk of unintended consequences.[237]

Additional information on this measure can be found in the 2016 Measures Under Consideration Spreadsheet, available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367.*

We invited public comment on the possible future inclusion of this opioid prescribing measure in the Hospital IQR Program.

Comment: Some commenters supported the future inclusion of the Safe Use of Opioids measure in the Hospital IQR Program. The commenters believed that there is a need for measures that assess opioid follow-up, prescription, and appropriate prescribing, even though there are times when concurrent prescriptions of opioids and benzodiazepines are appropriate. There are studies that demonstrate that chronic pain patients are unlikely to become addicts or abuse their medication. Further, the addition of this measure would encourage appropriate pain management practices by providers and patients. In addition, commenters noted that adopting a measure that calculates the proportion of patients prescribed two or more different opioids or opioids and benzodiazepines concurrently has the potential to reduce preventable mortality and reduce the costs associated with adverse events. The commenters encouraged CMS to consider policies that promote alternatives to opioids for pain management, arguing that prescription opioids are often prescribed in the absence of affordable alternatives. The commenters also urged CMS to take an active role in educating prescribers about alternatives such as exercise, mindfulness, over-the-counter medications, etc. Lastly, the commenters suggested that implementation of a system that flags the surveys of frequent opioid users could be used to prevent addicts skewing hospital scores.

Response: We thank the commenters for their support. We understand the importance of provider education and will work towards including ''best practices'' for prescription protocols and opioid alternatives in our education and outreach efforts. We appreciate the commenters' suggestion of a survey monitoring system and will consult with the appropriate technological entities to discuss the impact on existing workflows and infrastructure, and the feasibility of implementing such a system. In addition, we will consider the commenters' suggestion to establish policies that promote alternatives to opioids for pain management in the future.

Comment: Many commenters indicated that they would support the future inclusion of the Safe Use of Opioids measure in the Hospital IQR Program measure set if CMS refined the measure in response to stakeholder feedback and if the measure obtained NQF endorsement. In addition, the commenter recommended that CMS prioritize the development and adoption of measures designed to improve identification of, and intervention with, patients at risk for developing a substance abuse disorder. Lastly, commenters advised CMS to consider the variation in States' prescribing requirements, citing concern that these differences may make the measure more complex and that in some cases, as determined by the physician, it can be appropriate for a patient to have multiple prescriptions.

Response: We thank the commenters for their support. We agree that the development and adoption of measures designed to improve identification of, and intervention with, patients at risk for developing a substance abuse disorder is valuable. We will continue to assess our measure set in alignment with our evolving programmatic goals to ensure we prioritize certain clinical topical areas appropriately. We

[229] Rudd, R., Aleshire, N., Zibbell, J., et al. ''Increases in Drug and Opioid Overdose Deaths—United States, 2000–2014.'' MMWR, Jan 2016. 64(50);1378–82 *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm.*

[230] Dowell, D., Haegerich, T., Chou, R. ''CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016.'' MMWR Recomm Rep 2016;65. Available at: *http://www.cdc.gov/media/dpk/2016/dpk-opioid-prescription-guidelines.html.*

[231] Jena, A., et al. ''Opioid prescribing by multiple providers in Medicare: retrospective observational study of insurance claims,'' BMJ 2014; 348:g1393 doi: 10.1136/bmj.g1393. Available at: *http://www.bmj.com/content/348/bmj.g1393.*

[232] Liu, Y., Logan, J., Paulozzi, L., et al. ''Potential Misuse and Inappropriate Prescription Practices Involving Opioid Analgesics.'' Am J Manag Care. 2013 Aug;19(8):648–65. Available at: *http://www.ajmc.com/journals/issue/2013/2013-1-vol19-n8/Potential-Misuse-and-Inappropriate-Prescription-Practices-Involving-Opioid-Analgesics/.*

[233] Mack, K., Zhang, K., et al. ''Prescription Practices involving Opioid Analgesics among Americans with Medicaid, 2010,'' J Health Care Poor Underserved. 2015 Feb; 26(1): 182–198. Available at: *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4365785/.*

[234] Park, T., et al. ''Benzodiazepine Prescribing Patterns and Deaths from Drug Overdose among US Veterans Receiving Opioid Analgesics: Case-cohort Study,'' BMJ 2015; 350:h2698. Available at: *http://www.bmj.com/content/350/bmj.h2698.*

[235] Herzig, S., Rothberg, M., Cheung, M., et al. ''Opioid utilization and opioid-related adverse events in nonsurgical patients in US hospitals.'' Nov 2013. DOI: 10.1002/jhm.2102. Available at: *http://onlinelibrary.wiley.com/doi/10.1002/jhm.2102/abstract.*

[236] 2016 Measures Under Consideration List (PDF), available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367.*

[237] ''2017 Considerations for Implementing Measures Hospitals-Final Report,'' available at: *http://www.qualityforum.org/map/.*

understand that NQF-endorsement lends credibility to quality measures, and we recognize that variation in State prescribing practices could affect the data extrapolated from hospitals that report on this measure. We will consider both of these factors, as well as the provided stakeholder feedback on suggested measure refinements, should we propose to adopt this measure in the Hospital IQR Program in the future.

Comment: A few commenters supported the future inclusion of a measure that assesses opioid prescribing patterns, specifically for patients already using an opioid or patients using benzodiazepine. However, commenters expressed concern that the ''Safe Use of Opioids'' measure may introduce unintended consequences, such as under treatment of pain and placing undue accountability on acute settings for long-term pain management. Other commenters indicated that due to existing infrastructure deficiencies, the adoption of this measure would place unnecessary burden related to accountability upon acute care facilities. Some commenters stated that inclusion of this measure could encourage anti-opioid sentiments to irrational extremes. A few commenters noted that there are circumstances in which it may be appropriate for patients to be treated concurrently with opioids and recommended that the measure provides for the exclusion of cases in which polypharmacy may be warranted.

Response: We thank the commenters for their support. We recognize the heightened sensitivity associated with opioid prescribing. We understand that there are existing operational and technological infrastructure hurdles that should be addressed to reduce the burden associated with electronically extrapolating data for this measure. We acknowledge that concurrent prescribing is appropriate in certain situations. We also note the intent of the measure is to raise prescriber awareness, when and if the patient requires concurrent prescriptions, and to take appropriate steps to provide education regarding potential side effects and alternative pain management techniques to the patient, in an effort to reduce adverse side effects and potentially prevent dependence. Should we decide to move forward with proposing to adopt this measure in the Hospital IQR Program in the future, we will be vigilant about potential unintended consequences, such as under treatment of pain and undue accountability based on care setting. We also note that the intent of any future inclusion of this measure in the Hospital IQR Program would not be to stigmatize the use of opioids, but to evaluate through quality measurement adherence to clinical standards that could help improve prescribing practices for these drugs and combat current misuse.

Comment: One commenter supported the future inclusion of all the eCQMs we sought public comment for future inclusion in the Hospital IQR Program, including the Safe Use of Opioids measure, noting that the addition of these measures would give hospitals more options in selecting eCQMs that are applicable to their patient populations.

Response: We thank the commenter for their support.

Comment: Some commenters did not support the proposed future inclusion of the Safe Use of Opioids measure in the Hospital IQR Program. The commenters stated that the measure lacks sensitivity to the needs of the specific patient (that is, adequate patient education). Specifically, the commenters also expressed that until all facilities, vendors, and pharmacies are required to implement ePrescribing of controlled substances, and given ample development, testing, and implementation time, there is a risk of prescriptions not being included in data transfer systems (that is, Sure Scripts, Dr. First, etc.). The commenters noted that these circumstances would allow for continued risks associated with overdose due to lack of information.

Response: We appreciate the commenters' concerns. We recognize the heightened sensitivity associated with opioid prescribing given the current opioid epidemic in our nation. We note again that the intent of the measure is not to completely eliminate concurrent prescriptions, but rather to raise provider awareness of appropriate prescribing practices and provide both education and alternative treatments to patients. In addition, we will monitor the impact of ePrescribing on streamlining hospital workflows as a part of efforts to better assess how to reduce the risk of overdose. Should we decide to move forward with proposing to adopt this measure in the Hospital IQR Program in the future, we will consider the impact of adequate patient education on the measure results as well as potential unintended consequences, such as patient overdose.

We thank the commenters, and we will consider their views as we develop future policy regarding the use of an eCQM version of the Safe Use of Opioids—Concurrent Prescribing (MUC16–167) measure in the Hospital IQR Program.

(2) Malnutrition Measures

(a) Background

Malnutrition is associated with many adverse outcomes including depression of the immune system, impaired wound healing, muscle wasting, and increased mortality.[238] [239] Patients who are malnourished during a hospital stay have an increased risk of complications, readmissions, and length of stay. In addition, evidence demonstrates an association between malnutrition risk and increased inpatient costs. One study found that patients identified with under-nutrition risk and high under-nutrition risk experience increased costs by 28.8 percent and 21.1 percent, respectively, when compared to non-malnourished patients.[240] Malnutrition risk screening, using a validated screening tool, can be useful in predicting certain patient outcomes including length of stay, mortality, and post-operative complications.[241] Nutrition assessments for patients identified as at-risk for malnutrition have been associated with improved patient outcomes including less weight loss, reduced length of stay, improved muscle function, better nutritional intake, and fewer readmissions.[242] Further, there is evidence of a performance gap with regard to nutrition screening and assessment. A national survey of hospital-based professionals in the United States focused on nutrition screening and assessment practices demonstrated that out of 1,777 unique respondents, only 36.7 percent reported completing nutrition screening at admission and 50.8 percent reported doing so within 24 hours.[243] Thus, there is an

[238] Corkins MR, Guenter P, Dimaria-ghalili RA, et al. Malnutrition diagnoses in hospitalized patients: United States, 2010. JPEN J Parenter Enteral Nutr. 2014;38(2):186–95.

[239] Barker LA, Gout BS, Crowe TC. Hospital malnutrition: prevalence, identification and impact on patients and the healthcare system. Int J Environ Res Public Health. 2011;8(2):514–27.

[240] Guerra RS, Sousa AS, Fonseca I, et al. Comparative analysis of undernutrition screening and diagnostic tools as predictors of hospitalization costs. J Hum Nutr Diet. 2016;29(2):165–73.

[241] Mueller C, Compher C & Druyan ME and the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) Board of Directors. A.S.P.E.N. Clinical Guidelines: Nutrition Screening, Assessment, and Intervention in Adults. J Parenter Enteral Nutr. 2011;35: 16–24.

[242] Mueller C, Compher C & Druyan ME and the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) Board of Directors. A.S.P.E.N. Clinical Guidelines: Nutrition Screening, Assessment, and Intervention in Adults. J Parenter Enteral Nutr. 2011;35: 16–24.

[243] Patel V, Romano M, Corkins MR, et al. Nutrition Screening and Assessment in Hospitalized Patients: A Survey of Current Practice in the United States. Nutr Clin Pract. 2014;29(4):483–490.

opportunity for hospitals to improve nutrition screening and assessment.

(b) Overview of Measures

The malnutrition measure set consists of the following four measures:

- Completion of a Malnutrition Screening within 24 Hours of Admission (MUC16–294);
- Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition within 24 Hours of a Malnutrition Screening (MUC16–296);
- Appropriate Documentation of a Malnutrition Diagnosis (MUC16–344); and
- Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment (MUC16–372).

These malnutrition measures are new eCQMs that collectively evaluate the quality of care rendered to adult patients that are identified as malnourished. These measures address the NQS priorities of: (1) Making care safer by reducing harm caused in the delivery of care; and (2) promoting effective communication and coordination of care. The Completion of a Malnutrition Screening within 24 Hours of Admission measure (MUC16–294) assesses whether patients age 18 years or older are screened for malnutrition within 24 hours of admission to the hospital. The Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition measure (MUC16–296) assesses whether patients age 65 years or older, who screen positive for being at-risk for malnutrition, have a nutrition assessment documented in the medical record within 24 hours of the most recent malnutrition screening. The Appropriate Documentation of a Malnutrition Diagnosis measure (MUC16–344) assesses whether patients age 65 years and older, who are found to be malnourished on the nutrition assessment, have adequate documentation of a malnutrition diagnosis in their medical record. This measure is important because there is often a disconnect between screening for malnutrition and documentation of a diagnosis of malnutrition, which is necessary for appropriate follow-up after hospital discharge. Data analyzed from the Healthcare Cost and Utilization Project (HCUP), a nationally-representative data set describing U.S. hospital discharges, indicated that approximately 3.2 percent of hospital discharges in 2010 included malnutrition as a diagnosis. However, this same research article notes that the prevalence of a malnutrition diagnosis may be significantly higher as past researchers, using validated screening tools, indicate a significantly higher prevalence of undiagnosed malnutrition in the hospital, ranging from 33 to 54 percent.[244] Lastly, the Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment measure (MUC16–372) assesses whether patients age 65 years and older, who are found to be malnourished on a completed nutrition assessment, have a nutrition care plan documented in their medical record.

These measures were reviewed by the MAP in December 2016 and received mixed support. The Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment (MUC16–372), Completion of a Malnutrition Screening within 24 Hours of Admission (MUC16–294), and Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition within 24 Hours of a Malnutrition Screening (MUC16–296) measures were recommended to be refined and resubmitted for consideration for programmatic inclusion. For these three measures, the MAP encouraged providing more evidence to prove clinical importance and recommended that the exclusions continue to be tested for validity.[245] The Appropriate Documentation of a Malnutrition Diagnosis measure (MUC16–344) was not supported because there was concern that there was insufficient evidence to support the link between documenting a malnutrition diagnosis and improved patient outcomes.

The MAP concluded that completing a malnutrition assessment provided the most potential value to the measure set and quality of care. The MAP also encouraged the measure developer to test the individual malnutrition measures as a composite in an effort to balance the number of measures in the Hospital IQR Program with the need to fill the measure gap addressing malnutrition.[246] We note that we received written support (formal letters addressed to CMS) of these measures from other stakeholders who noted that addressing malnutrition among beneficiaries is an important clinical issue.

Additional information on these measures is available at: *http://www.qualityforum.org/ProjectMeasures.aspx?projectID=80741*.

We invited public comment on the possible future inclusion of one or more of these malnutrition measures in the Hospital IQR Program. In addition, we invited public comment on the possible future inclusion of a composite measure comprised of all or a subset of these individual malnutrition measures in the Hospital IQR Program.

Comment: Several commenters supported the future inclusion of the malnutrition measure set as individual measures. These commenters stated malnutrition is an ongoing healthcare issue with demonstrated impacts on patient outcomes and, as such, it is imperative to have performance measures that quantify the degree to which established best practices are carried out. The commenters noted poor nutrition status is also associated with poor functional and clinical outcomes for patients and increased costs to healthcare systems, and asserted taking a systematic approach to increasing awareness of malnutrition and improving management of nutrition in hospitals would improve health outcomes and reduce the associated costs imposed on healthcare systems.

The commenters also noted that the measures are reliable and valid, and that their implementation in the Hospital IQR Program would satisfy a measure gap area and incentivize the adoption of evidence-based malnutrition care best practices, thereby improving patient outcomes. Several commenters also noted that there is a need for more validated malnutrition screening tools to promote reliability between practitioners and to reduce the number of false-positive referrals that are being made due to use of invalid tools. The commenters indicated that the malnutrition eCQMs reflect key components of the recommended malnutrition clinical workflow, and that malnutrition intervention is a low-risk, low-cost clinical strategy that would help improve care coordination and the quality of hospital care.

Commenters stated that Medicare beneficiaries would benefit from the adoption of malnutrition eCQMs that support prompt malnutrition screening, assessment, diagnosis, and development of a care plan. In addition, the commenters stated that because these eCQMs have been specifically designed and tested to be used with patient data included directly in the EHR, the burden of data collection and reporting

[244] Corkins, M.R., Guenter, P., DiMaria-Ghalili, R.A., Jensen, G.L., Malone, A., Miller, S., Patel, V., Plogsted, S. and Resnick, H.E., 2014. Malnutrition diagnoses in hospitalized patients: United States, 2010. Journal of Parenteral and Enteral Nutrition, 38(2), pp.186–195.

[245] "2017 Considerations for Implementing Measures Hospitals-Final Report," available at: *http://www.qualityforum.org/map/*.

[246] *Ibid.*

will be minimal. Lastly, the commenters stated that the inclusion of this measure set in the Hospital IQR Program could help improve outcomes and quality of life for patients, especially seniors and the disadvantaged. The commenters therefore recommended CMS adopt these measures into the Hospital IQR Program as soon as possible to ensure quality care for older adults.

Response: We thank the commenters for their support. We agree that a systematic approach to quality improvement is essential and could include increasing awareness of malnutrition and improving management of nutrition in hospitals. We acknowledge the benefits and need for inclusion of malnutrition measures, as outlined by the commenters, and will consider the feasibility of implementing these measures in the Hospital IQR Program in the future.

Comment: Some commenters supported the future proposed inclusion of the malnutrition measure set in the Hospital IQR Program as a composite measure, stating that this measure format would optimize assessment of nutrition care for those at risk of malnutrition or who are already malnourished in the hospital setting. These commenters further recommended that CMS adopt the measures as a composite immediately, as opposed to in the future.

Response: We thank the commenters for their support. We note that as discussed in the proposed rule (82 FR 20061), in the preliminary review of these individual measures, both the MAP and the NQF Health and Well-Being Standing Committee advocated for the resubmission of the individual measures as a composite. Moving forward, we will weigh the benefits of adopting these measures as a composite versus as individual indicators. However, because the measures have not yet been evaluated by the MAP as a composite, they would need to undergo MAP review as a composite measure before we could propose to adopt it for the Hospital IQR Program in the future. We also appreciate commenters' recommendation that we adopt the measures immediately; however, we are not able to adopt them at this time because: (1) We are considering the future inclusion of these measures as a composite measure, but they have not yet been submitted as a Measure Under Consideration or reviewed by the MAP as a composite; and (2) the measures were not proposed for adoption in the FY 2018 IPPS/LTCH PPS proposed rule.

Comment: A few commenters supported the future inclusion of the malnutrition eCQMs in the Hospital IQR Program only if they received NQF endorsement, to demonstrate that they are clinically important or linked to improved patient outcomes. A few commenters noted that these measures are not NQF-endorsed and did not receive MAP support for inclusion in Hospital IQR Program.

Response: We thank the commenter for their support. We agree with commenters regarding the importance of adopting sound, evidence-based performance measures, and will work to ensure that any measure included in the Hospital IQR Program is thoroughly vetted prior to adoption. If the measure steward submits this measure for NQF endorsement review under the next applicable call for measures, we will consider the NQF's endorsement status prior to moving forward with proposing to adopt these measures in the Hospital IQR Program. However, we note that NQF endorsement is not a requirement for inclusion in the Hospital IQR Program measure set. Section 1886(s)(4)(D)(ii) of the Act provides that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorse by, the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

Comment: One commenter supported the future inclusion of the malnutrition eCQMs in the Hospital IQR Program, and recommended that ''Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition within 24 Hours of a Malnutrition Screening'' measure be extended to all age groups.

Response: We thank the commenter for their support. We note that these measures are intended to operate as a group, and as such, expanding the patient population in one measure would most likely require the expansion of the patient population in all the measures. We reiterate that the focus of this set of measures as currently specified is the assessment of malnutrition care among elderly patient populations (age 65 years and older), as they have been identified as the most at-risk cohort. We offer that if future testing of these measures yields results that improve care for this designated patient population, we could potentially assess how patients in other age groups are affected by malnutrition and whether the observed improvements could be broadly applied.

Comment: A few commenters did not support the inclusion of the malnutrition measures in the Hospital IQR Program because nutritional screening is already a requirement under the CMS Conditions of Participation (CoP), therefore, these commenters believed these measures would provide no additional incentives for performance improvement. Further, the commenters stated that these measures would create a distracting documentation ''checkbox'' process which is unlikely to advance meaningful care improvement.

Response: We note the measure steward is performing additional testing on all four of the malnutrition measures. Malnutrition is an ongoing healthcare issue with demonstrated impacts on patient outcomes. As such, we believe there could be important benefits to patients of having malnutrition measures that quantify the degree to which established best practices are carried out, improve health outcomes, and reduce cost burdens to healthcare systems. By referring to ''checkbox'' practices, we interpret that commenters have concerns about implementing process measures. We will take the concerns into consideration, however, we also believe these measures could be an important first step to incentivizing hospitals to improve malnutrition awareness and care.

Comment: Some commenters made suggestions on how to improve the malnutrition eCQM measures set. Specifically, the commenters suggested that the timeframe associated with the ''Completion of a Nutrition Assessment'' measure be modified such that hospitals can define their own time-intensive guidelines for documentation of assessments, as well as determining other patient populations who may be at potential nutrition risk. Other commenters suggested that the components of each assessment should be defined by each organization, arguing that organizations should guide practice based on their unique patient populations. In addition, the commenters recommended that consideration be given to the follow-up care provided for patients afflicted with malnutrition. The commenters also noted that nutrition assessment tools should be validated via clinical trials.

Response: We appreciate the commenters' suggestions. If the measure steward moves forward with additional testing of these measures, both individually and as a composite, we will consider the impact of follow-up care for patients afflicted with malnutrition, should we move forward with proposing to adopt these measures

in the Hospital IQR Program in the future. We understand the importance of hospitals having the autonomy to define their own guidelines related to the timing of documentation, however, we do not believe it is appropriate to allow hospitals to establish uniquely defined components for each measure based on their specific patient population because doing so introduces an untenable degree of variability and may mask disparities in patient care. It is imperative to evaluate the patient population as defined by the measures' denominators, as opposed to an individual hospital's or organization's parameters, in order to retain measurement integrity and not to skew the observed results with information bias. We agree with the commenters about the importance of ensuring the validity of tools and should we decide to move forward with proposing to adopt these measures for the Hospital IQR Program in the future, we will consider the feasibility of conducting a clinical trial of the nutrition assessment tools.

We thank the commenters and we will consider their views as we develop future policy regarding the use of eCQM versions of one or more measures in the malnutrition measure set and the possible future inclusion of a composite measure comprised of all or a subset of these individual malnutrition measures in the Hospital IQR Program.

(3) Tobacco Use Measures

(a) Background

Tobacco use is the single greatest cause of disease in the United States today and accounts for more than 480,000 deaths each year.[247] Tobacco use creates a heavy cost to society as well as to individuals. Smoking is a known cause of multiple cancers, heart disease, stroke, complications of pregnancy, chronic obstructive pulmonary disease, other respiratory problems, poorer wound healing, and many other diseases.[248]

Smoking-attributable health care expenditures are estimated to cost at least $130 billion per year in direct medical expenses for adults and over $150 billion in lost productivity.[249] There is strong and consistent evidence that tobacco dependence interventions, if delivered in a timely and effective manner, significantly reduce the user's risk of suffering from tobacco-related disease and improve outcomes for those already suffering from a tobacco-related disease.[250] [251] [252] [253] Effective, evidence-based tobacco dependence interventions have been clearly identified and include brief clinician advice, individual, group, or telephone counseling, and use of FDA-approved medications. Tobacco cessation treatments are clinically effective and extremely cost-effective relative to other commonly used disease prevention interventions and medical treatments.[254] Performance on the chart-abstracted versions of these measures, as reported by The Joint Commission, yields that the Tobacco Use Screening (TOB–1) measure had a screening rate of 98.15 percent, based on a reporting period of July 2015–June 2016.[255] TOB–1 is necessary to operationalize Tobacco Use Treatment Provided or Offered (TOB–2)/Tobacco Use Treatment (TOB–2a) and Tobacco Use Treatment Provided or Offered at Discharge (TOB–3)/Tobacco Use Treatment at Discharge (TOB–3a) measures. The goal of TOB–1 is to achieve 100 percent screening so that all tobacco users are consistently identified and offered appropriate interventions, which are evaluated by TOB–2/2a and TOB–3/3a. As noted in the table[256] below, the performance rates for the chart-abstracted versions of TOB–2/2a and TOB–3/3a measures suggest that there is an opportunity for hospitals to improve tobacco use treatment during the hospital stay and at discharge.

TOBACCO USE MEASURES SCREENING RESULTS JULY 2015–JUNE 2016

Measure name	Screening rate (%)
Tobacco Use Treatment Provided or Offered (TOB–2)	66.41
Tobacco Use Treatment (TOB–2a)	32.97
Tobacco Use Treatment Provided or Offered at Discharge (TOB–3)	46.20
Tobacco Use Treatment at Discharge (TOB–3a)	10.71

(b) Overview of Measures

The tobacco use measure set consists of the following three measures:

- Tobacco Use Screening (TOB–1) (MUC16–50);
- Tobacco Use Treatment Provided or Offered (TOB–2)/Tobacco Use Treatment (TOB–2a) (MUC16–51); and
- Tobacco Use Treatment Provided or Offered at Discharge (TOB–3)/Tobacco Use Treatment at Discharge (TOB–3a) (MUC16–52).

The TOB measures are eCQMs that assess tobacco use screening and treatment for patients age 18 years or older during the hospital stay and at discharge. We note that these measures were derived from the chart-abstracted versions in use by The Joint Commission. The Joint Commission has been using the chart-abstracted versions of these measures for voluntary reporting since January 1, 2012.[257] In addition, the chart-abstracted versions of these measures (TOB–1, TOB–2/TOB–2a, and TOB–3/TOB–3a) are also part of the IPFQR Program measure set (81 FR 57246). These measures address the NQS priority of promoting the most effective prevention and treatment practices for the leading causes of mortality.

TOB–1 assesses the proportion of hospitalized patients who are screened, or refuse screening, within the three days prior to admission through 1 day after admission, for tobacco use during the 30 days prior to the screening. TOB–2 assesses the proportion of patients who are light tobacco users who received or refused practical counseling to quit within 3 days prior to or anytime during admission. TOB–2 also assesses the proportion of heavy tobacco users who received or refused practical counseling to quit and received, had a medical reason not to receive, or refused FDA-approved cessation medications within 3 days prior to or anytime during

[247] Centers for Disease Control and Prevention. Current Cigarette Smoking Among Adults—United States, 2005–2013. Morbidity and Mortality Weekly Report (MMWR) 2014. 63(47); 1108–1112. Available at: *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6347a4.htm?s_cid=mm6347a4.*

[248] U.S. Department of Health and Human Services. The health consequences of smoking—50 years of progress: a report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2014. Available at: *http://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf.*

[249] *Ibid.*

[250] U.S. Department of Health and Human Services. Reducing tobacco use: a report of the Surgeon General. Atlanta, GA, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2000.

[251] Baumeister SE, Schumann A, Meyer C, et al. Effects of smoking cessation on health care use: is elevated risk of hospitalization among former smokers attributable to smoking-related morbidity? Drug Alcohol Depend. 2007 May 11;88(2–3):197–203. Epub 2006 Nov 21.

[252] Lightwood JM. The economics of smoking and cardiovascular disease. Prog Cardiovasc Dis. 2003 Jul–Aug;46(1):39–78.

[253] Rigotti, et al. Interventions for smoking cessation in hospitalized patients. Cochrane Database of Systematic Reviews. 2012. Available from: *http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD001837.pub3/abstract.*

[254] *Ibid.*

[255] Joint Commission Quality Check Data, available at: *https://www.qualitycheck.org/.* (Data download.)

[256] The Joint Commission Quality Check Data available at: *https://www.qualitycheck.org/.*

[257] The Joint Commission, Substance Use Measures overview, available at: *https://www.jointcommission.org/core_measure_sets.aspx.*

admission. The subset measure TOB–2a only assesses light tobacco users who received practical counseling to quit within 3 days prior to or anytime during admission, and heavy tobacco users who received practical counseling to quit and received, or had a medical reason not to receive, FDA-approved cessation medications within 3 days prior to or anytime during admission. TOB–3 assesses the proportion of patients who are light tobacco users who were referred to or refused counseling within 3 days prior to admission through 1 day after discharge. TOB–3 also assesses the proportions of heavy tobacco users who were referred to or refused evidence-based counseling *and* received, had a medical reason not to receive, or refused a prescription for FDA-approved cessation medication upon discharge. The subset measure TOB–3a assesses light tobacco users who were referred to counseling within 3 days prior to admission through one day after discharge, and heavy tobacco users who were referred to evidence-based counseling and received, or had a medical reason not to receive, a prescription for FDA-approved cessation medication upon discharge.

We note that we previously solicited comments on the future inclusion of electronically-specified versions of the tobacco use measures TOB–1, TOB–2/2a and TOB–3/3a, previously referred to as TAM–1, TAM–2, and TAM–3, respectively, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53535). Commenters equally supported and opposed the future inclusion of the tobacco use measures in the Hospital IQR Program. Commenters highlighted the importance of high validation rates such as 95 percent, across the electronic data capture method and manual chart-abstraction (77 FR 53535). We note that at the time we sought public comments on these measure concepts related to tobacco use, electronically-specified measures were not yet developed.

In the most recent MAP deliberations in December 2016, only the Tobacco Use Screening (TOB–1) eCQM (MUC16–50) was reviewed. The TOB–2/TOB–2a (MUC16–51) and TOB–3/TOB–3a (MUC16–52) eCQMs were on the December 2016 MUC List, but were not submitted for MAP review because they were still undergoing field testing. We anticipate these measures should be ready for review by the MAP in the winter of CY 2017.

The TOB–1 eCQM was recommended to be refined and resubmitted for consideration for programmatic inclusion.[258] The MAP indicated that the measure should be tested to ensure that it returns accurate, reliable results. In addition, the MAP Hospital Workgroup noted that it will be important to carefully assess feasibility and burden of data collection.[259] As previously stated, the chart-abstracted versions of the Tobacco Use Screening measures (TOB–1, TOB–2/TOB–2a, and TOB–3/TOB–3a) are part of the IPFQR Program measure set (81 FR 57246); thus, future inclusion of the eCQM versions of these measures in the Hospital IQR Program measure set would promote programmatic alignment across these quality reporting programs.

Additional information on the chart-abstracted version of these measures is available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228775749207*.

We invited public comment on the possible future inclusion of one or more of the eCQM versions of these tobacco use measures (TOB–1, TOB–2/2a and TOB–3/3a) in the Hospital IQR Program. In addition, we invited public comment on the possible future inclusion of a composite measure comprised of all or a subset of these individual tobacco use measures in the Hospital IQR Program.

Comment: Many commenters supported the proposed future inclusion of the tobacco eCQM measure set. The commenters noted that hospitalizations and readmission rates are high among tobacco users, however, most hospitals have not placed high priority on systematically assessing (identifying, noting status, offering cessation methods and following-up with) smokers. As such, the inclusion of these measures would help address this lost clinical care opportunity and decrease the incidence of tobacco related illness. In addition, the commenters noted that the parameters evaluated by measures TOB–2a and TOB–3a are patient engagement activities that could help promote the adjustment of quality measures by social risk factors, as many times smoking habits are related to SES and/or SDS factors. Lastly, the commenters noted that the tobacco use measures address a gap area within the Hospital IQR Program measure set. The commenters recommended ensuring programmatic alignment with other regulatory bodies to align tobacco and smoking code sets and requirements or to provide mapping guidance because misalignment will result in increased provider burden.

Response: We thank the commenters for their support. We will continue to work with other quality reporting programs and regulatory bodies as needed to align tobacco and smoking code sets and requirements. We appreciate the commenters input regarding the potential impact of the inclusion of these measures in the Hospital IQR Program on the broader CMS goal of accounting for social risk factors in clinical quality measures.

Comment: A few commenters supported the future inclusion of the Tobacco Use eCQMs in the Hospital IQR Program only if they receive NQF endorsement to ensure they are clinically important and linked to improved patient outcomes.

Response: We note that currently, the eCQM versions of the measures are undergoing beta testing. Upon completion of the testing, and the availability of a suitable project provided by the NQF, the eCQM versions of these measures will be submitted for endorsement consideration via NQF's consensus development process. However, we note that NQF endorsement is not a requirement for inclusion in the Hospital IQR measure set. Section 1886(s)(4)(D)(ii) of the Act provides that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorse by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

Comment: Some commenters urged CMS to develop the protocols and testing environments necessary to validate eCQMs.

Response: We have previously finalized a validation process for eCQM data and we refer readers to section IX.A.11. of the preamble of this final rule for more details.

Comment: The commenters also recommended that CMS convene a TEP to identify eCQMs that are appropriate for use across care settings.

Response: An existing TEP has convened to assess these measures, and we will share the results of the beta testing of the eCQM versions prior to submission to NQF.

Comment: A few commenters expressed that the tobacco use measures should be included as individual indicators, as opposed to a composite measure because the all-or-none scoring

[258] "2016–2017 Spreadsheet of Final Recommendations to HHS and CMS, available at: *http://www.qualityforum.org/map/*.

[259] *Ibid.*

of a composite measure could potentially dilute the quality improvement aspect of the measures' respective measurement domains. In addition, the commenters noted that combining multiple metrics into a composite measure increases challenges exponentially and does not allow the level of granularity necessary to know where improvements should be made. Further, commenters suggested that it would be less burdensome for hospitals to identify where improvement is required if the measures remain separate as opposed to determining deficiencies within a composite measure. The commenters urged CMS not to consider composite eCQMs until current single measure eCQMs are proven to be reliable and accurate.

Response: We thank the commenters for their support. We acknowledge the commenters' concerns about the importance of retaining the integrity of the quality improvement aspect garnered by scoring each measure individually, as opposed to combining them into a composite. In addition, we recognize that there may be differences in burden associated with data collection and the level of granularity associated with observed results for the individual indicators, as opposed to a composite measure. We will take these factors into account if we move forward with proposing to adopt these measures in the Hospital IQR Program in the future.

Comment: Some commenters did not support the future inclusion of the Tobacco measure set in the Hospital IQR Program because these measures are redundant and capturing these data elements electronically has proven to be a challenge. The commenters suggested that these measures be combined and reported as treatment provided/offered at any time during the hospital stay. Further, the commenters noted that capturing these data elements electronically has proven to be a challenge and has required substantial, time consuming electronic medical record revisions. The commenters acknowledged that while specifying the measures as eCQMs may eliminate some of the burden on hospitals, the measures should be field tested as eCQMs in acute care hospitals prior to consideration in the Hospital IQR Program to ensure the measures are accurately assessing clinically relevant variations in care. Finally, the commenters expressed concern that it would be difficult to submit information for TOB–2/2a in an eCQM format and believed that implementation of the TOB–1 as a standalone measure outside of the psychiatric setting would be most appropriate in the Hospital IQR Program. In addition, the commenters recommended that the tobacco use measures be tested as eCQMs, to ensure the measures are appropriately assessing clinically relevant variations in care, prior to being proposed for adoption in the Hospital IQR Program. Finally, the commenters recommended that CMS wait to implement these measures as eCQMs until the current core measures are more mature.

Response: We note that the eCQM versions of the measures are currently undergoing beta testing, to ensure the feasibility of electronic data abstraction and to ensure that these measures are appropriately assessing clinical variations in care. In both the alpha and beta testing phases we have not observed any significant difficulty in electronically capturing the data elements for these measures. We will continue to monitor the level of effort associated with electronic data extraction and make note of any significant challenges (for example, electronic medical record revisions) that arise. We are considering combining these measures into a composite, however, we will continue to solicit stakeholder feedback on how to implement these measures (individually or as composite) in the Hospital IQR Program should we elect to move forward with proposing to adopt them in the future.

We disagree with commenters that the measures are redundant, as there are currently no measures of behavioral health in the Hospital IQR Program. We also disagree that only the Tobacco Use Screening (TOB–1) measure is suitable for inclusion in the Hospital IQR Program. The performance rates for the chart-abstracted versions of Tobacco Use Treatment Provided or Offered (TOB–2)/Tobacco Use Treatment (TOB–2a) and Tobacco Use Treatment Provided or Offered at Discharge (TOB–3)/Tobacco Use Treatment at Discharge (TOB–3a) measures suggest that there is an opportunity for hospitals to improve tobacco use treatment during the hospital stay and at discharge. We reiterate that these measures are intended to be used as part of a linked set. Specifically, the TOB–2/2a and TOB–3/3a measures ensure hospitals are not only screening patients for tobacco use, but also offering evidence-based interventions to improve the quality of care for patients with tobacco use. Lastly, to address the commenters' statement regarding the maturity of the core measures, we note that the chart-abstracted versions of these measures (TOB–1, TOB–2/TOB–2a, and TOB–3/TOB–3a) are also part of the IPFQR Program measure set (81 FR 57246).

Comment: One commenter recommended that the Tobacco Use Measures be included in ambulatory quality reporting programs rather than in the Hospital IQR Program.

Response: We thank the commenter for their suggestion, and acknowledge increased screening in ambulatory settings could lead to increased overall tobacco cessation success. We recognize these results could be used by researchers and health-care providers to learn of opportunities for tobacco cessation as a covered health benefit. Currently, these measures are not specified to assess care in ambulatory settings, however, this may be something we consider in future rulemaking. We thank the commenters, and we will consider their views as we develop future policy regarding the use of eCQM versions of one or more measures in the tobacco use measure set and the possible future inclusion of a composite measure comprised of all or a subset of these individual tobacco use measures in the Hospital IQR Program.

(4) Substance Use Measures

(a) Background

Excessive alcohol consumption and drug misuse or abuse have a significant impact on the health of the U.S. population.[260] Excessive alcohol consumption is a leading cause of preventable death and disability resulting in approximately 88,000 deaths per year with an estimated economic cost of $249 billion, including $28 billion (2010 dollars) in direct health care costs.[261] In 2015, approximately 20.8 million individuals were classified as having a substance use disorder. Of those individuals with substance use disorders, 13.1 million had an alcohol use disorder, 5.1 million had an illicit drug use disorder, and 2.7 million had an alcohol and illicit drug

[260] Excessive alcohol consumption includes binge drinking. heavy drinking, and any drinking by pregnant women or people younger than age 21. Definitions are available from the Centers for Disease Control and Prevention at: *https://www.cdc.gov/alcohol/fact-sheets/alcohol-use.htm.*

[261] Centers for Disease Control and Prevention Alcohol and Public Health: Alcohol-Related Disease Impact available at: *https://nccd.cdc.gov/DPH_ARDI/Default/Report.aspx?T=AAM&P=f6d7eda7-036e-4553-9968-9b17ffad620e&R=d7a9b303-48e9-4440-bf47-070a4827e1fd&M=8E1C5233-5640-4EE8-9247-1ECA7DA325B9&F=&D=* ; Sacks JJ, Gonzales KR, Bouchery EE, Tomedi LE, Brewer RD. 2010 national and state costs of excessive alcohol consumption. American journal of preventive medicine. 2015 Nov 30;49(5): e73–9.; Stahre M, Roeber J, Kanny D, Brewer RD, Zhang X. Contribution of Excessive Alcohol Consumption to Deaths and Years of Potential Life Lost in the United States. Prev Chronic Dis 2014;11:130293. DOI: *http://dx.doi.org/10.5888/pcd11.130293.*

use disorder.[262] Excessive alcohol consumption and substance use disorders can increase the risk of preventable injury, worsen existing chronic diseases, such as mental illness, and lead to the development of diseases, such as heart disease, cancer, and liver disease.[263] Studies show the majority of individuals who consume alcohol excessively do not meet the clinical criteria for diagnosis of a substance use disorder; yet evidence demonstrates screening and brief interventions, especially prior to the onset of a substance use disorder, can improve health and reduce costs.[264] Similar benefits have been observed for individuals with substance use disorders who are identified and referred to treatment.[265] [266] The table below provides performance rates based on the July 2015–June 2016 reporting period for the chart-abstracted versions of these measures, as reported by The Joint Commission.[267] The results show that there is an opportunity for hospitals to improve substance use screening, brief intervention, and treatment.

SUBSTANCE USE MEASURES SCREENING RESULTS JULY 2015–JUNE 2016

Measure name	Screening rate (%)
Alcohol Use Screening (SUB–1)	85.30
Alcohol Use Brief Intervention Provided or Offered (SUB–2)	62.68
Alcohol Use Brief Intervention (SUB–2a)	57.43
Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge (SUB–3)	65.46
Alcohol & Other Drug Use Disorder Treatment at Discharge (SUB–3a)	54.27

(b) Overview of Measures

The substance use measure set consists of the following three measures:

- Alcohol Use Screening (SUB–1) (MUC16–179);
- Alcohol Use Brief Intervention Provided or Offered (SUB–2)/Alcohol Use Brief Intervention (SUB–2a) (MUC16–178); and
- Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge (SUB–3)/Alcohol & Other Drug Use Disorder Treatment at Discharge (SUB–3a) (MUC16–180).

The SUB–1, SUB–2/2a and SUB–3/3a measures address the NQS priority of promoting the most effective prevention and treatment practices for the leading causes of mortality. These measures are intended to be used as part of a linked set. Specifically, the SUB–2/2a and SUB–3/3a measures will ensure hospitals are not only screening patients for excessive alcohol use, but also offering evidence-based interventions to improve the quality of care for patients with excessive alcohol use or other use disorders. The SUB–1 Alcohol Use Screening measure assesses whether hospital patients 18 years of age and older are screened for alcohol use using a validated screening questionnaire for excessive drinking during their inpatient stay. A validated screening questionnaire is defined as an instrument that has been psychometrically tested for reliability (the ability of the instrument to produce consistent results), validity (the ability of the instrument to produce true results), and sensitivity (the probability of correctly identifying a patient with the condition).

As previously noted, these measures are intended to be implemented as a set. As such, it would be necessary to adopt the SUB–1 measure in order to implement the other two measures. The SUB–2/2a measure assesses whether hospital patients age 18 years of age or older who screened positive for excessive alcohol use or an alcohol use disorder receive or refuse a brief intervention during the hospital stay (SUB–2). Subset measure SUB–2a includes only those patients who receive a brief intervention. A brief intervention is defined as a single session or multiple sessions conducted by a qualified healthcare professional or trained peer support person, which includes motivational discussion focused on increasing patient insight and awareness regarding alcohol use and motivating behavioral change. The SUB–3/3a measures assess whether hospitals patients 18 years of age or older with a substance use disorder (alcohol or drug) receive or refuse at discharge a medication prescription for treatment or receive or refuse a referral for substance use disorder treatment (SUB–3). Subset measure SUB–3a includes only those patients who receive a medication prescription or treatment referral at discharge.

The chart-abstracted versions of these three measures, not the eCQM versions, were added to the MUC List in the summer of 2016,[268] and reviewed by the MAP in December 2016 as discussed in the MAP Pre-Rulemaking Report and Spreadsheet entitled ''2016–2017 Spreadsheet of Final Recommendations to HHS and CMS.'' [269] The MAP recommended that the SUB–1 measure (MUC16–179) be refined and resubmitted. The MAP noted that the measure encourages hospitals to screen patients for excessive alcohol use and can prevent life-threatening alcohol withdrawal syndrome, but recommended that the measure be paired with an appropriate intervention and follow-up measure. The MAP did not support the SUB–2/2a measure

[262] Substance Abuse and Mental Health Services Administration (SAMHSA) Key Substance Use and Mental Health Indicators in the United States: Results from the 2015 National Survey on Drug Use and Health available at: *https://www.samhsa.gov/data/sites/default/files/NSDUH-FFR1-2015/NSDUH-FFR1-2015/NSDUH-FFR1-2015.pdf*.

[263] Excessive alcohol consumption includes binge drinking. heavy drinking, and any drinking by pregnant women or people younger than age 21. Definitions are available from the Centers for Disease Control and Prevention at: *https://www.cdc.gov/alcohol/fact-sheets/alcohol-use.htm*.

[264] Esser MB, Hedden SL, Kanny D, Brewer RD, Gfroerer JC, Naimi TS. Prevalence of Alcohol Dependence Among US Adult Drinkers, 2009–2011. Prev Chronic Dis 2014;11:140329. DOI: *http://dx.doi.org/10.5888/pcd11.140329*; American Psychiatric Association. (1994). Diagnostic and statistical manual of mental disorders (DSM–IV) (4th ed.). Washington, DC.

[265] Maciosek MV, Coffield AB, Edwards NM, Flottemesch TJ, Goodman MJ, Solberg LI. Priorities among effective clinical preventive services results of a systematic review and analysis. Am J Prev Med Jul 2006;31(1):52–61.

[266] Saitz R, Palfai TP, Cheng DM, Horton NJ, Freedner N, Dukes K, et al. Brief intervention for medical inpatients with unhealthy alcohol use: a randomized, controlled trial. Ann Intern Med. 2007; 146:167–76.

[267] Joint Commission Quality Check Data, available at: *https://www.qualitycheck.org/*. (Data download.)

[268] 2016 Measures Under Consideration Spreadsheet, available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*.

[269] ''2016–2017 Spreadsheet of Final Recommendations to HHS and CMS, available at: *http://www.qualityforum.org/map/*.

(MUC16–178) for adoption into the Hospital IQR Program. Proponents of the SUB–2/2a measure supported the incorporation of behavioral health measures into the Hospital IQR Program and noted that hospitalization is a prime opportunity to discuss harmful substance use because patients may be more amenable to a brief intervention during a hospital stay. Other stakeholders acknowledged the significant health impact of screening and brief intervention for substance use, but cited the burden of chart-abstracted data collection and encouraged the continued development of an electronic measure. MAP stakeholders also expressed concern the use of the measure in the hospital inpatient setting, rather than a primary care setting, was not strongly linked to improved patient outcomes. The MAP also did not support SUB–3/3a (MUC16–180) due to similar concerns as identified with the SUB–2/2a measure regarding the measure's link to improved outcomes.[270]

With respect to MAP stakeholder concerns regarding the evidence supporting the use of the measures in the inpatient setting, we note such supporting evidence, including the evidence of the generalizability of studies to the acute inpatient setting, was included as part of the endorsement process and these measures received NQF endorsement. Sufficient evidence exists linking the measures to improved patient outcomes [271] [272] in the inpatient setting.[273] In addition, in light of the significant health impact of harmful substance use, and its associated healthcare costs, we believe the benefits of collecting these measure data from hospitals and publicly reporting the information outweigh the burden, and address a critical topic impacting a patient's quality of care and health outcomes.

We note that The Joint Commission has been using these chart-abstracted measures for optional reporting since January 1, 2012.[274] The chart-abstracted versions of the Substance Use measures (SUB–1, SUB–2/2a and SUB–3/3a) are also part of the IPFQR Program measure set (81 FR 57246); thus, future inclusion of the eCQM versions of these measures in the Hospital IQR Program measure set would promote programmatic alignment across these quality reporting programs. Lastly, we note that electronic versions of these measures are in development by SAMHSA; we anticipate that the eCQM versions will be ready for review within the next 18–24 months.

Additional information on the chart-abstracted versions of these measures is available in TJC's *Specification Manual for National Hospital Inpatient Quality Measures* at: *https://www.jointcommission.org/specifications_manual_for_national_hospital_inpatient_quality_measures.aspx.*

We invited public comment on the possible future inclusion of one or more of the eCQM versions of the Substance Use measures (SUB–1, SUB–2/2a and SUB–3/3a) in the Hospital IQR Program. In addition, we invited public comment on the possible future inclusion of a composite measure comprised of all of these individual substance use measures in the Hospital IQR Program.

Comment: Many commenters supported the proposed future inclusion of the Substance Use eCQM measure set. The commenters stated that substance use disorders are health issues that cause a great deal of illness in our country, but are terribly under-addressed by the treatment system. The commenters also stated that inclusion of these measures would incentivize screening, assessment, and evidence-based treatment for individuals with opioid and other substance use disorders. In addition, commenters agreed that these measures fill a gap area within the Hospital IQR Program measure set.

Some commenters recommended that the substance use measures should be added as individual measures as opposed to a composite because all-or-none scoring of a composite measure could potentially dilute the quality improvement aspect of the Substance Use measures and diminish the integrity of the quality improvement process. Further, commenters suggested that it would be less burdensome for hospitals to identify where improvement is required if the measures remain separate as opposed to determining deficiencies within a composite measure.

Response: We thank the commenters for their support. We acknowledge the commenters' concerns about the importance of retaining the integrity of quality improvement aspect garnered by scoring each measure individually, as opposed to combining them into a composite, and we will take these factors into account if we move forward with proposing to adopt these measures in the Hospital IQR Program in the future.

Comment: Some commenters supported the future inclusion of the Substance Use eCQMs in the Hospital IQR Program only if they receive NQF endorsement to ensure that they are clinically important and linked to improved patient outcomes.

Response: We thank the commenters for their support. We note that currently the eCQM versions of the measures are undergoing beta testing. Upon completion of the testing, and the availability of a suitable project provided by the NQF, the eCQM versions of these measures will be submitted for endorsement consideration via NQF's consensus development process. However, we note that NQF endorsement is not a requirement for inclusion in the Hospital IQR Program measure set. Section 1886(s)(4)(D)(ii) of the Act provides that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorse by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

Comment: Some commenters urged CMS to develop the protocols and testing environments necessary to validate eCQMs.

Response: We have previously finalized a validation process for eCQM data and we refer readers to section IX.A.11. of the preamble of this final rule for more details.

Comment: Some commenters also recommended that CMS convene a TEP to identify eCQMs that are appropriate for use across care settings.

Response: We also note that an existing TEP has convened to assess these measures and we will share the results of the beta testing of the eCQM versions prior to submission to NQF.

Comment: Some commenters expressed concern with the proposed future inclusion of the substance use eCQM measures. Specifically, the commenters noted that capturing these

[270] "2017 Considerations for Implementing Measures Hospitals-Final Report," available at: *http://www.qualityforum.org/map/*.

[271] Kaner EF, Dickinson HO, Beyer FR, Campbell F, Schlesinger C, Heather N, Saunders JB, Burnand B, Pienaar ED. Effectiveness of brief alcohol interventions in primary care populations. Cochrane Database of Systematic Reviews 2007, Issue 2. Art. No.: CD004148. DOI: 10.1002/14651858.CD004148.pub3.

[272] Whitlock EP, Polen MA, Green CA, Orleans CT, Klein J. Behavioral Counseling Interventions in Primary Care to Reduce Risky/Harmful Alcohol Use by Adults: A Summary of the Evidence for the U.S Preventive Services Task Force. Ann Intern Med. 2004; 140:558–569.

[273] McQueen J, Howe TE, Allan L, Mains D, Hardy V. Brief interventions for heavy alcohol users admitted to general hospital wards. Cochrane Database Syst Rev. 2011 Jan 1;8(8).

[274] The Joint Commission, Substance Use Measures overview, available at: *https://www.jointcommission.org/core_measure_sets.aspx.*

data elements electronically has proven to be a challenge and has required substantial, time consuming electronic medical record revisions. The commenters acknowledged that while specifying the measures as eCQMs may eliminate some of the burden on hospitals, the measures should be field tested as eCQMs in acute care hospitals prior to consideration in the Hospital IQR Program to ensure the measures are accurately assessing clinically relevant variations in care. Finally, the commenters expressed concern that it would be difficult to submit information for SUB–2/2a in an eCQM format and believed that implementation of the SUB–1 as a standalone measure outside of the psychiatric setting would be most appropriate.

Response: We acknowledge the commenters concerns. We note that currently, the eCQM versions of the measures are undergoing beta testing in acute care hospitals to ensure the feasibility of electronic data abstraction and to ensure that these measures are appropriately assessing clinical variations in care. We also note that in both the alpha and beta testing phases we have not observed any significant difficulty in electronically capturing the data elements for any of these measures.

We disagree that the Alcohol Use Screening (SUB–1) measure is more suitable for implementation in the Hospital IQR Program than the Alcohol Use Brief Intervention Provided or Offered (SUB–2)/Alcohol Use Brief Intervention (SUB–2a) and Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge (SUB–3)/Alcohol & Other Drug Use Disorder Treatment at Discharge (SUB–3a) measures. We reiterate that these measures are intended to be used as part of a linked set. Specifically, the SUB–2/2a and SUB–3/3a measures ensure hospitals are not only screening patients for excessive alcohol use, but also offering evidence-based interventions to improve the quality of care for patients with excessive alcohol use or other use disorders.

Comment: One commenter recommended that the Substance Use Measures be included in ambulatory quality reporting programs rather than in the Hospital IQR Program.

Response: We thank the commenter for their suggestion and acknowledge that preventable substance use events are common in ambulatory settings, with many resulting in hospitalization. Currently, these measures are not specified to assess care in ambulatory settings, however, this may be something we consider in future rulemaking. We note that quality improvement programs at large could benefit from targeting substance use disorders among patients.

We thank the commenters, and we will consider their views as we develop future policy regarding the use of a one or more eCQM versions of the substance use measures and the possible future inclusion of a composite measure comprised of all of these individual substance use measures in the Hospital IQR Program.

10. Form, Manner, and Timing of Quality Data Submission

a. Background

Sections 1886(b)(3)(B)(viii)(I) and (b)(3)(B)(viii)(II) of the Act state that the applicable percentage increase for FY 2015 and each subsequent year shall be reduced by one-quarter of such applicable percentage increase (determined without regard to sections 1886(b)(3)(B)(ix), (xi), or (xii) of the Act) for any subsection (d) hospital that does not submit data required to be submitted on measures specified by the Secretary in a form and manner, and at a time, specified by the Secretary. Previously, the applicable percentage increase for FY 2007 and each subsequent fiscal year until FY 2015 was reduced by 2.0 percentage points for subsection (d) hospitals failing to submit data in accordance with the description above. In accordance with the statute, the FY 2018 payment determination will begin the fourth year that the Hospital IQR Program will reduce the applicable percentage increase by one-quarter of such applicable percentage increase.

In order to participate in the Hospital IQR Program, hospitals must meet specific procedural, data collection, submission, and validation requirements. For each Hospital IQR Program payment determination, we require that hospitals submit data on each specified measure in accordance with the measure's specifications for a particular period of time. The data submission requirements, Specifications Manual, and submission deadlines are posted on the QualityNet Web site at: *http://www.QualityNet.org/*. The annual update of electronic clinical quality measure (eCQM) specifications and implementation guidance documents are available on the eCQI Resource Center Web site at: *https://ecqi.healthit.gov/*. Hospitals must register and submit quality data through the secure portion of the QualityNet Web site. There are safeguards in place in accordance with the HIPAA Security Rule to protect patient information submitted through this Web site.

b. Procedural Requirements for the FY 2020 Payment Determination and Subsequent Years

The Hospital IQR Program's procedural requirements are codified in regulation at 42 CFR 412.140. We refer readers to these codified regulations for participation requirements, as further explained by the FY 2014 IPPS/LTCH PPS final rule (78 FR 50810 through 50811) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57168). In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20064), we did not propose any changes to these procedural requirements.

c. Data Submission Requirements for Chart-Abstracted Measures

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51640 through 51641), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53536 through 53537), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50811) for details on the Hospital IQR Program data submission requirements for chart abstracted measures. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20064), we did not propose any changes to the data submission requirements for chart abstracted measures.

d. Changes to the Reporting and Submission Requirements for eCQMs

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20064 through 20066), we proposed changes to the Hospital IQR Program eCQM reporting and submission requirements to align them with the Medicare EHR Incentive Program for eligible hospitals and CAHs.

(1) Background

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57157 through 57159), we finalized policies to require hospitals to submit a full calendar year (four quarterly reporting periods) of data on at least 8, self-selected eCQMs from the available eCQMs in the Hospital IQR Program for the CY 2017 reporting period/FY 2019 payment determination and the CY 2018 reporting period/FY 2020 payment determinations. In this final rule, we are finalizing modified versions of our proposals regarding the CY 2017 reporting period/FY 2019 payment determination and the CY 2018 reporting period/FY 2020 payment determination eCQM reporting requirements such that hospitals are required to submit one, self-selected, calendar quarter of data for 4 eCQMs. We refer readers to section IX.A.8. of the preamble of this final rule for more detail on these policies. Consistent with previous years, with these finalized policies we have sought to align the

Hospital IQR Program eCQM reporting requirements and the CQM electronic reporting requirements in the Medicare EHR Incentive Program to the extent feasible for the CY 2017 reporting period/FY 2019 payment determination and the CY 2018 reporting period/FY 2020 payment determination in order to reduce reporting burden and confusion for hospitals and their health IT vendors. We refer readers to the finalized policies for the Medicare and Medicaid EHR Incentive Programs for eligible hospitals and CAHs in section IX.E.2.b. of the preamble of this final rule. We are finalizing these changes for both programs in order to assist hospitals in their efforts as they transition towards more robust electronic reporting of quality measure data and to be responsive to the feedback we have received about the challenges of eCQM reporting and recommendations to allow more time to become familiar with and improve upon eCQM reporting capabilities.

(2) Changes to the Reporting and Submission Requirements for eCQMs for the FY 2019 Payment Determination and Subsequent Years

In the FY 2018 IPPS/LTCH PPS proposed rule, we did not propose any changes to our file format requirements or reporting deadlines. However, we proposed changes to our requirements related to eCQM electronic specification and certification. These are discussed in more detail below.

(a) File Format

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49708), we finalized that hospitals must submit eCQM data via the Quality Reporting Document Architecture Category I (QRDA I) file format for the CY 2016 reporting period/FY 2018 payment determination. In addition, we finalized that for the CY 2016 reporting period/FY 2018 payment determination, hospitals may use third parties to submit QRDA I files on their behalf and can either use abstraction or pull the data from non-certified sources in order to then input these data into CEHRT for capture and reporting QRDA I (80 FR 49706). Consistent with previously finalized reporting requirements, hospitals can meet the reporting requirements by submitting data via QRDA I files, zero denominator declaration, or case threshold exemption. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57170), we finalized our proposal to continue these eCQM reporting policies for the CY 2017 reporting period/FY 2019 payment determination and subsequent years. These finalized requirements align with the CQM electronic reporting requirements of the Medicare EHR Incentive Program for eligible hospitals and CAHs (81 FR 57255 through 57257). In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20065), we did not propose any changes to these requirements.

(b) Changes to the Certification Requirements for eCQM Reporting

(i) Background and Changes to the CY 2018 Reporting Period/FY 2020 Payment Determination Certification Requirements

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57170 through 57171), we finalized policies that hospitals must: (1) Report eCQM data using EHR technology certified to either the 2014 or 2015 Edition certification criteria for the CY 2017 reporting period/FY 2019 payment determination; and (2) report eCQM data using EHR technology certified to the 2015 Edition beginning with the CY 2018 reporting period/FY 2020 payment determination and subsequent years. As we discuss in further detail in section IX.G.4. of the preamble of this final rule where the same considerations are discussed in detail for the Medicare and Medicaid EHR Incentive Programs, based on our past experience with the transition from the 2011 Edition to the 2014 Edition and concerns expressed by stakeholders, we understand that transitioning to technology certified to a new Edition can be complex and can require more resources and time than anticipated, including the time necessary to effectively deploy the upgraded system and make the necessary patient safety, staff training, and workflow investments. We understand and appreciate these concerns and are working in cooperation with our federal partners at ONC to monitor progress on the 2015 Edition upgrade. Nevertheless, we believe that there are many benefits of switching to EHR technology certified to the 2015 Edition. We will work with ONC to monitor the status of EHR technology certified to the 2015 Edition and the deployment and implementation of such technology. In the proposed rule (82 FR 20065), we noted that if we identify a change in the current trends and significant issues with the certification and deployment of the 2015 Edition, we will consider additional methods to offer flexibility in CY 2018 for those hospitals that are not able to implement 2015 Edition certification criteria for CEHRT, including the flexibility to use technology certified to the 2014 Edition or the 2015 Edition in CY 2018. Another option we noted is allowing a combination of EHR technologies certified to the 2014 Edition and 2015 Edition to be used in CY 2018, for those hospitals that are not able to fully implement EHR technology certified to the 2015 Edition. We invited public comment on these options for offering flexibility in CY 2018 with regard to EHR certification requirements.

Comment: A few commenters supported CMS' policy that eCQMs must be submitted using the 2015 Edition certification criteria for CEHRT for the CY 2018 reporting period/FY 2020 payment determination because it offers increased interoperability which would make both the sharing and usage of data easier.

Response: We thank the commenters for their support. We believe using the most recent version of CEHRT, which incorporates updated standards and criteria, is important as it allows us to collect more relevant and accurate electronic data. We believe improved systems interoperability and use of the most current standards will facilitate more robust and accurate quality data reporting. One of the main tenets of the ONC 2015 Edition final rule (80 FR 62601) is to facilitate greater interoperability for several clinical health information purposes and enable health information exchange through new and enhanced certification criteria, standards, and implementation specifications. We note that we have worked closely with ONC to enhance testing and validation of certified technology's ability to capture, exchange, and report electronic patient data, such as improved testing and certification through the Cypress CQM testing and certification tool.[275] As another example, we note that ONC proposed a ''CQM—report'' certification criterion at 45 CFR 170.315(c)(3) as part of its 2015 Edition certification criteria that we would then require as described in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24613 through 24614).

Furthermore, we believe there are many benefits associated with upgrading to EHR technology certified to the 2015 Edition. Specifically, the 2015 Edition includes updates to standards for structured data capture as well as data elements in the common clinical data set which can be captured in a structured format. The use of relevant, up-to-date, standards-based structured data capture with an EHR certified to the 2015 Edition supports

[275] Cypress Tool Overview, available at: *https://www.healthit.gov/cypress/*.

electronic clinical quality measurement. Further, the 2015 Edition certification criteria enables health information exchange through new and enhanced certification criteria standards, and implementation specifications for interoperability while incorporating changes that are designed to spur innovation and provide more choices to health care providers and patients for the exchange of electronic health information including new application access (API) certification criteria. For example, a new ''transitions of care'' certification criterion rigorously assess a product's ability to create and receive an interoperable Consolidated-Clinical Document Architecture (C–CDA). ONC also adopted certification criteria that both support interoperability in other settings and use cases, such as the Common Clinical Data Set summary record, data segmentation for privacy, and care plan certification criteria (80 FR 62603). For additional details about the updates to the 2015 Edition, we refer readers to ONC's Common Clinical Data Set resource, available at: *https://www.healthit.gov/sites/default/files/commonclinicaldataset_ml_11-4-15.pdf*.

The 2015 Edition certification criterion (that make up CEHRT) within the certification testing process includes features that are designed to improve the functionality and quality of eCQM data. Specifically, systems must demonstrate they can import and allow a user to export one or more QRDA files. This allows systems to share files and extract data for reporting into another system or send to another system. In addition, testing coverage is much more robust; all measures have >80 percent of test pathways tested in the test bundle with most >95 percent. The 2015 Edition certification criteria for CEHRT also includes optional certification criteria and program specific testing which can also support electronic clinical quality reporting. The filter criteria ensure a product can filter an electronic file based on demographics like sex or race, based on provider or site characteristics like TIN/NPI, and based on a diagnosis or problem. The testing for this function checks that patients are appropriately aggregated and calculated for this new function which supports flexibility, specificity and more robust analysis of eCQM data. Finally, the 2015 Edition provides optional testing to CMS requirements for reporting such as form and manner specifications and implementation guides. For these reasons, we encourage hospitals to deploy the 2015 Edition certification criteria as soon as practicable.

Comment: Many commenters did not support CMS' previously finalized policy that eCQMs must be submitted using the 2015 Edition certification criteria for CEHRT for the CY 2018 reporting period/FY 2020 payment determination.

Several commenters supported the options described in the FY 2018 IPPS/LTCH PPS proposed rule, such that hospitals be permitted to use the 2014 Edition certification criteria for CEHRT or a combination of 2014 and 2015 Editions for the CY 2018 reporting period/FY 2020 payment determination.

A few commenters recommended CMS delay the requirement for eCQMs to be submitted using the 2015 Edition certification criteria for CEHRT until the CY 2019 reporting period/FY 2021 payment determination. The commenters suggested that additional time is necessary because the requirements for the 2015 Edition certification criteria for CEHRT are extensive and expensive. In addition, developers continue to struggle with completing the certification process by January 1, 2018.

One commenter mentioned that turn over in the industry has caused a backlog in the certification process. Another commenter expressed concern that the slow pace of certification, the number of upgrades still to be performed, and the number of trainings yet to be held makes it highly unlikely that health systems and medical practices will be prepared to submit eCQMs using the 2015 Edition certification criteria for CEHRT for the CY 2018 reporting period/FY 2020 payment determination. Another commenter noted that implementing the 2015 Edition certification criteria for CEHRT does not automatically create the ability to submit ''appropriate'' or complete quality data.

Response: We recognize there is burden associated with the development and deployment of each new version of CEHRT, which may be labor intensive and expensive for hospitals. We understand that ONC considers trends within the industry when projecting for 2015 Edition readiness and has continued to update this tracking as the testing and certification process continues. This tracking, as of the end of the second quarter of CY 2017, indicates that overall progress is behind the first quarter projections.[276] ONC has therefore updated the overall estimate to reflect an estimate of greater than 75 percent of hospitals will be ready by the end of CY 2017.[277] We refer readers to section IX.G.4. of the preamble of this final rule for more discussion of ONC's efforts on this matter.

We acknowledge commenter concerns that vendor industry turnover may delay hospitals' ability to deploy the 2015 Edition certification criteria for CEHRT. Since the conclusion of the public comment period for the FY 2017 IPPS/LTCH PPS final rule, we have continued to receive frequent feedback (via email, webinar questions, help desk questions, and conference call discussions) from hospitals and health IT vendors about ongoing challenges of implementing eCQM reporting. A summary of the main concerns identified by these data submitters are outlined in section IX.A.8.a. of the preamble of this final rule. One significant issue that commenters specifically identified is the timing of transitioning to new EHR systems during CY 2017 (for example, transition to a new EHR vendor or system upgrades necessary to deploy the 2015 Edition certification criteria for CEHRT) affects hospitals' ability to complete the certification process by January 1, 2018.

Although we believe that the longer-term benefits of utilizing the 2015 Edition as discussed in the above response outweigh these costs and challenges, in response to stakeholder concerns, in part about the burden associated with upgrading EHR technology certified to the 2015 Edition, we will allow flexibility for hospitals to use the 2014 Edition, the 2015 Edition, or a combination of both for the CY 2018 reporting period/FY 2020 payment determination only. This is a change to our previously finalized policy that required hospitals to use the 2015 Edition certification criteria for CEHRT for the CY 2018 reporting period/FY 2020 payment determination (81 FR 57171).

We will continue to assess the progress of hospitals implementing certification requirements and engage in discussions with hospitals regarding their experiences as we consider certification policies related to eCQM reporting in future rulemaking. We intend to determine requirements for the CY 2019 reporting period/FY 2021 payment determination and subsequent years in future rulemaking. We are finalizing similar certification policies for the Medicare and Medicaid EHR Incentive Programs for hospitals and CAHs and refer readers to sections IX.E.2.b. of the preamble of this final rule.

Furthermore, we refer readers to section IX.A.8. of the preamble of this final rule for details on our modified eCQM reporting requirements for the CY

[276] *https://dashboard.healthit.gov/dev/ticker.php.*

[277] *Ibid.*

2018 reporting period/FY 2020 payment determination, such that hospitals will be required to report on 4 eCQMs for only one, self-selected calendar quarter of data (instead of a full calendar year) to reduce burden. By allowing providers to self-select which quarter of data they want to submit, they will have more flexibility to determine implementation timelines for EHR system upgrades, such as transitioning to the 2015 Edition.

We acknowledge the commenter's concern that implementing the 2015 Edition certification criteria for CEHRT may not automatically result in the ability to submit ''appropriate'' or complete quality data; however, as described above, we believe the most recent Edition of certification criteria for CEHRT will help support eCQM data capture and reporting in several ways.

Comment: Some commenters expressed concern that their current vendors will not be certifying to the 2015 Edition certification criteria for CEHRT and worried that CMS would not grant ECE requests for hospitals experiencing vendor issues or transitions. These commenters suggested that CMS revise its eCQM ECE policy to allow for EHR vendor changes. One commenter requested clarification on the statement that a hospital is ''not able to implement the 2015 Edition of CEHRT.'' The commenter noted the wide variety of 2015 Edition certified products that are available and suggested waivers for the requirement to use the 2015 Edition be sparingly given, if at all, since use of the updated edition is an important and significant requirement.

Response: While we strive to move forward in our electronic reporting efforts and aim to stay abreast of evolving infrastructure, we must balance those goals with being responsive to stakeholder concerns. We refer readers to our change in policy discussed above in order to provide greater flexibility to hospitals transitioning to 2015 Edition certification criteria for CEHRT. However, if a hospital still finds it is unable to meet the eCQM submission deadline or other submission requirements, the hospital should review our criteria for an eCQM-related Extraordinary Circumstances Extension/Exemption (ECE) (81 FR 57182) and consider submitting an ECE request by the ECE request deadline. Currently, the deadline for the CY 2017 reporting period/FY 2019 payment determination is April 1st following the applicable eCQM submission deadline (February 28, 2018) (82 FR 57172). Our current policy allows hospitals to utilize the existing ECE form to request an exception from the Hospital IQR Program's eCQM reporting requirement for the applicable program year based on hardships preventing hospitals from electronically reporting (81 FR 57182). Such hardships could include, but are not limited to, infrastructure challenges (hospitals must demonstrate that they are in an area without sufficient internet access or face insurmountable barriers to obtaining infrastructure) or unforeseen circumstances, such as vendor issues outside of the hospital's control (including a vendor product losing certification) (80 FR 49695 and 49713). ECE requests for the Hospital IQR Program are considered on a case by case basis (81 FR 57182). We will assess the hospital's request on a case-by-case basis to determine if an exception is merited. Therefore, our decision whether or not to grant an ECE will be based on the specific circumstances of the hospital. For additional information about eCQM-related ECE requests, we refer readers to, ''The *ECE Policy Clarification Questions and Answers*'' document located online at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228775554109*, link to document: *ECE Policy Clarification Questions and Answers,* question #5).

Comment: One commenter believed it unfair to double penalize hospitals which may have excellent quality and are able to submit the chart-abstracted versions of the measure, but do not have fully operational EHRs. The commenter noted that only 5 percent of hospitals failed meaningful use, however, feared that number may increase with the transition to 2015 Edition certification criteria for CEHRT.

Response: With respect to the commenter's assertion that it is unfair to double penalize hospitals that do not have fully operational EHRs, we disagree that the requirements for electronic reporting in the Hospital IQR Program duplicate penalties. In an effort to align the Hospital IQR and EHR Incentive Programs with regard to electronic quality reporting, we have specified that hospitals meeting eCQM reporting requirements for the Hospital IQR Program will be considered to have successfully electronically reported CQMs for the Medicare EHR Incentive Program as well. As noted by the commenter and as we previously stated in the FY 2016 IPPS/LTCH PPS final rule, our data show that 95 percent of hospitals already attest to successful eCQM reporting under the EHR Incentive Program and, accordingly, we believe that the majority of hospitals will be able to successfully report eCQMs to meet the Hospital IQR Program requirements (81 FR 57156). We do not believe that transition to the 2015 Edition certification criteria for CEHRT will materially impact the percentage of hospitals able to successfully report eCQM data, particularly in light of our change to previously finalized policy, discussed above, to allow flexibility for hospitals to use the 2014 Edition, 2015 Edition, or a combination of both for the CY 2018 reporting period/FY 2020 payment determination.

Comment: One commenter expressed concern that allowing flexibility on the use of a combination of the 2014 and 2015 Editions of CEHRT for the CY 2018 reporting period/FY 2020 payment determination might create more problems than it could potentially solve.

Response: We interpret the commenter's concern to be that allowing hospitals to use of a combination of the 2014 and 2015 Editions certification criteria for CEHRT might make it more difficult for them to meet the eCQM reporting requirements. We acknowledge the commenter's concern but do not share it; we have allowed hospitals to use a combination of the 2014 and 2015 Editions of CEHRT for the CY 2016 reporting period/FY 2018 payment determination and the CY 2017 reporting period/CY 2019 payment determination, and we are not aware of any specific issues in QRDA I file creation or submission. Based on the comments received, many hospitals and health IT vendors indicated they would prefer to have greater time and flexibility to implement upgrades to the 2015 Edition and specifically suggested we allow hospitals to use a combination of the 2014 and 2015 Editions of CEHRT to satisfy the eCQM certification requirements for the CY 2018 reporting period/FY 2020 payment determination. If we interpret commenter's concern to mean that delaying full transition to the 2015 Edition might stall progress toward more robust electronic data submission, we believe that we must balance these goals with other commenters' concerns about their ability to timely meet the certification requirements in the face of vendor issues and other challenges, as discussed above. We believe our changes, as discussed above, to the previously finalized policy allowing greater flexibility for hospitals transitioning to the 2015 Edition best achieves this balance. We will continue to assess the progress of hospitals implementing certification requirements and engage in discussions with

hospitals regarding their experiences as we consider certification policies in future rulemaking.

Comment: Several commenters noted their support for the previously finalized policy that eCQMs could be submitted via the 2014 or 2015 Edition certification criteria for CEHRT for the CY 2017 reporting period/FY 2019 payment determination and recommended that CMS extend this option to allow use of the 2014 or 2015 Edition certification criteria for CEHRT for the CY 2018 reporting period/FY 2020 payment determination, because it allows hospitals additional flexibility and enables facilities to spend appropriate time on implementation, testing, validation, and education of EHR systems.

Response: We refer these commenters and readers to our discussion above, expanding these policies through the FY 2020 payment determination.

Comment: A few commenters expressed concern that hospitals may be penalized more than once for failing to successfully report eCQMs in both the Hospital IQR and EHR Incentive Programs and thus a significant portion of their annual payment update hinges on the maturity of health IT vendor capabilities and the ability of CMS' QualityNet Secure Portal to manage and appropriately support the volume of incoming data submissions.

Commenters noted that hospitals continue to report barriers to successfully submitting eCQM data, including health IT vendor failures during the submission of production data (which did not present during test submissions) and limitations of the QualityNet Secure Portal, such as: (1) An inability to accept QRDA I files over a certain size; (2) an inability to run reports verifying that data have been submitted to CMS; and (3) frequent periods when the system is down because it cannot accommodate more than a certain number of users at one time. Moreover, a commenter expressed serious concerns about eCQM measure specification and data validation.

Response: We disagree with commenters that the requirements for electronic reporting in the Hospital IQR and Medicare EHR Incentive Programs duplicate penalties. As we previously stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57156), in an effort to align with the Medicare and Medicaid EHR Incentive Programs, we have specified that hospitals meeting electronic reporting requirements for the Hospital IQR Program will be considered to have successfully reported the eCQM requirement to the Medicare and Medicaid EHR Incentive Programs as well. Our data show that 95 percent of hospitals already attest to successful electronic clinical quality measure reporting under the EHR Incentive Program and, accordingly, we believe the majority of hospitals will be able to successfully report electronic clinical quality measures, meeting the Hospital IQR Program requirements (81 FR 57156). In addition, if a hospital is unable to meet the Hospital IQR Program's eCQM reporting requirements due to extraordinary circumstances, the hospital should review the Hospital IQR Program's ECE policy, available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228775554109*, and the EHR Incentive Program's hardship exception policy, available at: *https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/PaymentAdj_Hardship.html*. We also refer readers to section IX.A.15. of the preamble of this final rule for more details about our ECE policy.

Regarding the limitations of the QualityNet Secure Portal and QRDA I file submission difficulties that commenters described, we acknowledge that at certain times of high submission volume leading up to the submission deadline on February 28, 2017, some data submitters reported longer file processing times and inability to timely run feedback reports. We are actively taking steps to improve the data submission experience for the CY 2017 reporting period (the next submission deadline is February 28, 2018), such as working with the infrastructure contractor to increase system throughput and increase responsiveness to issues that arise. In addition, the development contractor is working to identify efficiencies that can be gained in our Hospital Quality Reporting system source code. These efficiencies should reduce the time it takes to receive submission confirmation and run reports.

Regarding the comment that failures during the submission of production data were not identified during the test file submission process, we note the Pre-Submission Validation Application (PSVA) tool [278] helps submitters to assess the QRDA I file format, however, hospitals and health IT vendors should submit files for testing in the CMS data receiving system via the QualityNet Secure Portal to ensure that production files are accepted prior to the submission deadline. Hospitals and their health IT vendors were notified via educational materials and presentations that the utilization of the PSVA tool assesses the format of the QRDA Category I file; however, the CMS data receiving system performs additional checks, such as the Clinical Document Architecture (CDA) schema, submission period dates, and authorization for a vendor to submit on a hospital's behalf. The PSVA tool is a good starting point for initial validation and will help hospitals and their vendors to work through many file format issues. Both validation methods provide value, but ultimately the hospital should aim to ensure that files are accepted through the CMS data receiving system.

Regarding the QRDA file size limitation, hospitals and vendors were notified via education and outreach efforts the file size limit of QRDA I files is 5 MB for eCQM reporting. For the CY 2016 reporting period, we received a relatively small number of files which were greater than 5 MB. These few files typically exceeded the file size limit due to lack of linearization (in other words, the files did not utilize XML tools to remove unnecessary spaces and line breaks) or contained excessive data unrelated to eCQM reporting. We were able to individually work with most data submitters to help them reduce file sizes over the 5 MB limitation. We are evaluating the feasibility of expanding the QRDA I file size for future eCQM reporting activities.

In addition, as described in section IX.A.11.b. of the preamble of this final rule, we intend to address concerns about the reliability and accuracy of electronic data through validation. In order to be able to effectively validate eCQM data, we need to continuously assess more data. Moreover, we believe it is appropriate to require reporting and validation of eCQMs given that measures available now and those being developed for the future are increasingly based on electronic standards (80 FR 49696).

As discussed above, after review of the comments received and in alignment with the Medicare and Medicaid EHR Incentive Programs, we are offering greater flexibility and finalizing a change to our previously finalized CY 2018 reporting period/FY 2020 payment determination certification requirements. Instead of requiring that all EHR technology used to report eCQM data be certified to the 2015 Edition for the CY 2018 reporting period/FY 2020 payment determination, we will allow hospitals to use: (1) Technology certified to the 2014 Edition; (2) technology certified to the 2015 Edition; or (3) a combination of

[278] *https://ecqi.healthit.gov/ecqm-tools-key-resources/tool-library/pre-submission-validation-application-psva.*

EHR technologies certified to the 2014 Edition and 2015 Edition for the CY 2018 reporting period/FY 2020 payment determination. We note the previously finalized certification requirements for the CY 2017 reporting period/FY 2019 payment determination will remain unchanged (81 FR 57170 through 57171). We intend to determine requirements for the CY 2019 reporting period/FY 2021 payment determination and subsequent years in future rulemaking. We refer readers to section IX.G.4. of the preamble of this final rule, where we are finalizing a similar policy for the Medicare and Medicaid EHR Incentive Programs.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20064 through 20065), we proposed two changes related to certification requirements with regard to eCQMs: (1) To require EHR technology certified to all eCQMs available to report; and (2) to note certified EHR technology does not need to be recertified each time it is updated to a more recent version of the eCQM specifications to align with the Medicare EHR Incentive Program requirements for eligible hospitals and CAHs. These proposals are discussed in more detail below.

(ii) Requirement for EHR Technology To Be Certified to all eCQMs That are Available To Report for the CY 2017 Reporting Period/FY 2019 Payment Determination and the CY 2018 Reporting Period/FY 2020 Payment Determination

We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705) where we noted that although we require CEHRT, eligible hospitals were not required to ensure their CEHRT products were recertified to the most recent version of the electronic specifications for the clinical quality measures. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20065 through 20066), we proposed new policies regarding the Hospital IQR Program eCQM specification requirements to align with the Medicare EHR Incentive Program's CQM electronic reporting requirements.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57256) for the Medicare EHR Incentive Program, we finalized the continuation of a policy that electronic submission of CQMs will require the use of the most recent version of the electronic specification for each eCQM to which the EHR is certified. For the Medicare EHR Incentive Program, we previously finalized that in the event an eligible hospital or CAH has EHR technology which is certified to the 2014 Edition but not certified to all of the eCQMs that are available to electronically report for the CY 2017 reporting period/FY 2019 payment determination, we will require the hospital to have its EHR technology certified to all such eCQMs in order to meet the reporting requirements for the CY 2017 reporting period/FY 2019 payment determination (81 FR 57256). Further, for the Medicare EHR Incentive Program, we stated that for the CY 2017 reporting period eligible hospitals and CAHs will be required to use the Spring 2016 version of the eCQM specifications available on the eCQI Resource Center Web site at: *https://ecqi.healthit.gov/*.

In order to align the Hospital IQR Program's eCQM certification requirements and the Medicare EHR Incentive Program CQM electronic submission requirements for eligible hospitals and CAHs, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20133), we proposed that for the CY 2017 reporting period/FY 2019 payment determination, a hospital using EHR technology certified to the 2014 or 2015 Edition, but for which such EHR technology is not certified to all 15 available eCQMs, would be required to have its EHR technology certified to all 15 eCQMs that are available to report under the Hospital IQR Program. We further proposed (at 82 FR 20066) that for the CY 2017 reporting period/FY 2019 payment determination, hospitals would be required to use the most recent version of the eCQM electronic specifications (in other words, the Spring 2016 version of the eCQM specifications and any applicable addenda) available on the eCQI Resource Center Web site at: *https://ecqi.healthit.gov/*.

For the CY 2018 reporting period/FY 2020 payment determination, we proposed to apply this same policy regarding the reporting of eCQMs, such that hospitals would be required to use the most recent version of the eCQM specifications for each eCQM to which the EHR is certified (82 FR 20066). For the CY 2018 reporting period/FY 2020 payment determination, this means hospitals would be required to use the most recent version of the eCQM electronic specifications (in other words, the Spring 2017 version of the CQM electronic specifications and any applicable addenda) available on the eCQI Resource Center Web site at: *https://ecqi.healthit.gov/*. In addition, we proposed requiring that hospitals need to have their EHR technology certified to all 15 available eCQMs in order to meet the reporting requirements for the CY 2018 reporting period/FY 2020 payment determination. Furthermore, we proposed that an EHR certified for eCQMs under the 2015 Edition certification criteria would not need to be recertified each time it is updated to a more recent version of the eCQMs. We believe it is not necessary for EHRs certified for eCQMs under the 2015 Edition certification criteria to be recertified each time it is updated to the most recent version of the eCQMs. This is because the EHR technology continues to meet the 2015 Edition certification criteria and any updates to the eCQM specifications would not impact any elements regarding certification. Therefore, we proposed that recertification would not be necessary and would reduce the burden associated with recertification. For further discussion regarding EHR certification requirements, we refer readers to section IX.G.4. of the preamble of this final rule.

We invited public comment on these proposals.

Comment: Several commenters supported the proposal to require EHR technology to be certified to all eCQMs for the CY 2017 reporting period/FY 2019 payment determination because all 15 eCQMs should be available for submission to allow for reporting flexibility to better reflect the populations hospitals serve.

Response: We thank the commenters for their support.

Comment: Several commenters did not support the proposal to require that EHRs be certified to all 15 eCQMs for the CY 2017 reporting period/FY 2019 payment determination. A few of these commenters noted there is no requirement as a condition of ONC certification for EHRs to support all eCQM reporting options for hospitals, leaving each hospital or health system to work independently with vendors in implementing their measures. The commenters expressed concern these conditions may result in additional costs and hours of additional work for providers, and cause a tremendous waste of limited financial and personnel resources.

Some commenters urged CMS to work with ONC and health IT vendors to ensure the 2015 Edition certified EHRs are capable of supporting hospitals' eCQM reporting, including the reporting of any of the eCQMs available to report in the Hospital IQR Program.

Response: We appreciate the commenters' concerns about the proposal to require EHRs be certified to all available eCQMs for the CY 2017 reporting period/FY 2019 payment determination, and we recognize the challenges associated with eCQM reporting. Although there is no specific requirement as a condition of ONC

certification for EHR technology to support all available eCQMs, ONC has adopted certification criteria that both support interoperability in other settings and use cases, such as the Common Clinical Data Set summary record, data segmentation for privacy, and care plan certification criteria (80 FR 62603). Specifically, systems must demonstrate they can import and allow a user to export one or more QRDA files. For additional details about certification criteria, we refer readers to ONC's Common Clinical Data Set resource, available at: *https://www.healthit.gov/sites/default/files/commonclinicaldataset_ml_11-4-15.pdf*.

We believe requiring EHRs to be certified to all available eCQMs for the Hospital IQR Program would help to streamline the process of collecting electronic data by allowing hospitals flexibility in the particular eCQMs they want to select for data capture and reporting. Having an EHR certified to all available eCQMs would help prevent hospitals from having to go back and consult their health IT vendors and certify individual measures each time they want/need to report on a new or different eCQM. The process of individual measure certification could potentially create a bottleneck in the process, as hospitals would be reliant on vendor availability and timelines. This would inadvertently increase the overall eCQM reporting burden. If EHRs are certified to all available eCQMs, however, hospitals would have greater flexibility in selecting which eCQMs they want to report for a given reporting period up until the eCQM submission deadline, and they would not need to select which measures in advance based upon availability of certified eCQMs offered by the vendor.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57256), we adopted policy for the Medicare EHR Incentive Program requiring that for an eligible hospital or CAH that has EHR technology certified to the 2014 Edition, the EHR technology must be certified to all CQMs that would be available for the Medicare EHR Incentive Program CY 2017 reporting period. Requiring EHRs to be certified to all available eCQMs in the Hospital IQR Program would align the Hospital IQR and EHR Incentive Programs, which would help streamline requirements across CMS programs, thereby reducing electronic reporting burden on hospitals. Because EHRs are already required to be certified to all available eCQMs for the EHR Incentive Program, most hospitals should already have EHR technology certified to all available eCQMs at least for the 2014 Edition.

With regard to commenters' suggestion that CMS work with ONC and health IT vendors to ensure technology certified to the 2015 Edition are capable of supporting hospitals' eCQM reporting, we will continue to seek stakeholder input and collaborate with colleagues at ONC to define standards for EHR organization and structure which would allow for documentation to fit into the clinical workflow and to ensure our policies are responsive to evolving electronic standards to the greatest extent possible. We will also work with ONC to monitor the status of EHR technology certified to the 2015 Edition and the deployment and implementation of such technology, including reporting of the eCQMs that are available to report in the Hospital IQR Program.

Comment: Some commenters expressed concern the proposal to require that EHRs be certified to all 15 eCQMs for the CY 2017 reporting period/FY 2019 payment determination inappropriately places the burden on hospitals, rather than vendors, to meet the requirement, especially for hospitals transitioning from 2014 to 2015 certified EHR technology and preparing for long-planned system upgrades.

Response: While we recognize that requiring EHRs to be certified to all available eCQMs initially creates some burden for both hospitals and health IT vendors, we disagree that it unduly places the burden on hospitals, rather than vendors, to meet the requirement. We believe requiring EHRs to be certified to all available eCQMs could help alleviate some reporting burden by offering hospitals greater flexibility to report eCQM data most appropriate and useful to internal quality improvement efforts rather than being limited to only those eCQMs selected and supported by their vendors. In addition, requiring EHRs to be certified to all eCQMs offers greater certainty to hospitals that their EHR systems will be capable of reporting the particular eCQMs they select and that they could decide to select different eCQMs if and when needed. Therefore, we believe the burden will be offset by the flexibility it allows hospitals to report on any eCQMs they choose and to select those most relevant for their purposes. Once the initial process of certifying the EHR to all available eCQMs has been completed, we believe the burden will be offset by the flexibility it allows hospitals to report on any eCQMs they choose, without having to potentially re-negotiate with their health IT vendor for additional work to certify measures individually. Further, we note that, a certified health IT module supporting eCQMs would not need to be recertified each time it is updated to a more recent version of the eCQMs as stated above, under this policy, EHR technology certified for reporting all available eCQMs would not need to be recertified each time it is updated to a more recent version of the eCQM specifications.

Comment: One commenter argued changes to certification requirements should be made in rules published by ONC, as this is the agency with authority over EHR certification standards.

Response: We believe changes to certification requirements related to electronic reporting of quality measure data in the Hospital IQR Program appropriately fall under the purview of the Hospital IQR Program to specify the ''form and manner'' of quality data. In addition, as we stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57111), our goal is to align electronic quality measure requirements of the Hospital IQR Program with various other Medicare and Medicaid programs, including those authorized by the Health Information Technology for Economic and Clinical Health (HITECH) Act, as much as feasible so that the reporting burden on providers will be reduced. We will continue to seek stakeholder input and collaborate with colleagues at ONC to define standards for EHR organization and structure. If we determine based upon stakeholder feedback that the benefits of requiring EHRs to be certified to all available eCQMs, as outlined above, do not outweigh the burden, we may revisit this requirement in future rulemaking.

Comment: One commenter expressed concern this policy eliminates the opportunity for a specialty product to focus on measures only applicable to its domain, such as a surgical suite product focusing on surgery measures. The commenter also noted its concern that this policy would reduce the availability of certified HIT for hospitals or lead to poorer workflows for capturing quality data.

Response: We appreciate the commenter's interest in specialty health IT products that may be even more applicable to their specialty services or patient population. We do not believe our eCQM certification requirements prevent health IT vendors from developing and offering such products or from providers asking for such products. With regard to our current eCQM measure set, adding new eCQMs that address unique and individual specialties, and incorporation of electronic products that assess specific clinical domains, is a consideration for future rules once the capabilities of

electronic reporting are more fully established. We will continue to seek stakeholder input and collaborate with colleagues at ONC to monitor the availability of certified health IT products for quality measure reporting.

After consideration of the public comments we received, for the CY 2017 reporting period/FY 2019 payment determination, we are finalizing our proposals as proposed to: (1) Require EHR technology used for eCQM reporting to be certified to all eCQMs, but that such certified EHR technology does not need to be recertified each time it is updated to a more recent version of the eCQM electronic specifications; and (2) require hospitals to use the most recent version of the eCQM electronic specifications. In addition, for the CY 2018 reporting period/FY 2020 payment determination, we are finalizing our proposals, as proposed, to: (1) Require EHR technology used for eCQM reporting to be certified to all eCQMs, but that such certified EHR technology does not need to be recertified each time it is updated to a more recent version of the eCQM electronic specifications; and (2) require hospitals to use the most recent version of the eCQM electronic specifications. We refer readers to section IX.G.4. of the preamble of this final rule where the EHR Incentive Program is finalizing similar policies.

(c) Electronic Submission Deadlines for the FY 2020 Payment Determination and Subsequent Years

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50256 through 50259) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49708) for our previously adopted policies to align eCQM data reporting periods and submission deadlines for both the Hospital IQR Program and the Medicare EHR Incentive Program for eligible hospitals and CAHs.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57172), we established eCQM submission deadlines for the Hospital IQR Program. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20066), we did not propose any changes to the eCQM submission deadlines for the FY 2020 payment determination or subsequent years. Specifically, we are not making any changes to the February 28, 2018 submission deadline for CY 2017 reporting or the February 28, 2019 submission deadline for CY 2018 reporting (81 FR 57172) to ensure that APU determinations for FY 2019 and FY 2020 payment determinations are not affected and to maintain the previously established alignment with the Medicare EHR Incentive Program's submission deadline (81 FR 57255).

While we did not propose any changes to these policies, we received a few comments related to the submission deadline and general eCQM data submission and are addressing them below.

Comment: One commenter recommended the submission deadline be moved to the end of the first quarter of 2019 instead of February 28, 2019 because this would allow for final ICD–10 coding and corrections potentially needed after receiving final documentation from physicians.

Response: We thank the commenter for the recommendation to adjust the eCQM submission deadline from February 28, 2019 to the end of the first quarter of 2019. We will take this suggestion into consideration; however, at this time, we do not plan to extend the previously finalized submission deadline.

Comment: One commenter recommended that the CMS testing tools, such as updates to the PSVA tool and the QualityNet Secure Portal, need to be available at least three months before the start of the reporting year, instead of halfway through the reporting year, so that health IT developers can test with the new specifications and give healthcare organizations ample time to implement before the reporting period begins on January 1, 2018, because without sufficient time for adoption and testing, many organizations would not be ready for early submission.

Response: We thank the commenter for their suggestion that updates to CMS testing tools, such as the PSVA tool, and availability of our data receiving system via the QualityNet Secure Portal be made available to developers before the reporting period, but due to operational constraints, earlier release of PSVA tool updates and earlier availability of the QualityNet Secure Portal is not possible. We note that we did not develop the PSVA tool specifically as a development tool, but as a tool for data submitters to test their QRDA I files before submitting the files as production files for program credit. In addition, we have designed the QualityNet Secure Portal to allow for test file submissions as well as production file submissions. QualityNet is the only CMS-approved Web site for secure communications and healthcare quality data exchange between: Quality improvement organizations (QIOs), hospitals, data vendors, and other providers. We will look further into how we may be able to release PSVA tool updates and make the QualityNet Secure Portal available sooner for hospitals and health IT vendors. We refer readers to section IX.A.8.b. of the preamble of this final rule, where we discuss the PSVA tool in more detail.

(d) Summary

As noted in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49759) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57257), we continue to encourage health IT developers to test any updates on an annual basis, including any updates to the eCQMs and eCQM reporting requirements for the Hospital IQR and Medicare EHR Incentive Programs based on the CMS Implementation Guide for Quality Reporting Document Architecture [QRDA] Category I and Category III Eligible Professional Programs and Hospital Quality Reporting (HQR) (CMS Implementation Guide for QRDA). The CMS Implementation Guide for QRDA, program specific performance calculation guidance, and eCQM electronic specifications and guidance documents are available on the eCQI Resource Center Web site at: *https://ecqi.healthit.gov/*.

As noted in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57172), we also continue to encourage all hospitals and health IT vendors to submit QRDA I files early, and to use one of the pre-submission testing tools for electronic reporting, such as the CMS PSVA tool, to allow additional time for testing and to make sure all required data files are successfully submitted by the deadline. The PSVA tool can be downloaded from the Secure File Transfer (SFT) section of the QualityNet Secure Portal at: *https://cportal.qualitynet.org/QNet/pgm_select.jsp*.

In summary, in section IX.A.10.d.(2)(b)(ii) of the preamble of the FY 2018 IPPS/LTCH PPS proposed rule, for the CY 2017 reporting period/FY 2019 payment determination, for the Hospital IQR Program we proposed: (1) A hospital using EHR technology certified to the 2014 or 2015 Edition of CEHRT, but for which such EHR technology is not certified to all available eCQMs, would be required to have its EHR technology certified to all eCQMs that are available to report; and (2) EHR technology that is certified to all available eCQMs would not need to be recertified each time the eCQMs are updated to a more recent version of the eCQM specifications.

For the CY 2018 reporting period/FY 2020 payment determination, for the Hospital IQR Program we proposed: (1) A hospital using EHR technology certified to the 2015 Edition certification criteria for CEHRT, but for which such EHR technology is not

certified to all available eCQMs, would be required to have its EHR technology certified to all eCQMs that are available to report; and (2) EHR technology that is certified to all available eCQMs would not need to be recertified each time the eCQMs are updated to a more recent version of the eCQM specifications. Further, we proposed: (1) For the CY 2017 reporting period, hospitals would be required to use the most recent version of the eCQM electronic specifications (in other words, the Spring 2016 version of the eCQM specifications, and any applicable addenda); and (2) for the CY 2018 reporting period, hospitals would be required to use the most recent version of the eCQM electronic specifications (in other words, the Spring 2017 version of the eCQM specifications, and any applicable addenda). These eCQM specifications are available on the eCQI Resource Center Web site at: *https://ecqi.healthit.gov/*. We refer readers to section IX.E.3.c. of the preamble of this final rule, where similar policies are described for the Medicare EHR Incentive Program for eligible hospitals and CAHs.

We are reiterating our policies we are finalizing in this final rule related to the reporting and submission requirements of eCQM data for the Hospital IQR Program: (1) For the CY 2017 reporting period/FY 2019 payment determination and for the CY 2018 reporting period/FY 2020 payment determination, we will offer flexibility, such that hospitals may use: (a) EHR technology certified to the 2014 Edition; (b) EHR technology certified to the 2015 Edition; or (c) a combination of EHR technologies certified to the 2014 Edition and 2015 Edition; (2) for the CY 2017 reporting period/FY 2019 payment determination and the CY 2018 reporting/FY 2020 payment determination, EHR technology certified to the 2014 or 2015 Edition must be certified to all 15 eCQMs available to report in the Hospital IQR Program; (3) for the CY 2017 reporting period/FY 2019 payment determination, hospitals will be required to use the most recent version of the eCQM electronic specifications (in other words, the Spring 2016 version of the eCQM specifications and any applicable addenda); (4) for the CY 2018 reporting period/FY 2020 payment determination, hospitals will be required to use the most recent version of the eCQM electronic specifications (in other words, the Spring 2017 version of the eCQM specifications and any applicable addenda); and (5) an EHR certified for eCQMs under the 2014 or 2015 Edition certification criteria would not need to be recertified each time it is updated to a more recent version of the eCQM electronic specifications.

e. Submission Form and Method for the Voluntary Hybrid Hospital Wide Readmission Measure With Claims and Electronic Health Record Data (NQF #2879)

(1) Background

In section IX.A.7. of the preamble of the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20045 through 20049), we proposed voluntary reporting of the Hybrid Hospital-Wide Measure with Claims and Electronic Health Record Data. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49701 through 49704), we signaled our intent to use core clinical data elements in the Hospital IQR Program and requested comment on the use of the QRDA Category I (QRDA I) file format for this purpose. In that rule, we noted many commenters supported submitting the core clinical data elements using an EHR technology certified by the ONC. In addition, some commenters were supportive of our suggested use of QRDA I specifically for reporting core clinical data elements and recommended aligning the standards for data transmission requirements with those used in other reporting programs.

(2) Certification and File Format Requirements for Core Clinical Data Element Submissions

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20067), we proposed that hospitals that voluntary report data for the Hybrid Hospital-Wide Readmission measure use EHR technology certified to the 2015 Edition. We also referred readers to our discussion of EHR certification requirements for eCQM reporting above and in section IX.G.4. of the preamble of this final rule where the same proposed requirements are discussed in detail for the Medicare EHR Incentive Program for eligible hospitals and CAHs. In addition, we proposed that the 13 core clinical data elements and six linking variables for the Hybrid Hospital-Wide Readmission measure be submitted using the QRDA I file format.

In order to ensure the data have been appropriately connected to the encounter, the core clinical data elements specified for risk adjustment need to be captured in relation to the start of an inpatient encounter. The QRDA I standard enables the creation of an individual patient-level quality report that contains quality data for one patient for one or more quality measures. We note that as described in section IX.A.7. of the preamble of this final rule, participating hospitals are expected to successfully submit data values for vital signs and six linking variables and are required to merge with the CMS claims data on more than 95 percent of all Medicare FFS patients who are 65 years and older and are discharged from the hospital during the voluntary data collection period. In addition, participating hospitals are expected to successfully submit values for laboratory test results on more than 50 percent of these patients discharged over the same time period. For further detail on QRDA I, the most recently available QRDA I specifications can be found at: *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35*.

We invited public comment on our proposals related to the reporting and submission requirements of core clinical data elements and linking variables for the proposed, voluntary Hybrid Hospital-Wide Readmission measure as discussed above.

Comment: Several commenters supported the proposed voluntary reporting of the Hybrid Hospital-Wide Readmission (HWR) measure, noting that the inclusion of core clinical data elements and laboratory test results may provide additional clinical variables that would enhance the administrative coding data that is utilized currently in the risk model variables. Other commenters supported the measure, because it is low burden and would further efforts to harmonize core clinical data elements with other measures and reporting requirements, without impacting payment. One commenter noted it displayed good use of EHR data, and testing this approach will develop useful information that could apply to other Medicare claims-based measures. In addition, commenters noted testing a measure through voluntary collection could highlight any data collection issues, while providing hospitals time needed to redesign their EHRs to collect and validate these data prior to mandatory reporting. The commenters noted reporting hybrid measure data will add hospital burden as compared to a measure using only claims, but expressed support for use of a QRDA I file when submitting electronic clinical data for this measure. Specifically, the commenters noted that use of a QRDA I file would streamline the submission process and enable hospitals to continue to direct resources toward electronic abstraction. One commenter believed that requiring QRDA I files increased the burden on hospitals.

Response: We thank the commenters for their support. We refer readers to section IX.A.7. of the preamble of this final rule for more information about the voluntary Hybrid HWR measure that we are finalizing. We note that there is burden associated with the collection of the electronic data for the Hybrid HWR measure. We do not expect any additional burden on hospitals to report the claims-based portion of this measure, because these data are already reported to the Medicare program for payment purposes. We refer readers to section XIII.B.6.e. of the preamble of this final rule for more detail on these burden calculations.

Comment: Several commenters supported the proposed voluntary reporting of the Hybrid HWR measure, but expressed concern that hospitals need time to redesign their EHRs to collect and validate these data, and believed CMS should maintain flexibility in the reporting requirements for several years. One commenter suggested CMS change the proposed initial reporting period from January 1 through June 30, 2018, to July 1 through December 31, 2018, or to require only a single quarter of reporting for the initial reporting year.

Response: We thank the commenters for their support. We reiterate that reporting on the Hybrid HWR measure is voluntary; we will take into consideration the commenter's suggestion that reporting requirements should remain flexible for several years as we consider adopting the Hybrid HWR measure as mandatory for the Hospital IQR Program in future rulemaking. We do not anticipate that hospitals will need to redesign their EHR systems to accommodate reporting of the Hybrid HWR measure, because these data elements are currently recorded in EHRs for nearly all Medicare FFS beneficiaries admitted to acute care hospitals, as the Hybrid HWR measure cohort includes most hospital admissions. However, hospitals will need to map the data elements in their stored EHR data, validate that they have identified the first value captured at the start of the episode of care, and populate QRDA I templates for data reporting.

We acknowledge not all hospitals will be able to submit data for the voluntary Hybrid HWR measure as soon as July 1, 2018. We note that we proposed the first two calendar quarters of 2018 as the reporting period so as not to overlap with the submission of eCQM data, which is usually very active during the winter up through the eCQM submission deadline of February 28th. We hope this July submission deadline will increase participation in voluntary reporting of the hybrid measure. In addition, during Hybrid HWR measure development and testing, we demonstrated the core clinical data elements were feasibly extracted from hospital EHRs for nearly all adult patients admitted. The electronic specifications were tested in four separate health systems that used three separate EHR systems, and were successfully merged with our administrative claims data.

We are encouraging hospitals to participate in the voluntary reporting of the Hybrid HWR measure to gain experience validating the extracted EHR data. Participating hospitals would receive information and instruction on the use of the electronic specifications for this measure, have an opportunity to test extraction and submission of data to the QualityNet Secure Portal, and receive confidential feedback reports, downloadable from the QualityNet Secure Portal, with details on the success of their submission, such as the completeness and accuracy of the data. We will carefully consider these suggestions and all lessons learned from hospitals participating in the voluntary reporting of the Hybrid HWR measure before proposing any timeline for future potential implementation of the measure.

Comment: Some commenters suggested instead of jumping from 50 percent for the voluntary Hybrid HWR measure to 90 percent for the mandatory Hybrid HWR measure, the amount of data submitted should increase more gradually over time.

Response: Based on our previous testing of this measure, we believe successful submission of the EHR data used in the Hybrid HWR measure on at least 90 percent of adult inpatient admissions would be necessary in order to calculate the risk-standardized readmission rates and publicly report measure results in the future. During the voluntary phase of data submission, there will be no strict requirement. However, we will request that hospitals submit the data elements on at least 50 percent and as many as 100 percent of their admitted patients. Our intent in setting this 50 percent threshold is to mimic full reporting as closely as possible while also encouraging participation. We will carefully consider the success of data submission during the voluntary reporting period before proposing a timeline and data reporting expectations for mandatory measure implementation through future rulemaking.

Comment: One commenter recommended that if added to the Hospital IQR Program measure set as a mandatory measure, the measure should be considered an eCQM for reporting purposes, allowing hospitals to choose if they report this measure or other eCQMs.

Response: We thank the commenter for their suggestion and will take it into consideration should we propose the Hybrid HWR measure as mandatory for the Hospital IQR Program and/or the EHR Incentive Programs for electronic reporting of CQMs in the future. We strive to align the electronic quality measure reporting requirements with the EHR Incentive Programs in order to reduce administrative burden and confusion about different reporting requirements in CMS programs to the extent feasible.

Comment: Several commenters suggested CMS explore developing hybrid condition-specific readmission measures for the Hospital Readmissions Reduction Program.

Response: We thank commenters for their suggestion and will take this under consideration in crafting future policies for other CMS programs.

Comment: Several commenters noted they are dependent on their EHR vendor to produce the necessary code to capture and report in the QRDA I file format, and urged CMS to encourage the EHR vendor community to support this initiative. The commenters suggested CMS should solicit feedback from hospitals and vendors that choose to report the Hybrid HWR measure voluntarily before this measure is implemented as mandatory in the Hospital IQR Program. To make the reporting of this or any other hybrid measure viable in the long run, the commenters suggested that CMS would need the input from stakeholders on the feasibility of extracting the EHR data and the accuracy of measure results. The commenters also suggested CMS should release results of the voluntary collection efforts, including feedback on measure implementation and measure results from participating hospitals. The commenters noted hospitals would need to have sufficient experience prior to the measure being in mandatory reporting.

Response: We will engage with stakeholders, including hospitals and health IT vendors, through educational webinars and national provider calls and welcome any feedback from hospitals and vendors that participate in voluntary submission of data for the Hybrid HWR measure. One purpose for voluntary reporting of this measure is so that hospitals and health IT vendors can become familiar with data extraction and submission for hybrid quality measures prior to any mandatory reporting. We will consider feedback

received from voluntary reporting to inform the future process and the timing for any proposals related to mandatory reporting.

In addition, voluntary reporting of the Hybrid HWR measure by participating hospitals will allow us to calculate the measure results, provide participating hospitals with feedback about the extracted data (including the success of data submission and the measure results calculated using their EHR data), and to solicit input from participating hospitals about any feasibility issues with extracting the core clinical data elements. Because hospitals do not calculate the measure within the EHR and do not therefore report measure results to CMS, we will not provide information about the accuracy of measure results. Rather, we calculate the measure using a combination of data from claims and the EHR data that hospitals submit and share these results with participating hospitals. Hospitals that voluntarily submit data for this measure would receive confidential hospital-specific reports that detail submission results from the performance reporting period, as well as the Hybrid HWR measure results assessed from merged files created by us merging the EHR data elements submitted by each participating hospital with claims data from the same set of index admissions. EHR data or measure results for the voluntary reporting of the Hybrid HWR measure will not be publicly reported. However, if we propose to require mandatory reporting of the Hybrid HWR measure in future rulemaking, we intend for such a proposal to include a dry run, during which hospitals could preview their results. In addition, we will take into consideration comments suggesting that we inform stakeholders about lessons learned from hospitals that participate in the voluntary measure prior to proposing to adopt the Hybrid HWR measure as mandatory for the Hospital IQR Program.

Comment: Some commenters requested additional details related to the proposed voluntary reporting of the Hybrid HWR measure. Specifically, commenters sought clarification on whether QRDA I file format would be required or whether participants could submit data via QualityNet Secure File Exchange or another method.

Response: Hospitals electing to participate in voluntary reporting of the Hybrid HWR measure will be required to use QRDA I files for submission of electronic data, which is the current EHR data and measure reporting standard for adopted eCQMs implemented in the Hospital IQR Program. We refer readers to the measure specifications at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. We will not accept data via QualityNet Secure File Exchange or any other method. As discussed in our proposal above, in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49701 through 49704), we signaled our intent to use core clinical data elements in the Hospital IQR Program and requested comment on the use of the QRDA I file format for this purpose. In that rule, we noted many commenters supported submitting the core clinical data elements using an EHR technology certified by the ONC. In addition, some commenters were supportive of our suggested use of QRDA I specifically for reporting core clinical data elements and recommended aligning the standards for data transmission requirements with those used in other reporting programs.

Comment: Some commenters requested further guidance on whether the start ''0–24'' hours timing window for data capture for these data elements would be based on arrival time or admission time. Specifically, commenters asked if the 0–24 hours timeframe refers to the timeframe allotted to collect specimens for an ordered test or the timeframe to the result of the test.

Response: For hospitals that choose to voluntarily submit data, the Hybrid HWR measure requires submission of the first captured core clinical data element values for each Medicare FFS beneficiary who is 65 years or older and discharged from an acute care hospital during the measurement period.[279] This includes data values captured in any department, including outpatient or emergency department visits that end inpatient admissions.

To clarify the ''0–24'' hours timeframe for the core clinical data elements, they represent the result of the first collected data element (not the time of the order) after arrival at the hospital for care (not necessarily inpatient admission time). For example, if a patient receives care for several hours in the Emergency Department and is later admitted to the inpatient facility for additional treatment, the measure requires the first captured data value in the Emergency Department. Vital signs (heart rate, respiratory rate, temperature, systolic blood pressure, oxygen saturation), should be recorded within two hours (''0–2 hours''). Laboratory results (hematocrit, white blood cell count, sodium, potassium, bicarbonate, creatinine, and glucose) and weight should be recorded within 24 hours (''0–24 hours''). These time windows were based on empirical analysis of vital signs and laboratory test results captured in EHRs for patients admitted to acute care short stay hospitals. We assessed the time to capture of an initial set of vital signs and basic laboratory test results from the time of arrival at the facility for patients who were 65 years and older and subsequently admitted during the same encounter for treatment of a variety of medical conditions. We refer readers to the measure specifications[280] for more details.

Comment: Some commenters sought clarification on whether the expectation would be that an EHR would only send data on encounters that meet the measure population requirements, since an EHR might not be able to identify an index admission.

Response: We understand that all or nearly all hospitals maintain electronic administrative records which identify inpatient admissions to support billing for Medicare FFS beneficiaries and patients insured through other payers. We understand that for many hospitals these administrative systems are separate from the clinical EHR and that identifying inpatient admissions and then extracting the EHR data elements for those patients might require separate queries in the two systems. However, the testing we have performed in four volunteer hospitals that developed and deployed queries within their EHR and successfully extracted the data elements used in the voluntary Hybrid HWR measure demonstrated that hospitals were able to identify inpatient admissions using stored electronic data and were able to extract the EHR data elements for those patients.

As we stated in the proposed rule (82 FR 20047), hospitals would only submit data for index admissions that meet the Hybrid HWR measure cohort inclusion criteria, and the measure would only be calculated for this cohort. The inclusion and exclusion criteria of the Hybrid HWR measure are also aligned with the currently adopted Hospital-Wide All-Cause Unplanned Readmission measure, which can be found in the 2017 All-Cause Hospital-Wide Measure Updates and Specifications Report, available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-*

[279] Hybrid Hospital-Wide Readmission Measure with Electronic Health Record Extracted Risk Factors (Version 1.1). Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

[280] *Ibid.*

Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.

Further, we developed and tested a Measure Authoring Tool [281] that uses existing value sets where possible, which includes identifying inpatient encounters (index admissions). As stated in the proposed rule (82 FR 20046), the electronic specifications were tested in multiple health systems, and they all were able to appropriately identify acute care hospital inpatient encounters.

Comment: One commenter inquired about the proposed deadline and frequency for reporting.

Response: We refer readers to section IX.A.7.b. of the preamble of this final rule for details on reporting and deadlines. To summarize, the voluntary reporting of the Hybrid HWR measure has a one-time measurement period for discharges occurring over a 6-month period in the first two quarters of CY 2018 (January 1, 2018 through June 30, 2018), with data being reported to CMS in the fall of 2018. For this voluntary reporting effort, we ask hospitals to submit electronic data once on applicable Medicare FFS beneficiaries, on at least 50 percent of these patients.

Comment: Several commenters requested that CMS not set any date for either mandatory submission or public reporting of the Hybrid HWR measure. The commenters expressed concerns the hybrid measure is incredibly challenging to implement and CMS does not have a robust infrastructure to collect these data.

Several commenters requested that CMS provide at least an eighteen-month window, and as much as 24-months, to organizations before a hybrid measure is implemented. The commenters recommended that CMS not require mandatory reporting of the Hybrid HWR measure until it has reviewed the experience of hospitals submitting the measure on a voluntary basis.

Response: We appreciate the suggestions on the timing of future implementation. Although, we recognize there is some burden to hospitals in identifying the data elements required for the Hybrid HWR measure, it is important to note that these data elements are currently recorded in EHRs for nearly all Medicare FFS beneficiaries admitted to acute care hospitals, as the Hybrid HWR measure cohort includes most hospital admissions. We do not anticipate hospitals will need to alter clinical workflows to capture these data. However, hospitals will need to map the data elements in their stored EHR data, validate that they have identified the first value captured at the start of the episode of care, and populate QRDA I templates for data reporting.

We note reporting on the Hybrid HWR measure is purposefully voluntary and that we have not set any date for either mandatory submission or public reporting of the Hybrid HWR measure. We intend to review the experience of hospitals submitting the Hybrid HWR measure data on a voluntary basis prior to potentially proposing to adopt this measure as mandatory in the future.

With respect to commenters' concerns that CMS does not have a robust infrastructure to collect data for the Hybrid HWR measure, we disagree. Hybrid HWR measure data are derived from both claims and clinical EHR data, via submission of QRDA I files; we already collect and utilize claims data and QRDA I file data for other measures in the Hospital IQR Program measure set.

We refer readers to section IX.A.10.d.(2)(b) of the preamble of this final rule, where we are finalizing a policy to allow hospitals greater flexibility, such that hospitals may use EHR technology that is: (1) Certified to the 2014 Edition; (2) certified to the 2015 Edition; or (3) a combination of both the 2014 Edition and 2015 Edition. As a result, we are modifying our proposal for the Hybrid HWR measure from requiring use of EHR technology certified to the 2015 Edition to giving hospitals that elect to submit data voluntarily the option to use EHR technology that is: (1) Certified to the 2014 Edition; (2) certified to the 2015 Edition; or (3) a combination of both the 2014 Edition and 2015 Edition.

We recognize that these activities require effort and collaboration with health IT vendors and we will continue to solicit feedback from stakeholders throughout voluntary reporting of this measure and carefully consider provider burden before proposing any timeline for mandatory adoption or public reporting of hybrid measures.

Comment: One commenter requested CMS delay implementation until further improvements have been made related to submitting data using the QRDA I file format.

Response: We disagree that we should delay implementation until further improvements have been made related to submitting data using the QRDA I file format. We have experienced widespread utility of the QRDA I format among hospitals, dating back to electronic reporting pilots from 2012 and 2013, which included electronic reporting via QRDA I, as the basis for aligned reporting in 2014 for the Medicare EHR Incentive and the Hospital IQR Programs (79 FR 50905). In addition, QRDA I is the current EHR data and measure reporting standard for adopted eCQMs implemented in the Hospital IQR and Medicare EHR Incentive Programs.

Comment: One commenter did not support the voluntary Hybrid HWR measure as they were concerned with the standardization of values.

Response: We interpret this comment to mean that the commenter had concerns about how the core clinical data elements were selected for potential use in the voluntary Hybrid HWR measure. To be feasible for use in the measure, we applied a strict set of criteria that the data elements must be: (1) Consistently obtained in the target population based on current clinical practice; (2) captured with a standard definition and recorded in a standard format; and (3) entered in structured fields that are feasibly retrieved from current EHR systems. These criteria align with those proposed by the NQF for assessing the feasibility of EHR data elements in quality measurement.[282] We established that the data elements used in the voluntary Hybrid HWR measure meet these criteria through empirical analysis of data provided by hospitals on patients who were 65 years and older admitted for treatment of a variety of conditions. This testing confirmed that the data elements are consistently obtained, captured as structured data, and recorded in standard format across different EHRs and different hospitals.

After consideration of the public comments we received, we are finalizing our proposals related to the voluntary reporting and submission of core clinical data elements and linking variables for the Hybrid Hospital-Wide Readmission measure as proposed, with one modification. Instead of requiring use of EHR technology certified to the 2015 Edition, we are allowing greater flexibility and will accept use of EHR technology that is: (1) Certified to the 2014 Edition; (2) certified to the 2015 Edition; or (3) a combination of both the 2014 Edition and 2015 Edition.

f. Sampling and Case Thresholds for the FY 2020 Payment Determination and Subsequent Years

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50221), the FY 2012 IPPS/LTCH PPS final rule (76

[281] CMS Measure Authoring Tool. Available at: *https://www.emeasuretool.cms.gov/*.

[282] NQF Measure Evaluation Criteria. Available at: *http://www.qualityforum.org/Measuring_Performance/Endorsed_Performance_Measures_Maintenance.aspx*.

FR 51641), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819), and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49709) for details on our sampling and case thresholds for the FY 2016 payment determination and subsequent years. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20067), we did not propose any changes to our sampling and case threshold policies.

g. HCAHPS Administration and Submission Requirements for the FY 2020 Payment Determination and Subsequent Years

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50220), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641 through 51643), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537 through 53538), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819 through 50820) for details on previously-adopted HCAHPS requirements. We also refer hospitals and HCAHPS Survey vendors to the official HCAHPS Web site at: *http://www.hcahpsonline.org* for new information and program updates regarding the HCAHPS Survey, its administration, oversight, and data adjustments. We refer readers to section IX.A.6.a. of the preamble of this final rule for details on our proposal to refine the three questions of the Pain Management measure in the HCAHPS Survey. While we proposed to refine the survey with respect to the questions about pain management in section IX.A.6.a. of the preamble of the proposed rule, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20067), we did not propose any changes to the HCAHPS administration nor the HCAHPS submission requirements.

h. Data Submission Requirements for Structural Measures for the FY 2020 Payment Determination and Subsequent Years

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51643 through 51644) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53538 through 53539) for details on the data submission requirements for structural measures. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20067), we did not propose any changes to data submission requirements for structural measures.

i. Data Submission and Reporting Requirements for HAI Measures Reported via NHSN

For details on the data submission and reporting requirements for HAI measures reported via the CDC's NHSN Web site, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51629 through 51633; 51644 through 51645), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50821 through 50822), and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50259 through 50262). The data submission deadlines are posted on the QualityNet Web site at: *http://www.QualityNet.org/*. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20067), we did not propose any changes to data submission and reporting requirements for HAI measures reported via the NHSN.

11. Modifications to the Validation of Hospital IQR Program Data

a. Background

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539 through 53553), we finalized the processes and procedures for validation of chart-abstracted measures in the Hospital IQR Program for the FY 2015 payment determination and subsequent years; the FY 2013 IPPS/LTCH PPS final rule also contains a comprehensive summary of all procedures finalized in previous years that are still in effect. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50822 through 50835), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50262 through 50273), and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49710 through 49712) for detailed information on the modifications to these processes finalized for the FY 2016, FY 2017, and FY 2018 payment determinations and subsequent years.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57173 through 57181), we finalized our proposal to update the validation procedures in order to incorporate a process for validating eCQM data for the FY 2020 payment determination and subsequent years. Specifically, we finalized a policy to: (1) Validate eCQM data submitted by up to 200 hospitals selected via random sample; (2) exclude any hospital selected for chart-abstracted measure validation as well as any hospital that has been granted a Hospital IQR Program Extraordinary Circumstances Exemption for the applicable eCQM reporting period; and (3) randomly select 32 cases from the QRDA I files submitted by each hospital selected for eCQM data validation for the FY 2020 payment determination and subsequent years. As described in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57176), we will not conduct the first validation of eCQM data until spring of 2018 to validate data from the CY 2017 reporting period. Validation of CY 2017 data during spring of 2018 affects the FY 2020 payment determination (81 FR 57177). Accordingly, below we refer to the CY 2017 reporting period/FY 2020 payment determination for validation of data for encounters occurring during CY 2017 and the CY 2018 reporting period/FY 2021 payment determination for validation of data for encounters during CY 2018.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20067 through 20070), we proposed to change these previously finalized policies for eCQM data validation for the FY 2020 payment determination and subsequent years. First, for hospitals selected to participate in validation of eCQMs, we proposed that we will select eight cases per quarter for the CY 2017 reporting period/FY 2020 payment determination and subsequent years. We noted this proposal was contingent upon whether or not our proposed modifications to eCQM reporting requirements for the CY 2017 reporting period/FY 2019 payment determination and CY 2018 reporting period/FY 2020 payment determination, as described in section IX.A.8. of the preamble of this final rule, were finalized as proposed. Second, we proposed to add additional exclusion criteria to our hospital and case selection process for eCQM data validation for the CY 2017 reporting period/FY 2020 payment determination and subsequent years. Third, we proposed to continue our previously finalized medical record submission requirements for the FY 2021 payment determination and subsequent years as well as to provide clarification of our previously finalized policy.

For validation of chart-abstracted measures data, we proposed to update our educational review process for the FY 2020 payment determination and subsequent years. These proposals are discussed in more detail below.

b. Changes to the Existing Processes for Validation of Hospital IQR Program eCQM Data for the FY 2020 Payment Determination and Subsequent Years

(1) Number of Cases

We finalized in the FY 2017 IPPS/LTCH PPS final rule that we would select eight cases per quarter, for four quarters, for a total of 32 cases (individual patient-level reports), from the QRDA I files submitted by each hospital selected for eCQM data validation (81 FR 57178). In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20068), we proposed to update that requirement, such that we would select eight cases per quarter, (the number of quarters required would vary by specific

FY payment determination) to complete eCQM data validation for the FY 2020 payment determination and subsequent years, instead of 32 cases, over all four quarters, as previously finalized. This proposal was made in conjunction with our proposals to modify the number of quarters required for eCQM data submission from: (1) Four quarters to two, self-selected quarters for CY 2017 (with validation of these data affecting the FY 2020 payment determination); and (2) four quarters to the first three quarters for CY 2018 (with validation of these data affecting the FY 2021 payment determination). If all of these proposals were finalized as proposed, hospitals selected for eCQM data validation would be required to submit: (1) 16 cases over two calendar quarters (eight cases × two quarters) for the CY 2017 reporting period/FY 2020 payment determination; and (2) 24 cases over three quarters (eight cases × three quarters) for the CY 2018 reporting period/FY 2021 payment determination. We invited public comment on the proposals we made in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20068) as discussed above.

Comment: Several commenters supported the reduction to the number of eCQM cases to be validated from 32 to 16 cases for the CY 2017 reporting period, which would impact the FY 2020 payment determination, and to 24 cases for the CY 2018 reporting period, which would impact the FY 2021 payment determination.

Response: We thank the commenters for their support.

Comment: One commenter urged CMS to consider reducing the number of cases selected for validation each quarter from 8 to a lower number in order to minimize reporting burden for hospitals.

Response: We consider a sample of eight cases for each quarter to be the minimum sample size needed to accurately ascertain the quality of the reported data by measure. We believe using a sample size of eight cases per quarter balances the burden on hospitals of providing medical records for eCQM data validation with our need for a sufficient minimum number of cases to be able to properly evaluate the data. However, we refer readers to section IX.A.8. of the preamble of this final rule, where we are finalizing a modified policy to further reduce the eCQM reporting requirements, such that hospitals are only required to submit one, self-selected calendar quarter of data for 4 eCQMs for both the CY 2017 reporting period/FY 2019 payment determination and the CY 2018 reporting period/FY 2020 payment determination. This does not directly change our proposal to select eight cases per quarter for eCQM data validation for the FY 2020 payment determination and subsequent years (for validation of eCQM data reported in CY 2017 data and subsequent years). However, in effect, due to these finalized modifications to the eCQM reporting requirements, hospitals selected for validation will be required to submit only 8 cases in total for each of the CY 2017 reporting period/FY 2020 payment determination (8 cases × 1 quarter) and CY 2018 reporting period/FY 2021 payment determination (8 cases × 1 quarter), instead of: (1) 16 cases over two calendar quarters (8 cases × 2 quarters) for the CY 2017 reporting period/FY 2020 payment determination; and (2) 24 cases over 3 quarters (8 cases × 3 quarters) for the CY 2018 reporting period/FY 2021 payment determination as discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20068).

After consideration of the public comments we received, we are finalizing our proposal, as proposed, to reduce the number of cases selected for eCQM data validation to eight cases per quarter for the FY 2020 payment determination and subsequent years.

(2) Selection of Hospitals and Cases

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20068 through 20069), for the CY 2017 reporting period/FY 2020 payment determination and subsequent years, we proposed changes to our policies related to the selection of hospitals and cases for eCQM data validation to: (1) Expand the types of hospitals that could be excluded; and (2) expand the types of cases excluded from selection. These proposals are discussed in more detail below.

(a) Selection of Hospitals

As previously finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57174 through 57178), we will validate eCQM data submitted by up to 200 hospitals selected via random sample. Further, we finalized that the following hospitals may be excluded from this random sample of 200 hospitals selected for eCQM data validation (81 FR 57178):

- Any hospital selected for chart-abstracted measure validation; and
- Any hospital that has been granted a Hospital IQR Program Extraordinary Circumstances Exemption for the applicable eCQM reporting period.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20068), we proposed to expand the types of hospitals that could be excluded. For the FY 2020 payment determination and subsequent years, we proposed to also exclude any hospital that does not have at least five discharges for at least one reported eCQM included among their QRDA I file submissions. In addition, we proposed that the three exclusions described above would be applied before the random selection of 200 hospitals for eCQM data validation, so that hospitals meeting any of these exclusions would not be eligible for selection. We believe that these proposals improve the likelihood that there would be sufficient data for validation obtained from the hospitals selected for eCQM data validation.

We invited public comment on our proposals to: (1) Exclude any hospital that does not have at least five discharges for at least one reported eCQM included among their QRDA I file submissions in eCQM data validation; and (2) to exclude from selection hospitals meeting either of the two exclusion criteria finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57178) as discussed above. We note that the proposed rule (at 82 FR 20068) included a technical error stating ''and/or (2) to exclude from selection hospitals meeting either of the two exclusion criteria finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57178).'' We have corrected the language in this final rule to state ''and,'' instead of ''and/or.''

Comment: A few commenters supported the exclusion of hospitals from eCQM data validation selection that have already been selected for chart-abstracted measure validation or that have been granted a Hospital IQR Program Extraordinary Circumstances Exemption because it provides relief of undue burden on facilities and increases the chance that selected hospitals will have an adequate sample size for validation.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing our proposals, as proposed, for the FY 2020 payment determination and subsequent years: (1) To exclude any hospital that does not have at least five discharges for at least one reported eCQM included among their QRDA I file submissions; and (2) to exclude from selection hospitals meeting either of the two exclusion criteria finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57178). This means that the three exclusion criteria described would be applied before random selection of 200 hospitals for eCQM data validation, such that hospitals meeting one or more of these exclusion criteria would not be eligible for selection.

(b) Selection of Cases

We have not previously specified processes for the selection of cases for eCQM data validation. For the FY 2020 payment determination and subsequent years, we proposed to exclude the following cases from validation for those hospitals selected to participate in eCQM data validation:

- Episodes of care that are longer than 120 days; and
- Cases with a zero denominator for each measure.

We believe excluding episodes of care that are longer than 120 days will reduce the reporting burden on hospitals selected for eCQM data validation, as the volume of data reported for longer cases is greater. Further, we believe excluding cases with zero denominators for each measure would ensure we perform validation only on cases with applicable measure data. We note this proposed exclusion applies to cases, rather than measures. However, a measure would not be validated if a hospital did not have any applicable cases for the measure.

We invited public comments on our proposal to exclude: (1) Episodes of care that are longer than 120 days; and (2) cases with a zero denominator for each measure from eCQM data validation for the FY 2020 payment determination and subsequent years as discussed above.

Comment: A few commenters supported the proposed policy of adding additional exclusion criteria to the hospital and case selection process for eCQM data validation to include: (1) Episodes of care that are longer than 120 days; and (2) cases with a zero denominator for each measure, because these exclusions would decrease hospital reporting burden.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal, as proposed, for the FY 2020 payment determination and subsequent years, to add exclusion criteria to the hospital and case selection process for eCQM data validation to include: (1) Episodes of care that are longer than 120 days; and (2) cases with a zero denominator for each measure.

(3) Medical Record Submission Requirements and Scoring

(a) Medical Record Submission Requirements

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57179), we finalized that hospitals participating in eCQM data validation for the FY 2020 payment determination and subsequent years are required to: (1) Submit data by 30 calendar days following the medical records request date listed on the CDAC request form; (2) provide sufficient patient level information necessary to match the requested medical record to the original Hospital IQR Program submitted eCQM measure data record; and (3) submit records in PDF file format through QualityNet using the Secure File Transfer (SFT). We also finalized for hospitals selected for eCQM data validation (for the FY 2020 payment determination only): (1) We require submission of at least 75 percent of sampled eCQM measure medical records in a timely and complete manner; and (2) the accuracy of eCQM data submitted for validation would not affect a hospital's validation score (81 FR 57180). In the FY 2018 IPPS/LTCH PPS proposed rule, we did not propose to make any changes related to these operational procedures. However, we proposed to continue these policies for the FY 2021 payment determination and subsequent years. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20068 through 20069), we proposed to extend to the FY 2021 payment determination and subsequent years our previously finalized medical record submission policy for eCQM data validation, as finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57181), requiring submission of at least 75 percent of sampled eCQM measure medical records in a timely and complete manner. We also proposed to extend to the FY 2021 payment determination our previously finalized medical record submission policy for eCQM data validation, as finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57181), that the accuracy of eCQM data submitted for validation would not affect a hospital's validation score. (We note that this policy is discussed in more detail in the next section and refer readers below.) We noted that if our proposals in section IX.A.8 of the preamble of the FY 2018 IPPS/LTCH PPS proposed rule, which proposed two quarters of data for CY 2017 eCQM data submission and eight cases per quarter for hospitals selected for validation (16 total cases for the entire data collection period), were finalized as proposed, and hospitals selected for eCQM data validation are required to submit complete information for 75 percent of requested cases as previously finalized, then those hospitals would be required to submit information for at least 12 records, or 75 percent of the requested 16 records for the FY 2020 payment determination. Similarly, if our proposals: (1) To continue our medical record submission policies for the FY 2021 payment determination and subsequent years; (2) to require three quarters of data for CY 2018 eCQM data submission and eight cases per quarter for hospitals selected for validation (24 total cases for the entire data collection period) as detailed in section IX.A.8 of the preamble of the FY 2018 IPPS/LTCH PPS proposed rule; and (3) hospitals selected for eCQM data validation are required to submit complete information for 75 percent of requested cases, were all finalized as proposed, then those hospitals would be required to submit complete information for at least 18 records, or 75 percent of the requested 24 records for the FY 2021 payment determination.

Furthermore, as finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57180) for the FY 2020 payment determination, in the proposed rule (82 FR 20069), we proposed, for the FY 2021 payment determination and subsequent years, that any hospital that fails any validation requirement, such as submission of records in PDF file format within 30 days of the date listed on the CDAC medical records request, and/or submission of complete information for at least 75 percent of the requested records, would be considered not to have met the eCQM validation requirements and would be subject to a one-quarter reduction of the applicable percentage increase for not meeting all Hospital IQR Program requirements.

We invited public comment on the proposals we made in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20068 through 20069) as discussed above.

Comment: One commenter recommended CMS reconsider the process of submitting PDF copies of the medical records for validation, suggesting that a more accurate method would be for CMS to send an auditor onsite to validate the data directly from the EHR.

Response: We thank the commenters for the input. At this time, we believe the most feasible and less burdensome approach to hospitals is to continue the current process for medical record submission for validation via PDF file submission. In particular, we recognize the significant time and resources that hospitals would be required to address CMS onsite validator needs and access to onsite information. We strongly believe that hospital resources would be better devoted to caring for and communicating with patients and their caregivers. We also note that hospitals are familiar with this method of

reporting medical records for chart-abstracted measure validation.

Comment: One commenter requested clarification on which format (complete medical record, including free text or printout of the QRDA I file) CMS will use to validate eCQM data.

Response: Per the FY 2017 IPPS/LTCH PPS final rule (81 FR 57179), the format will be a portable document format (PDF) of the entire medical record.

After consideration of the public comments we received, we are finalizing our proposals, as proposed, for the FY 2021 payment determination and subsequent years, that: (1) Hospitals selected for eCQM data validation are required to submit at least 75 percent of sampled eCQM measure medical records in a timely and complete manner; and (2) any hospital that fails any validation requirement would be considered not to have met the eCQM validation requirements and would be subject to a one-quarter reduction of the applicable percentage increase for not meeting all Hospital IQR Program requirements. As discussed in section IX.A.8 of the preamble of this final rule, we are finalizing a modification to the eCQM reporting requirements such that hospitals are required to submit one, self-selected calendar quarter of data for 4 eCQMs for both the CY 2017 reporting period/FY 2019 payment determination and the CY 2018 reporting period/FY 2020 payment determination. Furthermore, we refer readers to section IX.A.11.b.(1) of the preamble of this final rule where we are finalizing our proposals to require hospitals selected for eCQM data validation to submit eight cases for the selected calendar quarter. As applied to our finalized policies here for the FY 2021 payment determination, selected hospitals would be required to submit complete information for at least 6 records, or 75 percent of the requested 8 records.

(b) Scoring

As finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57178) for the FY 2020 payment determination only, the accuracy of eCQM data (the extent to which eCQM data reported for validation matches the data previously reported in the QRDA I files for eCQM reporting) submitted for validation will not affect a hospital's validation score. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20069), we proposed the continuation of this policy for the FY 2021 payment determination, such that the accuracy of eCQM data submitted for validation would not affect a hospital's validation score. We intend for the accuracy of eCQM data validation to affect validation scores in the future and would propose any changes related to this in future rulemaking. The data submission deadlines and additional details about the eCQM data validation procedures will be posted on the QualityNet Web site at: *http://www.QualityNet.org/*. We invited public comment on this proposal as discussed above.

We did not receive any public comments on our proposal. We are finalizing our proposal, as proposed, that the accuracy of eCQM data submitted for validation will not affect a hospital's validation score for the FY 2021 payment determination. We also received general comments about the eCQM data validation process in the Hospital IQR Program; these are discussed below.

Comment: A few commenters did not support the proposed modifications to the eCQM data validation process in the Hospital IQR Program. The commenters noted that validation of eCQMs should not be done until additional measures are accepted and built by vendors to allow hospitals the opportunity to submit data which aligns with their population and workflow rather than those currently available from the vendor. In addition, commenters stated that small hospitals without pediatrics, perinatal care, or stroke centers are very limited in their ability to submit eCQMs.

Response: We understand eCQM data validation imposes some burden on hospitals, but as we seek to evaluate the established validation procedures and expand electronic data reporting and validation, we believe validating data starting with the CY 2017 reporting period is necessary. Furthermore, because the accuracy of eCQM data submitted for validation will not affect a hospital's validation score for the FY 2021 payment determination, as finalized above, we believe this will balance any hospital burden or need for additional time to update their systems with our need to evaluate the quality of reported eCQM data. We disagree that validation of eCQM data should be delayed until additional measures are built by health IT vendors to allow hospitals the opportunity to submit data which aligns with their population and workflow because eCQM data submission is already a requirement in the Hospital IQR Program. Moreover, we believe validation is a critical component in the overall process of electronic reporting, as it informs hospitals about potential workflow refinements to ensure efficient extrapolation and enables us to ensure the accuracy of eCQM data prior to future public reporting of the data. We encourage small hospitals that may be experiencing difficulty meeting the Hospital IQR Program's eCQM reporting requirements to review the Hospital IQR Program's ECE policy. We refer readers to section IX.A.15 of the preamble of this final rule for more information.

Finally, we note that hospitals are able to select which eCQMs best align with their population and workflow. We also refer readers to section IX.A.10.d.(2)(b)(ii) of the preamble of this final rule, in which we are finalizing a policy that requires EHRs to be certified to all available eCQMs, which will offer hospitals greater flexibility to report eCQM data most appropriate for their population and workflow, rather than being limited to those eCQMs selected and supported by their vendors.

Comment: Some commenters requested that CMS consider delaying mandatory validation of eCQM data for selected hospitals until the spring of 2020, using CY 2019 performance year for the FY 2021 payment determination, noting that this delay would allow hospitals sufficient time to install the 2015 Edition certification criteria for CEHRT, make necessary refinements and workflow process improvements, and complete internal validation to ensure the data output from the certified EHR technology's eCQM calculation is accurate.

Response: We do not believe that delaying validation of eCQM data is necessary at this time, because we are finalizing several policies in this final rule to help reduce the burden associated with eCQM reporting requirements. We refer readers to section IX.A.10.d.(2)(b)(i) of the preamble of this final rule, in which we are finalizing greater flexibility to our previously finalized certification policy for the CY 2018 reporting period/FY 2020 payment determination, and section IX.A.8. of the preamble of this final rule, where we are finalizing modified, reduced eCQM reporting requirements. We believe validation is a critical component in the overall process of electronic reporting, as it informs hospitals about potential workflow refinements to ensure efficient extrapolation and enables us to ensure the accuracy of eCQM data prior to future public reporting of the data.

Comment: One commenter suggested that CMS develop a detailed plan for how validation will be performed, including which fields of structured data will be used for validation and how that will compare with medical record review. The commenter stated that the hospital and vendor communities

should have an opportunity to comment on this detailed plan, and then CMS should undertake a second expanded pilot to test and further refine the plan in collaboration with stakeholders prior to implementation.

Response: We thank the commenters for their suggestion. More details on eCQM data validation will be provided at a later date, similar to the specifications that are posted on the QualityNet Web site for the validation of chart-abstracted measures. In addition, we encourage stakeholders to continue sharing feedback with us, to provide more information on their experience with the eCQM data validation process. This feedback will help us refine the process moving forward.

c. Modifications to the Educational Review Process for Chart-Abstracted Measures Validation

(1) Background

In the FY 2015 IPPS/LTCH PPS final rule, we stated that we rely on hospitals to request an educational review or appeal cases to identify any potential CDAC or CMS errors (79 FR 50260). We also noted that a hospital may request from CMS at any time an educational review to better understand whether or not we reached a correct conclusion during validation; hospitals that fail to meet Hospital IQR Program validation requirements have 30 days to appeal after this determination (79 FR 50260). We have described our processes for educational review on the QualityNet Web site.[283] We note that historically this process functioned as an outreach opportunity we provided hospitals, but based on our experience, and more robust validation requirements, we believe that it would beneficial to hospitals to propose formalizing this process.

Under the current process, if the results of an educational review indicate that CDAC or CMS has incorrectly scored a hospital, those scores are not changed unless and until the hospital submits a reconsideration request. Therefore, In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20069 through 20070), we proposed: (1) To formalize this process; and (2) to update the process to specify that if the results of an educational review indicate that we incorrectly scored a hospital, the corrected score would be used to compute the hospital's final validation score whether or not the hospital submits a reconsideration request. These proposals are discussed in more detail below. Stakeholder feedback, provided via email, has indicated that while the educational review process is helpful to participating hospitals, it is limited in its impact, given that a hospital's score is not corrected even after an educational review determines that CMS reached an incorrect conclusion regarding a hospital's validation score for a given quarter. Based on this feedback, we proposed to change the Hospital IQR Program's chart-abstracted measure validation educational review process. Our goal is to reduce the number of reconsideration requests by identifying and correcting errors before the final yearly validation score is derived. By identifying and correcting any mistakes early on, this process could help decrease the burden during the annual reconsideration process, both for hospitals and CMS.

(2) Educational Review Process Modifications for the FY 2020 Payment Determination and Subsequent Years

(a) Request for Educational Review

Under this proposal, the educational review request process, as well as our procedures for responding to requests, remain the same. Specifically, under the current process, hospitals may request an educational review if they believe they have been scored incorrectly or if they have questions about their score. We would provide the results of the educational review, outlining the findings of whether the scores were correct or incorrect, to the requesting hospital through secure file transfer.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20069), we proposed to formalize this process. In formalizing our current procedures, the educational review request process, as well as our procedures for responding to requests, would remain the same. First, we proposed that, for the FY 2020 payment determination and subsequent years, a hospital may request from CMS an educational review to better understand whether or not CDAC or CMS reached a correct conclusion during validation for the first three quarters of validation. Specifically, upon receipt of an unsatisfactory score, a hospital would have 30 calendar days to contact the Validation Support Contractor (VSC) to solicit a written explanation of the provided score. We note that currently hospitals receive validation results on a quarterly basis, and that would not change under this proposed process. Accordingly, under this proposal, an educational review could be requested on a quarterly basis for the first three quarters of validation. Results of the educational review would be provided to hospitals via secure file transfer.

Second, we proposed that the process used to evaluate whether or not validation results are correct would be the same in both an educational review and a reconsideration request. Specifically, as finalized in the FY 2012 IPPS/LTCH PPS final rule for the Hospital IQR Program's reconsideration request process, we proposed that upon receipt of an educational review request, we would review the data elements that were labeled as mismatched, as well as the written justifications provided by the hospitals, and make a decision on the educational review request.

(b) Scoring Update

For the FY 2020 payment determination and subsequent years, we proposed that if an educational review, that is requested for any of the first 3 quarters of validation, yields incorrect CMS validation results for chart-abstracted measures, we would use the corrected quarterly score, as recalculated during the educational review process, to compute the final confidence interval (CI). These corrected scores would be applicable to the corresponding quarter, within the first 3 quarters of validation, for which a request was submitted. We note that under this proposal, the quarterly validation reports issued to hospitals would not be changed to reflect the updated score due to the burden associated with reissuing corrected reports. Beginning with the FY 2020 payment determination, we proposed to use the revised score identified through an educational review when determining whether or not a hospital failed validation. Further, under this proposal, as with the current educational review process, corrected scores identified through the educational review would only be used if they indicate that the hospital performed more favorably than previously determined.

Under this proposal, the educational review request process, as well as our procedures for responding to requests, remain the same. We also note that, in accordance with our previously established policies, a hospital may still request reconsideration even if an educational review determined that a hospital was scored correctly. Hospitals that fail Hospital IQR Program requirements, which include validation, can request reconsideration at the end of the year after the annual payment update has been made. We refer readers to section IX.A.14. of the preamble of this final rule for a discussion about our

[283] QualityNet: Validation—Educational Review. *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228775419006.*

reconsideration and appeals process. We note that under this proposal, corrected scores identified through the educational review would only be used if they indicate that the hospital performed more favorably than previously determined. In addition, we note that for the last quarter of validation, because of the need to calculate the confidence interval in a timely manner and the insufficient time available to conduct educational reviews, the existing reconsideration process would be used to dispute an unsatisfactory validation result. If a hospital does not fail validation they still would have the opportunity to request an educational review within 30 days of receiving the results.

We invited public comment on our proposals to formalize the educational review process and use this process to correct scores for the first three quarters of chart-abstracted measure validation as discussed above.

Comment: A few commenters supported the proposal to formalize the educational review process so that incorrect validation scores may be corrected for the first three quarters of validation for chart-abstracted measures. One commenter believed that this change would make the process more meaningful and valuable to hospitals across the nation.

Response: We thank the commenters for their support.

Comment: One commenter expressed concern about the scoring metrics used to validate the educational review process of hospitals and emphasized the need to do more than just obtain a ''passing'' score.

Response: We thank the commenters for their input. We do not apply scoring metrics to validate the educational review process. If an error is found during an educational review, then the case reliability would be updated prior to computing the overall confidence interval. For example, if the provider has 1 mismatch out of 10 total cases for the quarter, therefore having a quarterly case reliability of 9/10, and upon educational review it is determined that the mismatch should *not* have occurred, we would update the quarterly case reliability to 10/10 prior to computing the overall confidence interval.

After consideration of the public comments we received, we are finalizing our proposals, as proposed, for the FY 2020 payment determination and subsequent years, to: (1) Formalize the educational review process for chart-abstracted measures; and (2) use this process to correct quarterly scores for any of the first 3 quarters of validation in order to compute the final confidence interval (CI).

12. Data Accuracy and Completeness Acknowledgement (DACA) Requirements for the FY 2020 Payment Determination and Subsequent Years

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554) for previously-adopted details on DACA requirements. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20070), we did not propose any changes to the DACA requirements.

13. Public Display Requirements for the FY 2020 Payment Determination and Subsequent Years

a. Background

We refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47364), the FY 2011 IPPS/LTCH PPS final rule (75 FR 50230), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277), and the FY 2016 final rule (80 FR 49712 through 49713) for details on public display requirements. The Hospital IQR Program quality measures are typically reported on the *Hospital Compare* Web site at: *http://www.medicare.gov/hospitalcompare*, but on occasion are reported on other CMS Web sites such as: *https://data.medicare.gov*.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20070 through 20074), we did not propose any changes to public display requirements; however, we solicited public comment on potential options for confidential and public reporting of measures stratified by patient dual eligibility status as early as the summer of 2018 using data from the FY 2019 reporting period (July 1, 2014 through June 30, 2017). We previously sought public comment on the potential public reporting of quality measures data stratified by SES factors and future hospital quality measures that incorporate health equity in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57167 through 57168). In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20071), we sought additional public comment on the potential confidential and public reporting of Hospital 30-day, All-Cause, Risk-Standardized Readmission Rate Following Pneumonia Hospitalization (NQF #0506), (the Pneumonia Readmission measure), and the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization (NQF #0468), (the Pneumonia Mortality measure), data stratified specifically by patient dual eligibility status. These are discussed in more detail below.

b. Potential Options for Confidential and Public Reporting of Hospital IQR Measures Stratified by Patient Dual Eligibility Status

(1) Background

In section IX.A.1.d. of the preamble of the proposed rule, we discussed the importance of improving beneficiary outcomes including reducing health disparities, and our commitment to ensuring that medically complex patients, as well as those with social risk factors, receive excellent care. As we noted in section IX.A.1.d. of the preamble of the proposed rule, studies show that social risk factors, such as earning a low-income, belonging to a racial or ethnic minority group, or living with a disability, are associated with poor health outcomes, some of which are related to the quality of health care.[284] One of our core objectives is to improve health outcomes for all beneficiaries, and to ensure that complex patients as well as those with social risk factors receive excellent care. Within this context, recent reports by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academies of Sciences, Engineering, and Medicine have examined the influence of social risk factors in CMS value-based purchasing programs.[285] In addition, as noted in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57185), the NQF has undertaken a 2-year trial period in which certain new measures and measures undergoing maintenance review have been assessed to determine if risk adjustment for social risk factors is appropriate for these measures.[286] Since publishing the proposed rule, we have verified that the NQF trial period ended in April 2017 and a draft report is available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*.

[284] See, for example, United States Department of Health and Human Services. ''Healthy People 2020: Disparities. 2014,'' *http://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities* or National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: National Academies of Sciences, Engineering, and Medicine 2016.

[285] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.'' December 2016, *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[286] *http://www.qualityforum.org/SES_Trial_Period.aspx.*

Also as part of this effort, we solicited feedback on which social risk factors provide information that is most valuable to stakeholders. We also sought public comment on confidential reporting and future public reporting of some of our measures, specifically the Pneumonia Readmission measure (NQF #0506) and the Pneumonia Mortality measure (NQF #0468), stratified by patient dual eligibility. There are two potential purposes for providing information on hospital results stratified by dual eligibility. The approach we are considering would illuminate differences in outcome rates among patient groups within a hospital and would also allow for a comparison of those differences, or disparities, across hospitals. We also considered an alternative approach that would measure outcome rates for subgroups of patients, such as the dual eligible patients, across hospitals; however, this alternative would not allow for an examination of the difference in rates between groups (for example dual eligible patients compared to non-dual eligible patients).

The goals of measuring and monitoring disparities in patient outcomes for specific sub-groups of patients within hospitals is to reduce health inequities, improve health care quality for vulnerable populations, and promote greater transparency for health care consumers. This is in alignment with the CMS Quality Strategy [287] and the ASPE report [288] to Congress, which stated performance rates, including readmission rates, stratified by social risk should be developed and considered for hospital specific confidential preview reports and public reporting in places such as the *Hospital Compare* Web site, so hospitals, health systems, policymakers, and consumers can see and address important disparities in care.

Many levers exist for addressing and improving disparities in care and outcomes. The 21st Century Cures Act (Pub. L. 114–255) addresses payment penalty scoring in the Hospital Readmissions Reduction Program by identifying hospitals based on their proportion of dual eligible patients and supporting improvement efforts for hospitals caring for patients with social risk factors by setting penalty thresholds among similar peer hospitals.[289] As discussed in sections V.I.7. through V.I.10. of the preamble of this final rule, the Hospital Readmissions Reduction Program, as required by the statute, proposed to use dual eligibility as a marker of poverty, one key patient social risk factor, and we would like to move in that direction for the Hospital IQR Program as well in the future. In the Hospital IQR Program, we are exploring methods to distinguish vulnerable patients with social risk factors, such as poverty. As such, we intend to use dual eligible status among the over 65 year old patients included in the measures as a marker of poverty.

Dual eligible status describes whether Medicare beneficiaries are also enrolled in Medicaid. We use dual enrollment in Medicare and Medicaid as a marker for a beneficiary having low income and/or few assets. The recent report to Congress by ASPE has shown that dual eligibility was the most powerful predictor of poor health care outcomes among the social risk factors they tested.[290]

The *Hospital Compare* Web site currently displays readmission rates for each hospital, but does not specifically highlight a hospitals quality of care for vulnerable populations. We believe stratifying data by social risk factors would supplement the current reporting of the Pneumonia Readmission measure (NQF #0506) and the Pneumonia Mortality measure (NQF #0468) by highlighting disparities, that is, differences in outcomes, within hospitals that are not simply due to differences in illness severity, to the extent that such disparities exist for any given hospital. To do so, we developed a method to quantify the disparities of readmission and mortality between these groups within each hospital after accounting for patient case mix. The disparities indicator used in the hospital specific confidential preview reports would provide information assessing the increased odds, or rates, of readmission for dual eligible patients admitted to the same hospital, after accounting for differences in age and comorbidities.

For the Hospital IQR Program, we are considering options to improve health disparities among patient groups within hospitals by increasing the transparency of disparities among patients within hospitals and the ability to compare these disparities across hospitals. This would be accomplished by the methods described below. Our alternative approach, also described below, to measure outcome rates for subgroups of patients, such as the dual eligible patients, across hospitals, would examine the performance of hospitals on the subgroup of dual eligible patients.

We previously sought public comment on the potential public reporting of quality measure data stratified by race, ethnicity, sex, and disability and future hospital quality measures that incorporate health equity in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57167 through 57168). In general, commenters supported the development of health equity measures and their inclusion in the Hospital IQR Program (81 FR 57167). In particular, stakeholders noted that stratified measures could serve as tools for hospitals to identify gaps in outcomes for different groups of patients, improve the quality of health care for all patients and empower consumers to make informed decisions about health care. The stakeholders encouraged us to stratify measures by other social risk factors such as age, income, and educational attainment (81 FR 57167); however, commenters raised concerns about the small denominator sample size associated with measure stratification by social risk factors, which would skew the reliability of stratified quality measures. Commenters also expressed concern that it may not be a simple task to stratify measures by race, ethnicity, sex, and disability because specific considerations are required for every measure and each reporting mechanism to implement such a requirement (81 FR 57168). For more details on the public comments, we refer the readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57167 through 57168).

We acknowledge the complexity of interpreting stratified outcome measures. Due to this complexity, prior to publicly reporting stratified outcome measure data, as early as the summer of 2018 using data from the FY 2019 reporting period (July 1, 2014 through June 30, 2017), we are considering first providing hospitals with confidential results showing outcomes stratified by patient dual eligibility within the hospital, or more specifically, differences in outcome rates for the dual eligible and non-dual eligible patients in the measures. This would allow us to obtain feedback on reporting options and to ensure the information is reliable, valid, and understandable prior to any future public display on the *Hospital Compare* Web site. Our goal in producing stratified results is to provide information about disparities in patient

[287] *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/qualityinitiativesgeninfo/cms-quality-strategy.html.*

[288] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.'' December 2016. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[289] *Ibid.*

[290] *Ibid.*

outcomes within hospitals to the extent that they exist for a given hospital. This information would supplement the assessment of overall hospital quality provided through the current measures of readmission and mortality rates; these measures would remain unchanged. We discuss below the methods and results of stratification for the current Hospital 30-day, All-Cause, Risk-Standardized Readmission Rate Following Pneumonia Hospitalization (NQF #0506) (the READM–30–PN or Pneumonia Readmission measure).

The stratified results would provide hospitals with confidential reporting with information that could illuminate any disparities in care and outcome that can be targeted through quality improvement efforts. Then for the future, we are considering publicly posting both of these results on *Hospital Compare* to allow consumers and other stakeholders to view critical information about the care and outcomes of subgroups of patients, particularly those with social risk factors. This information could drive consumer choice and spark improvement efforts targeting dual eligible patients. In the future, we would also consider expanding this approach to other social risk factors and other measures.

We invited public comment on: (1) Which social risk factors provide information that is most valuable to stakeholders; (2) providing hospitals with confidential preview reports containing stratified results for certain Hospital IQR Program measures, specifically the Pneumonia Readmission measure (NQF #0506) and the Pneumonia Mortality (MORT–30–PN) measure (NQF #0468); (3) a potential methodology for illuminating differences in outcomes rates among patient groups within a hospital that would also allow for a comparison of those differences, or disparities, across hospitals; (4) an alternative methodology that compares performance for patient subgroups across hospitals but does not provide information on hospital disparities and any additional suggested methodologies for calculating stratified results by patient dual eligible status; and (5) future public reporting of these same measures stratified by patient dual eligibility status on the *Hospital Compare* Web site. These are discussed in more detail below.

(2) Confidential Hospital Specific Preview Reports Prior to Publicly Reporting Stratified Data

We sought public comment on the possibility of providing confidential hospital specific preview reports containing the results of the Pneumonia Readmission (NQF #0506) and Pneumonia Mortality (NQF #0468) measures stratified by patient dual eligibility, as early as the summer of 2018 using data from the FY 2019 reporting period (July 1, 2014 through June 30, 2017), prior to any future potential public reporting of this data. The current publicly reported measures used in the Hospital IQR Program and reported on the *Hospital Compare* Web site would remain unchanged. Following the time period during which hospitals received confidential preview reports, we may display stratified results on the *Hospital Compare* Web site solely for the purpose of ''stratification,'' that is, producing results to describe differences between subgroups within the hospital.

(3) Potential Methodology for Calculating Stratified Results by Patient Dual Eligibility Status

(a) Background

Under any future option to stratify measure results by patient dual eligibility status, we intend to focus on disparities between dual eligible patients and non-dual eligible patients, because dual eligibility is an important social risk factor among the Medicare FFS population and is feasible to measure.[291] In order to provide information about differences in readmission outcomes for dual eligible patients and non-dual eligible patients within a hospital that may be due to quality differences, we need a methodology that accounts for any differences in comorbidities, age, and other risk factors between these groups of patients. Such a methodology ensures that differences in outcomes are not simply due to differences in clinical severity and comorbid conditions among the patient groups. Therefore, any approach to identifying within-hospital disparities for readmission measures by patients' dual eligibility status would build on the methodology used to calculate the currently implemented RSRRs.[292] As the Pneumonia Readmission measure (NQF #0506) is currently specified, risk-adjusted rates are estimated using a hierarchical logistic regression to account for the clustering of observations within hospitals and differences in the number of admissions across hospitals.[293]

(b) Option To Measure Difference in Outcomes By Adding Three Additional Factors to Current Statistical Models

There is both a hospital and patient-level effect of dual eligibility on readmission risk. We have considered the hospital fixed effect in our approaches to stratifications (described in section IX.A.13.b.(3)(a) of the preamble of this final rule), because without it, we will introduce bias in the patient-level dual eligibility, which would produce misleading results. The statistical approach we may employ in the future would use current statistical models and add three additional factors to the statistical model for the purposes of measuring differences in outcomes: (1) An indicator for patient-level dual eligibility; (2) a hospital-level dual eligible factor[294] (for example, percentage of dual eligible patients in each hospital); and (3) a hospital-specific indicator (random coefficient) for dual eligibility. This third factor, the hospital-specific random coefficient for dual eligibility, assesses the disparity or difference in readmissions for dual eligible patients within a specific hospital after accounting for other factors, such as differences in clinical disease or comorbid conditions. The first two factors, (the patient-level dual eligibility coefficient, which represents the overall difference between dual and non-dual groups in the entire country, and the hospital-level dual eligible factor, which reflects the difference in readmission rate between hospitals with different proportions of dual eligible patients) are only included in order to be able to interpret the third factor random coefficient and ensure it is specific to a particular hospital. It is the third factor, the hospital-specific indicator, which would be used to calculate the differences in readmission rates between the dual and non-dual eligible patients within the hospital. Using this method, within-hospital disparities in readmissions between

[291] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.'' December 2016, *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[292] *http://www.qualitynet.org/dcs/ContentServer?cid=1219069855841&pagename=QnetPublic%2FPage%2FQnetTier4&c=Page.*

[293] Krumholz H, Normand SL, Keenan P, et al. Hospital 30-Day Pneumonia Readmission Measure Methodology: Report prepared for the Centers for Medicare & Medicaid Services, 2008, *http://www.qualitynet.org/dcs/ContentServer?cid=1219069855841&pagename=QnetPublic%2FPage%2FQnetTier4&c=Page.*

[294] We note that although hospital-level dual eligible effect was not of interest, it often mixed with patient-level effect. Therefore, by breaking down the dual eligible effect into patient-level and hospital-level components, we were able to better assess of relationship between readmission and patient-level dual eligibility.

dual eligible patients and non-dual eligible patients would be included in confidential hospital specific preview reports in addition to the currently calculated and displayed Pneumonia Readmission (NQF #0506) and Pneumonia Mortality (NQF #0468) measures. We would provide information in the form of odds ratios (that is, the increased odds of readmission for dual eligible patients at a given hospital) or, alternatively, the average difference in readmission rates between dual and non-dual patients after accounting for differences in other risk-factors.

To calculate odds ratios, we would convert hospital-specific coefficients for dual eligibility into odds ratios. Odds ratios compare dual eligible patients relative to non-dual eligible patients in terms of their risk of readmission, assuming that the two groups have the same case mix (that is, comorbidities). If the readmission rate is the same in both groups, the odds ratio is 1. If the odds ratio is greater than 1, it would mean that dual eligible patients have worse readmission rates, and vice versa. To estimate the average difference of readmission rates between dual and non-dual beneficiaries for each hospital, we would first calculate the predicted probabilities of being readmitted by assuming all patients are dual eligible or all patients are non-dual eligible in a hospital. The difference between the two predicted probabilities is the average difference in the readmission rates between the two groups of patients at each hospital.

Rather than assuming a uniform impact of dual eligible and non-dual eligible status across hospitals, this approach would assess the impact of dual eligibility across all hospitals separately, recognizing that socioeconomic disparities of patients may be greater or lesser at some hospitals as compared with others. This approach would allow quantification of the difference in readmissions between dual eligible patients and non-dual eligible patients within each hospital, as long as a hospital has a sufficient number of cases to produce a reliable estimate for both groups.

In summary, this statistical model would uniquely identify disparities in readmission rates for dual eligible beneficiaries compared to non-dual eligible beneficiaries, after controlling for patients' prior medical history and age for each hospital. This random coefficient for dual eligibility within the statistical model would indicate how readmission rates at the same hospital would differ between two patients at that hospital with exactly the same age and underlying risk factors (those comorbid clinical conditions included in the statistical model), but differ with respect to dual eligibility.

(c) Option To Measure Difference in Outcomes Using Current Statistical Models

Depending on the information that is most useful to stakeholders, an alternative approach to examining readmission rates among dual eligible patients could be considered. To examine the relative performance of hospitals on readmission rates for their dual eligible patients, rather than to compare hospitals on within-hospital disparities, we could calculate the current measures' statistical model (without the additional factors mentioned above) and include only dual eligible patients. Similarly, this could be done for non-dual eligible patients. This approach of using two separate models for the separate patient subgroups would produce information on readmission rates for dual eligible patients at one hospital compared to another (or non-dual eligible patients across hospitals). Because of the use of two separate statistical models, this approach would not ensure consistent treatment of risk factors across patient groups and could not be used to compare readmission rates for two groups within a hospital.

(d) Summary of Statistical Method Options

We intend to provide information on the difference in readmission rates of dual eligible and non-dual eligible beneficiaries within hospitals and also provide information for hospitals and consumers on the relative disparities across hospitals. We solicited public comment on the information that stakeholders would find most useful and any additional suggested methodologies for calculating stratified results by patient dual eligible status. The confidential hospital specific preview reports containing data stratified by patient dual eligibility status would be modeled after current confidential hospital specific preview reports and include patient-level data for hospitalizations included in the measure. The current confidential hospital specific preview reports would be supplemented by information for each patient on their dual eligible status and a summary of the difference in readmission rates for dual eligible patients in the hospital as compared to other hospitals in the State and nation.

We invited public comment on both methodologies, as described above, to produce stratified results by determining the differences in readmission and mortality by dual eligible status within a hospital, and a comparison of those disparities across hospitals, accounting for differences in comorbidities, age, and other risk factors between dual eligible and non-dual eligible patients.

All comments received are summarized under section IX.A.13.b.(6) of the preamble of this final rule, below.

(4) Data Sources

To provide an example of the statistical approach we could apply, we describe stratified results by patient dual eligibility for the Pneumonia Readmission measure (NQF #0506), using the first calculation method described in section IX.A.13.b.(3)(b) of the preamble of this final rule. To calculate the example rate, we used the CMS administrative claims data from each index pneumonia hospitalization, as well as from inpatient and outpatient Medicare claims from the 12 months prior to the hospitalization from July 2012 to June 2015 to calculate the publicly reported RSRRs following pneumonia hospitalization (NQF #0506) in the July 2016 *Hospital Compare* update. Both the cohort and the risk-adjustment approach remain unchanged. For more details on the publicly reported RSRRs following pneumonia as currently implemented, we refer readers to its measure methodology report and measure update zip file on our Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. The data was then linked to CMS denominator files [295] (2012 to 2015) to derive the indicator of dual eligibility for each patient admission (1.3 percent index admissions were excluded because there is no information available in the denominator files).

We conducted preliminary analyses on the Pneumonia Readmission measure (NQF #0506) [296] and determined that there is a total of 3,851 hospitals that have at least 25 included index hospitalizations overall, and at least 10 dual eligible and 10 non-dual eligible index hospitalizations for which we could report outcome disparity (82 percent of hospitals). The minimum sample size for 25 hospitalizations is consistent with the current publicly

[295] *https://www.cms.gov/research-statistics-data-and-systems/files-for-order/limiteddatasets/denominatorlds.html.*

[296] 1,456,289 hospitalizations (98.7 percent) were linked to the denominator data and 24.4 percent of those hospitalizations are from dual eligible patients.

reported outcomes measures. We imposed an additional requirement of at least 10 dual eligible and 10 non-dual eligible index hospitalizations for this example to ensure we had adequate numbers to observe any meaningful differences in outcome. We used this requirement because if a hospital has fewer than 10 patients in one subgroup of patients, it is neither clear that readmission rates for that group as compared to others would be reliable, nor that it is meaningful or has face validity to measure stratified rates for hospitals with very few of one of the categories of patients. We welcomed public comment on this sample size determination.

The observed readmission rate within 30-days of index discharge for all patients was 17.1 percent when we did not adjust for patients' prior medical history, and dual eligible beneficiaries had an approximately 3 percent higher readmission rate. Results from the hierarchical model [297] indicate that there is a statistically significant association between dual eligibility and pneumonia readmission (adjusted odds ratio, 1.07; 95 percent CI, 1.06–1.08). In addition, there is substantial variation in the relationship between dual eligibility and readmission across hospitals (Median odd ratio, 1.06; Min., 0.95; Max., 1.22). Findings also revealed that dual eligible patients are more likely to get readmitted in 95 percent of hospitals.

(5) Future Potential Public Display

We invited public comment on the potential future public reporting of certain outcomes measures, such as the Pneumonia Readmission measure (NQF #0506) and the Pneumonia Mortality measure (NQF #0468), stratified by social risk factors, specifically dual eligible status, to illuminate within-hospital disparities. If we decide to display measure data stratified by dual eligible status on the *Hospital Compare* Web site, we would clearly differentiate between the measure information we currently display and the measure information that is stratified by patients' dual eligible status. In addition, as discussed above, if we decide to display measure data stratified by dual eligible status on the *Hospital Compare* Web site, hospitals would receive information about their stratified readmission rates for a certain period of time through confidential hospital specific preview reports prior to the public reporting of any information.

We invited public comment on this future consideration to display the stratified measure results, in addition to the current measure results, for certain Hospital IQR Program measures in future reporting years. We note that public display of measure data stratified by social risk factors such as dual eligible status would not occur until after a period of confidential reporting.

All comments received are summarized under section IX.A.13.b.(6) of the preamble of this final rule below.

(6) Summary

To summarize, we invited public comment on: (1) Which social risk factors provide the most valuable information to stakeholders; (2) providing hospitals with confidential preview reports containing stratified results for certain Hospital IQR Program measures, specifically the Pneumonia Readmission measure (NQF #0506) and the Pneumonia Mortality measure (NQF #0468); (3) a potential methodology for illuminating differences in outcomes rates among patient groups within a hospital and would also allow for a comparison of those differences, or disparities, across hospitals; (4) an alternative methodology that compares performance for patient subgroups across hospitals but does not provide information on within hospital disparities and any additional suggested methodologies for calculating stratified results by patient dual eligibility status; and (5) future public reporting of these same measures stratified by patient dual eligibility status on the *Hospital Compare* Web site as discussed above.

Comment: Several commenters supported providing confidential reports to hospitals for the Pneumonia Readmission measure (NQF #0506) and the Pneumonia Mortality measure (NQF #0468) stratified by patient dual eligible status and publicly reporting stratified measure data in the future. The commenters believed this information would be informative to hospitals and would drive improvement.

One commenter stated that this would be a positive direction for CMS when proposing new methodologies for quality metrics whether it be population stratification, risk adjustment, or any other significant changes in reporting.

Response: We thank the commenters for their support on stratifying outcome measures. We believe that highlighting disparities in outcomes between sub-groups of patients could contribute to improved care for vulnerable patients.

Comment: A few commenters urged CMS to explore if additional factors should be used to stratify or risk adjust the measures beyond dual eligibility as a marker of poverty and consider the full range of differences in patients' backgrounds that might affect outcomes (such as readmission rates).

Response: We appreciate the commenters' suggestion to stratify outcome measures by additional social risk factors. Consistent with the findings of the ASPE and National Academies of Sciences, Engineering, and Medicine reports, we will consider stratifying outcome measures by appropriate additional social risk factors in the future as we continue to engage stakeholders and determine the availability of appropriate social risk factors that might influence outcomes such as readmission. Measure stratification is intended to identify disparities or differences by patient subgroup to support hospitals' efforts to improve care. Stratified reporting would allow us to provide measure data stratified by patient subgroup or the disparity between patient subgroups for each measure, via confidential hospital specific preview reports or public display on the *Hospital Compare* Web site.

We note that there are several methods for stratification of patients by dual eligible status, two of which are: (1) Calculating the differences in outcomes between dual and non-dual eligible patients within hospitals, and (2) stratifying by groups of patients so that a given provider would receive a score for each group (one for dual eligible patients, one for non-dual eligible patients, etc.). We will continue to explore which of the two methodologies is most appropriate and how best to provide confidential reports to hospitals for the Pneumonia Readmission measure (NQF #0506), the Pneumonia Mortality measure (NQF #0468), or other outcome measures in the Hospital IQR Program stratified by patient dual eligible status in the future. We will also continue to evaluate what may be the best method or methods of publicly displaying stratified outcome measure information to ensure the public's understanding of the data.

Comment: Most commenters expressed concern that CMS allow hospitals sufficient time to review and analyze stratified rates prior to publicly reporting.

Response: We acknowledge the commenters' concern that hospitals have sufficient time to review and analyze stratified measure data prior to

[297] Our hierarchical model is described in our measure methodology reports. See, for example, Krumholz H, Normand SL, Keenan P, et al. Hospital 30-Day Pneumonia Readmission Measure Methodology: Report prepared for the Centers for Medicare & Medicaid Services, 2008, *http://www.qualitynet.org/dcs/ContentServer?cid=1219069855841&pagename=QnetPublic%2FPage%2FQnetTier4&c=Page*.

public reporting. We believe confidential hospital specific preview reports of stratified measure data will allow us to obtain feedback on reporting options and to ensure the information is reliable, valid, and understandable prior to any future public display on the *Hospital Compare* Web site. We intend to continue to engage with hospitals about their experience with and recommendations for stratified measure data as we begin to provide confidential hospital specific preview reports prior to potentially proposing to publicly display stratified measure data in the future. Any display of stratified quality measures on the *Hospital Compare* Web site would be proposed through future rulemaking.

Comment: One commenter agreed that public reporting on the *Hospital Compare* Web site should be considered in the future, but urged CMS to devote careful consideration to what type of display would be most useful to the public. The commenter suggested CMS conduct focus groups to test messaging and understanding of the data.

Response: We recognize the importance of eventual public reporting of stratified outcome measures information. We will continue to evaluate what may be the best method or methods of publicly displaying stratified outcome measure information to ensure the public accurately understands the data. We will consider conducting focus groups or other outreach efforts to collect public feedback as part of this effort.

Comment: Another commenter suggested that stratification and risk adjustment be a measure-by-measure consideration that is incorporated into the measure specifications.

Response: We agree with the commenter that stratification and risk adjustment should be a measure-by-measure consideration. During the NQF SDS two-year trial period that ended in April 2017, we assessed measures individually to determine whether risk adjustment for social risk factors was warranted. Similarly, we are adopting a measure-by-measure approach when considering stratification of quality measures. We plan to engage stakeholders through future rulemaking prior to any public reporting of stratified quality measures.

Comment: One commenter did not support providing confidential reports to hospitals for the Pneumonia Readmission measure (NQF #0506) and the Pneumonia Mortality measure (NQF #0468) stratified by patient dual eligible status and publicly reporting stratified measure data in the future, raising concerns about the small sample size associated with measure stratification by social risk factors, which would skew the reliability of stratified quality measures. The commenter believed the proposed statistical approach using a hospital-specific indicator (random coefficient) for dual eligibility would allow quantification of the difference in readmissions between dual and non-dual eligible patients within each hospital only if a hospital has a sufficient number of cases to produce a reliable estimate for both groups. In other words, this approach may not be effective for hospitals with a small sample size of cases, and results reported for such hospitals may be skewed and inaccurate. The commenter suggested CMS study this issue further to determine the appropriate size of the patient pool to produce reliable results and should consider not reporting results for hospitals with an insufficient number of cases.

Response: We agree with the commenter that some hospitals may have few dual eligible patients and that small samples sizes can skew the reliability of stratified quality measure results. Small sample sizes could be especially challenging for measure stratification because some hospitals might have few patients with social risk factors. One of our described stratification approaches (by patient group) would report disparities only for hospitals with at least 25 patients and 10 patients for each sub-group. The same cut-off could be used for the second stratification methodology described in the proposed rule (specifically, measuring differences in outcomes for dual and non-dual beneficiaries separately). We note the overall sample size of 25 patients is consistent with the quality outcome measures currently implemented. This sample size ensures our measure is reliable and includes as many hospitals as possible. This particular methodology further adjusts for small sample sizes by partially pooling the data so that hospitals with a small sample size and, therefore, less reliable estimates are pulled to the overall mean. Using this cut-off in sample size, preliminary analysis using the first proposed methodology (that is, measuring disparities in outcomes between dual and non-dual beneficiaries) suggests we could report disparities for 3,851 hospitals (82.1 percent) for the Pneumonia Readmission measure (NQF #0506) and 3,844 hospitals (82.0 percent) for the Pneumonia Mortality measure stratified by dual eligibility status.

We note that these results would be used under the first described stratification methodology (adding three additional factors), as described in section IX.A.13.b.(3)(b) of the preamble of this final rule, above. We also note that if we used the second described methodology of calculating the difference in current statistical models, as described in section IX.A.13.b.(3)(c) of the preamble of this final rule, above, we anticipate the results would not be as effective. We will continue to explore alternative approaches to determine the appropriate sample size to produce reliable results. We note that we would not provide disparities results or differences in outcomes for different patient groups if a given hospital has fewer than the minimum number of patients within a sub-group in the measure.

Comment: One commenter requested that CMS publicly release the analytic file, model results, and research findings related to the pneumonia readmissions model with the added dual-eligible variables and recommended changes to the model should be vetted during the MAP pre-rulemaking recommendation process. The commenter stated that during the NQF socio-demographic (SDS) trial period, the measure steward for the pneumonia readmission and mortality models, Yale Center for Outcomes Research and Evaluation (Yale CORE), presented their results for accounting for various SDS variables in the condition-specific readmissions models and the conclusion was that while there was a statistically significant relationship between dual-eligibility and readmissions, the addition of dual-eligible status did not improve the model or meaningfully change hospital results. Since this conflicts with the ASPE findings, the commenter would like to better understand the Yale CORE model.

Response: Risk adjustment and stratification are two distinct ways of accounting for the importance of social risk factors on health outcomes. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20072 through 20074), we detailed the findings of our modeling for the Pneumonia Readmission measure (NQF #0506) to share one example of stratified results. We note, however, that the approach presented for the Pneumonia Readmission measure (NQF #0506) stratification differs from the approach presented in the condition-specific readmission models described in the NQF two-year SDS trial by the measure steward. The analytical model and results for the NQF SDS Trial of these measures are publicly available on the NQF Web site at: *http://www.qualityforum.org/Project_Pages/*

All-Cause_Admissions_and_Readmissions_2015–2017.aspx.

As part of the SDS two-year trial, we assessed the impact of the addition of socioeconomic status, such as dual eligibility, in the risk adjustment model on readmissions on a case-by-case basis. The measure steward's results are largely consistent with the findings of the ASPE report. Both the ASPE report and the measure steward's findings show a relationship between socioeconomic factors and health outcomes when there is no other risk-adjustment. In the multi-variate, or fully adjusted model, results indicate that the effect of SES variables on readmission rates was significant but small. However, the measure steward has shown that adjusting for patient dual-eligible status in the overall measure changes hospital performance on the measure very little. Similarly, when ASPE simulated the effect of risk adjustment for patient dual eligible status on Hospital Readmissions Reduction Program penalties, they found that it would have a small overall impact on hospitals' performance and their ranking.

Comment: One commenter discussed the two methodological approaches for SES stratification presented in the FY 2018 IPPS/LTCH PPS proposed rule. The commenter expressed a preference for reporting two rates, one rate for dual eligible patients and one rate for non-dual eligible patients, for the pneumonia readmission and mortality measures (Approach 2). The commenter encouraged CMS to adopt Approach 2 for now, because the commenter believed it minimizes the risk of mixed signals on measure performance. The commenter noted that Approach 2 is easier to understand for providers, because it uses the same risk adjustment model as our overall quality measures.

The commenter continued and stated that on the other hand, Approach 1 calculates differences in outcomes by adding three additional factors to the statistical model currently used in our outcome measures, including: (1) An indicator for patient-level dual eligibility; (2) a hospital-level dual eligible factor (that is, percentage of dual eligible patients in each hospital); and (3) a hospital-specific indicator (random coefficient) for dual eligibility. The commenter stated it would support Approach 1 if CMS decided to directly risk adjust measures included in the Hospital Readmissions Reduction Program for patient level SES.

Response: We thank the commenter for their recommendation. As noted in the proposed rule and our responses above, there are potential merits and limitations to each approach. We will continue to explore multiple options and will solicit further feedback from stakeholders before deciding on a specific method or approach for providing confidential feedback reports or potential future public reporting of stratified measure data.

One example of these methods could be noted in the efforts currently underway in the Hospital Readmissions Reduction Program under the 21st Century Cures Act, as described in section V.I.8. of the preamble of this final rule. We distinguish stratified reporting for the purposes of identifying disparities from the approach in the Hospital Readmissions Reduction Program under the 21st Century Cures Act that compares peers with peers based on hospital's share of patients with risk factors for benchmarking and/or calculation of payment adjustment. Further, we distinguish that the Hospital Readmissions Reduction Program is using this method for payment calculations and the Hospital IQR Program would not be using the data in this manner, but rather is considering these approaches as options for deriving confidential reports to hospitals and potential public reporting in the future.

To summarize, we invited public comment on: (1) Which social risk factors provide the most valuable information to stakeholders; (2) providing hospitals with confidential preview reports containing stratified results for certain Hospital IQR Program measures, specifically the Pneumonia Readmission measure (NQF #0506) and the Pneumonia Mortality measure (NQF #0468); (3) a potential methodology for illuminating differences in outcomes rates among patient groups within a hospital and would also allow for a comparison of those differences, or disparities, across hospitals; (4) an alternative methodology that compares performance for patient subgroups across hospitals but does not provide information on within hospital disparities and any additional suggested methodologies for calculating stratified results by patient dual eligibility status; and (5) future public reporting of these same measures stratified by patient dual eligibility status on the *Hospital Compare* Web site, as discussed above.

We thank the commenters, and we will consider all of the comments received as we develop policy regarding potential options for confidential and public reporting of Hospital IQR Program measures stratified by patient social risk factors, such as dual eligibility status and, specifically, as we develop policy regarding potential options on the future confidential and public reporting of the Pneumonia Readmission measure (NQF #0506) data and the Pneumonia Mortality measure (NQF #0468) data stratified specifically by patient dual eligibility status.

After considering the public comments we received, we will continue to evaluate: (1) Which social risk factors provide the most valuable information to stakeholders; (2) which Hospital IQR Program outcome measures to provide stratified measure data; (3) how best to display information in the confidential hospital specific preview reports; (4) when to begin providing the confidential hospital specific preview reports; (5) potential methodologies for illuminating differences in outcomes; and (6) ways to most effectively publicly display this data. We will continue to consider beginning to provide confidential hospital specific preview reports as early as summer of 2018, using data from the FY 2019 reporting period (July 1, 2014 through June 30, 2017), however, it may take us longer in light of our plans for continued evaluation as described above and operational considerations. If we make such a determination to begin providing confidential hospital specific preview reports of measure data for the Pneumonia Readmission measure, the Pneumonia Mortality measure, or other outcome measures in the Hospital IQR Program stratified by patient dual eligibility status to hospitals, we will convey this decision through routine communication channels to hospitals, vendors, and QIOs, including, but not limited to, issuing memos, emails, and notices on the QualityNet Web site.

14. Reconsideration and Appeal Procedures for the FY 2020 Payment Determination and Subsequent Years

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650 through 51651), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836), and 42 CFR 412.140(e) for details on reconsideration and appeal procedures for the FY 2017 payment determination and subsequent years. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20074), we did not propose any changes to the reconsideration and appeals procedures.

15. Change to the Hospital IQR Program Extraordinary Circumstances Exceptions (ECE) Policy

a. Background

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651 through 51652), the FY 2014 IPPS/LTCH

PPS final rule (78 FR 50836 through 50837), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49713), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57181 through 57182), and 42 CFR 412.140(c)(2) for details on the current Hospital IQR Program ECE policy.

We also refer readers to the QualityNet Web site at: *http://www.QualityNet.org/* for our current requirements for submission of a request for an extension or exemption. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20075), we made one proposal and a clarification in order to align the ECE policy across CMS quality programs. We also proposed updates to 42 CFR 412.140(c)(2) to reflect our ECE policy.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20074 through 20075), we stated that many of our quality reporting and value-based purchasing programs share common processes for requesting an exception from program reporting due to an extraordinary circumstance not within a provider's control. The Hospital IQR Program, Hospital OQR Program, IPFQR Program, ASCQR Program, and PCHQR Program, as well as the Hospital VBP Program, HAC Reduction Program, and the Hospital Readmissions Reduction Program, share common processes for ECE requests. We refer readers to the Hospital IQR Program (76 FR 51651 through 51652, 78 FR 50836 through 50837, 79 FR 50277, 81 FR 57181 through 57182, and 42 CFR 412.140(c)(2)), Hospital OQR Program (77 FR 68489, 78 FR 75119 through 75120, 79 FR 66966, and 80 FR 70524), and ASCQR Program (77 FR 53642 through 53643 and 78 FR 75140 through 75141) along with the HAC Program (80 FR 49579 through 49581), Hospital Readmissions Reduction Program (80 FR 49542 through 49543), IPFQR (77 FR 53659 through 53660 and 79 FR 45978), and PCHQR Program (78 FR 50848) for program specific information about extraordinary circumstances exceptions requests.

In reviewing the policies for these programs, we recognized there are five areas in which these programs have variance regarding ECE requests. These are: (1) Allowing the facilities or hospitals to submit a form signed by the facility's or hospital's CEO versus CEO or designated personnel; (2) requiring the form be submitted within 30 days following the date the extraordinary circumstance occurred versus within 90 days following the date the extraordinary circumstance occurred; (3) inconsistency regarding specification of a timeline for us to provide our formal response notifying the facility or hospital of our decision; (4) inconsistency regarding specification of our authority to grant ECEs due to CMS data system issues; and (5) referring to the program as ''extraordinary extensions/exemptions'' versus as ''extraordinary circumstances exceptions.'' We believe addressing these five areas across programs, can improve administrative efficiencies for affected facilities or hospitals.

b. Proposals To Align the Hospital IQR Program ECE Policy With Other CMS Quality Programs

With the exception of the timeline for us to provide our formal response (item 3 above) and the nomenclature used to refer to the ECE process (item 5 above), the Hospital IQR Program is aligned with the ECE policies across the other CMS quality programs described above. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20075), we proposed to: (1) Update the nomenclature to align with the ECE policies across the other CMS quality programs and update the regulatory text to reflect this change; and (2) update our regulatory text to reflect other existing ECE policies. Also, we are clarifying the timing of our response to ECE requests. These proposals are discussed in more detail below.

(1) ECE Policy Nomenclature

We have observed that while all quality programs listed above have developed similar policies to provide exceptions from program requirements to facilities that have experienced extraordinary circumstances, such as natural disasters, these programs refer to these policies using inconsistent terminology. Some programs refer to these policies as ''extraordinary circumstances extensions/exemptions'' while others refer to the set of policies as ''extraordinary circumstances exceptions.'' Several programs (specifically, the Hospital VBP Program, HAC Reduction Program, and the Hospital Readmissions Reduction Program) are not able to grant extensions to required data reporting timelines due to their reliance on data external to their program, and thus the term, ''extraordinary circumstances extensions/exemptions'' is not applicable to all programs. However, all of the described programs are able to offer exceptions from their reporting requirements. Therefore, we proposed to change the name of this policy from ''extraordinary circumstances extensions/exemptions'' to ''extraordinary circumstances exceptions'' for the Hospital IQR Program, beginning October 1, 2017, and to revise section 412.140(c)(2) of our regulations to reflect this change. We note that changing the name of this policy does not change the availability for a hospital to request an extension under the Hospital IQR Program.

We invited public comment on this proposal as discussed above.

Comment: Several commenters supported the proposed alignment of the extraordinary circumstances exceptions (ECE) policies in the Hospital Readmissions Reduction Program, the HAC Reduction, and the Hospital IQR Programs.

Response: We thank the commenters for their support.

Comment: A few commenters supported the proposed alignment of the extraordinary circumstances exceptions (ECE) policies in the Hospital Readmissions Reduction Program, the HAC Reduction, and the Hospital IQR Programs, but requested an ECE specifically for Indian Health Services (IHS) and tribal healthcare programs.

Response: We thank the commenters for their support. We note that ECE requests for the Hospital IQR Program are considered on a case by case basis (81 FR 57182). We will assess the hospital's request on a case-by-case basis to determine if an exception is merited. Therefore, our decision whether or not to grant an ECE will be based on the specific circumstances of the hospital. For additional information about eCQM-related ECE requests, we refer readers to section IX.A.15. of the preamble of this final rule.

We will explore the feasibility of creating a specific exemption policy for IHS and tribal health programs as a part of our future strategic initiatives.

After consideration of the public comments we received, we are finalizing our proposals to change the name of this policy from ''extraordinary circumstances extensions/exemptions'' to ''extraordinary circumstances exceptions'' for the Hospital IQR Program, beginning October 1, 2017, and to revise section 412.140(c)(2) of our regulations to reflect this change as proposed.

(2) Timeline for CMS Response to ECE Requests

We strive to provide our formal response notifying the facility of our decision within 90 days of receipt of the facility's ECE request. We believe that it is important for facilities to receive timely feedback regarding the status of ECE requests. We strive to complete our review of each ECE request as quickly as possible. However, we recognize the

number of requests we receive and the complexity of the information provided impacts the actual timeframe to make ECE determinations. To improve transparency of our process, we believe it is appropriate to clarify that we will strive to complete our review of each request within 90 days of receipt.

(3) Updates to CFR

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20075), we proposed to make conforming changes to the regulations at 42 CFR 412.140(c)(2) to reflect our previously finalized policy that the ECE request form be submitted within 90 days following the date the extraordinary circumstance occurred (81 FR 57181 through 57182). In addition, we proposed to make conforming changes to the regulations to codify our other existing policies in the Hospital IQR Program: (1) At 42 CFR 412.140(c)(2)(i), that a separate submission deadline of April 1 following the end of the reporting calendar year in which the extraordinary circumstance occurred and applies to a hospital that wishes to request an extraordinary circumstances exception with respect to the reporting of electronic clinical quality measure data (81 FR 57182); (2) at 42 CFR 412.140(c)(2)(ii), that at the discretion of CMS, an exception may be granted to a hospital if a systemic problem arises with CMS data collection systems which directly affected the ability of a hospital to submit data (78 FR 50837), and that CMS may also grant exceptions to hospitals that have not requested them if an extraordinary circumstance affects an entire region or locale (76 FR 51651).

We invited public comments on these proposals as discussed above.

We received no public comments on our proposals to make conforming changes to the regulations to codify certain existing policies in the Hospital IQR Program. Therefore, we are finalizing our proposals to make conforming changes to the regulations to codify certain existing policies in the Hospital IQR Program as proposed.

B. PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

1. Background

Section 3005 of the Affordable Care Act added new sections 1866(a)(1)(W) and (k) to the Act. Section 1866(k) of the Act establishes a quality reporting program for hospitals described in section 1886(d)(1)(B)(v) of the Act (referred to as ''PPS-Exempt Cancer Hospitals'' or ''PCHs'') that specifically applies to PCHs that meet the requirements under 42 CFR 412.23(f). Section 1866(k)(1) of the Act states that, for FY 2014 and each subsequent fiscal year, a PCH must submit data to the Secretary in accordance with section 1866(k)(2) of the Act with respect to such fiscal year.

The PCHQR Program strives to put patients first by ensuring they are empowered to make decisions about their own healthcare along with their clinicians using information from data-driven insights that are increasingly aligned with meaningful quality measures. We support technology that reduces burden and allows clinicians to focus on providing high quality health care for their patients. We also support innovative approaches to improve quality, accessibility, and affordability of care while paying particular attention to improving clinicians' and beneficiaries' experience when interacting with CMS programs. In combination with other efforts across the Department of Health and Human Services, we believe the PCHQR Program helps to incentivize hospitals to improve healthcare quality and value, while giving patients the tools and information needed to make the best decisions for them. We recognize that the PCHQR Program represents a key component of the way that we provide patients with quality measurement data for use in healthcare decision-making, and we have made efforts to review existing policies to identify how to move the program forward in the least burdensome manner possible while continuing to incentivize improvement in the quality of care provided to patients. For additional background information, including previously finalized measures and other policies for the PCHQR Program, we refer readers to the following final rules: FY 2013 IPPS/LTCH PPS final rule (77 FR 53556 through 53561); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50838 through 50846); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277 through 50288); the FY 2016 IPPS/LTCH PPS final rule (80 FR 49713 through 49723); and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57182 through 57193).

2. Criteria for Removal and Retention of PCHQR Program Measures

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57182 through 57183), we adopted policies for measure retention and removal. We generally retain measures from the previous year's PCHQR Program measure set for subsequent years' measure sets, except when we specifically propose to remove or replace a measure. We adopted the following measure removal criteria for the PCHQR Program, which are based on criteria established in the Hospital IQR Program (80 FR 49641 through 49642):

- Measure performance among PCHs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures);
- A measure does not align with current clinical guidelines or practice;
- The availability of a more broadly applicable measure (across settings or populations) or the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic;
- Performance or improvement on a measure does not result in better patient outcomes;
- The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic;
- Collection or public reporting of a measure leads to negative unintended consequences other than patient harm; and
- It is not feasible to implement the measure specifications.

For the purposes of considering measures for removal from the program, we consider a measure to be ''topped-out'' if there is statistically indistinguishable performance at the 75th and 90th percentiles and the truncated coefficient of variation is less than or equal to 0.10.

However, we recognized that there are times when measures may meet some of the outlined criteria for removal from the program, but continue to bring value to the program. Therefore, we adopted the following criteria for consideration in determining whether to retain a measure in the PCHQR Program, which also are based on criteria established in the Hospital IQR Program (80 FR 49641 through 49642):

- Measure aligns with other CMS and HHS policy goals;
- Measure aligns with other CMS programs, including other quality reporting programs; and
- Measure supports efforts to move PCHs towards reporting electronic measures.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20076), we did not propose any changes to these policies.

3. Retention and Removal of Previously Finalized Quality Measures for PCHs Beginning With the FY 2020 Program Year

a. Background

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53556 through 53561), we

finalized five quality measures for the FY 2014 program year and subsequent years. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50837 through 50847), we finalized one new quality measure for the FY 2015 program year and subsequent years and 12 new quality measures for the FY 2016 program year and subsequent years. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50278 through 50280), we finalized one new quality measure for the FY 2017 program year and subsequent years. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49713 through 49719), we finalized three new CDC NHSN measures for the FY 2018 program year and subsequent years, and finalized the removal of six previously finalized measures for fourth quarter (Q4) 2015 discharges and subsequent years. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57183 through 57184), for the FY 2019 program year and subsequent years, we finalized one additional quality measure and updated the Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382) measure.

We refer readers to the final rules referenced in section IX.B.1. of the preamble of this final rule for more information regarding these previously finalized measures.

b. Removal of Measures From the PCHQR Program Beginning With the FY 2020 Program Year

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20076 through 20077), based on a review of the above criteria, we proposed to remove the following clinical process/cancer specific treatment measures from the PCHQR Program beginning with the FY 2020 program year because they are topped-out:

- Adjuvant Chemotherapy is Considered or Administered Within 4 Months (120 Days) of Diagnosis to Patients Under the Age of 80 with AJCC III (Lymph Node Positive) Colon Cancer (PCH–01/NQF #0223);
- Combination Chemotherapy is Considered or Administered Within 4 Months (120 Days) of Diagnosis for Women Under 70 with AJCC T1c, or Stage II or III Hormone Receptor Negative Breast Cancer (PCH–02/NQF #0559); and
- Adjuvant Hormonal Therapy (PCH–03/NQF #0220).

We first adopted these three Clinical Process/Cancer Specific Treatment measures for the FY 2014 program year in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53556 through 53561). We refer readers to that rule for a detailed discussion of the measures. However, based on an analysis of data from January 1, 2014 through September 30, 2015, we have determined that these three measures meet our topped-out criteria. This analysis, performed by the HCQIS Reports and Analytics Team, evaluated data sets provided from Program Data Management and calculated the 5th, 10th, 25th, 50th, 75th, 90th, and 95th percentiles of national facility performance for each measure. For measures where higher values indicate better performance, the percent relative difference (PRD) between the 75th and 90th percentiles were obtained by taking their absolute difference divided by the average of their values and result multiplied by 100. To calculate the truncated coefficient of variation (TCV), the lowest 5 percent and the highest 5 percent of hospital rates were discarded before calculating the mean and standard deviation for reach measure.

The following criteria were applied to the results:

- For measures ranging from 0–100 percent, with 100 percent being best, national measure data for the 75th and 90th percentiles have a relative difference of <=5 percent, or for measures ranging from 0–100 percent, with 100 percent being the best, performance achieved by the median hospital is >=95 percent, and national measure data have a truncated coefficient of variation <=0.10.
- For measures ranging from 0–100 percent, with 0 percent being best, national measure data for the complement of the 10th and 25th percentiles have a relative difference of <=5 percent, or for measures ranging from 0–100 percent, with 0% being best, national measure data for the median hospital is <=5 percent, or for other measures with a low number indicating good performance, national measure data for the 10th and 25th percentiles have a relative difference of <=5 percent, and national measure data have a truncated coefficient of variation <=0.10.

The results for 2014 and 2015 are set out in the tables below.

TOPPED-OUT ANALYSIS RESULTS FOR PCHQR MEASURES

[2014]

Measure	Mean	Median	75th Percentile	90th Percentile	Relative difference (%)	TCV	Topped-out
PCH–01	.9680	.9800	1.0000	1.0000	0.0000	.0313	Yes
PCH–02	.9501	.9595	.9821	1.0000	1.8018	.0358	Yes
PCH–03	.9714	.9682	.9823	.9930	1.0807	.0149	Yes

TOPPED-OUT ANALYSIS RESULTS FOR PCHQR MEASURES

[2015]

Measure	Mean	Median	75th Percentile	90th Percentile	Relative difference (%)	TCV	Topped-out
PCH–01	.9824	1.0000	1.0000	1.0000	0.0000	.0169	Yes
PCH–02	.9389	.9434	.9750	1.0000	2.532	.0431	Yes
PCH–03	.9383	.9449	.9556	.9703	1.535	.0232	Yes

Based on this analysis, we have concluded that these three measures are topped-out and, as discussed below, we believe that collecting PCH data on these measures does not further program goals.

We believe that continuing to collect PCH data on these measures does not further program goals of improving quality, given that measure performance is so high and unvarying that meaningful distinctions and

improvements in performance can no longer be made. We believe that these measures also do not meet the criteria for retention of an otherwise topped-out measure, as they do not align with other HHS and CMS policy goals, such as moving toward outcome measures; do not align with other CMS programs; and do not support the movement to electronic clinical quality measures due to the chart abstraction required to collect the data for these measures. If we determine at a subsequent point in the future that hospital adherence to these practices has unacceptably declined, we may propose to readopt these measures in future rulemaking.

We invited public comment on our proposal to remove these three measures from the PCHQR Program beginning with the FY 2020 program year.

Comment: Several commenters agreed with the proposal to remove the three cancer-specific measures from the PCHQR Program because they meet topped-out criteria. Commenters agreed that, once topped-out, the measures no longer add value to the program, and removing them will remove the burden of collecting and submitting the performance data.

Response: We thank the commenters for their support.

Comment: One commenter recommended that the measures be removed as quickly as possible, and to cease public reporting of the data once the last quarter of data is publicly posted. The commenter stated that waiting until the FY 2020 program year would continue to impose an unwarranted data burden on providers to collect data for measures that are known to be topped-out.

Response: We thank the commenter for the recommendation. We understand that continuing to submit performance data on measures that meet topped-out criteria while the measures are in the process of being discontinued is burdensome. At this time, we expect to begin removing the measures beginning with diagnoses occurring as of January 1, 2018 which will result in the last reporting of the three measures in February 2019.

Comment: One commenter expressed concern that the removal of three cancer-specific measures at once would leave a gap in the measure set's clinical process domain.

Response: We appreciate the commenter's concern. As the PCHQR Program evolves, it is necessary for us to evaluate whether existing measures continue to meet Program goals and advance the Program. We have concluded that these measures are topped-out pursuant to our topped-out criteria and no longer advance the goals of the program because measure performance is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made; therefore, continued data collection and public reporting does not further program goals of improving quality. In addition, these measures do not meet our criteria for retention because they do not align with other HHS and CMS policy goals, such as moving toward outcome measures; do not align with other CMS programs; and do not support the movement to electronic clinical quality measures due to the chart abstraction required to collect the data for these measures. For these reasons, we believe that their removal is appropriate. We will continue to evaluate the measure set on an annual basis to ensure that we are addressing gaps in the measure set.

Comment: One commenter stated that the removal of the three measures would result in the measure set no longer addressing care provided to two very common cancer types in the elderly population: breast and colon cancer.

Response: We appreciate the commenter's concern. We recognize that breast and colon cancer are both common cancer types, and we note that our measure set also contains measures specific to prostate cancer and to a broader set of cancers. As we maintain and evolve the PCHQR Program measure cohort, we take into consideration not just the specific cancer types addressed under a measure, but also whether the measures meet program and CMS goals. In this instance, we believe it is in the interest of program goals to remove these three topped-out clinical process measures despite the cancers they address as they do not meet the goal of moving toward outcomes measures, do not align with other CMS programs, and do not support the movement to electronic clinical quality measures due to the chart abstraction required to collect the data for these measures. We also do not believe it is in the best interest of the program to continue to require PCHs to report on measures for which the performance level is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made and therefore does not further program goals of improving quality.

Comment: One commenter disagreed with the conclusion that the measures are topped-out, citing data that it gathered from its own clinical data registry of over 1,300 reporting programs that indicate disparities in measure performance.

Response: We appreciate the commenter's views. We have proposed to remove the measures from the PCHQR Program because our analysis shows that the measures are topped-out for the cancer hospitals that participate in the PCHQR Program. Measure performance for the small group of providers that make up the PCHs is, unsurprisingly, different than that gathered from a broader range of providers in a much larger population of 1,300. As we stated, we will continue to monitor performance in this area and reserve the option to propose to reintroduce these measures if we feel that performance merits such reintroduction.

Comment: One commenter recommended retaining the three measures as a composite measure to continue to measure compliance, particularly in sub-populations that demonstrate disparities in care.

Response: We thank the commenter for the suggestion. We have proposed to remove the three measures from the PCHQR Program because our analysis of measure performance indicates that they meet the program's topped-out criteria, and that measure performance is so high or unvarying that no meaningful distinctions can be drawn from continued performance reporting. Given the burden of the chart abstraction required to collect these three measures, it is not practicable to retain these topped-out measures in the program as a composite measure when performance has been shown to be consistently high over more than one performance period. We also do not believe a composite measure would address the issue of the measures' topped-out status, which is an issue of lack of variation in performance. We will continue to evaluate the measure set in each rulemaking cycle, and should we determine that these measures should be reintroduced in future rulemaking, we will take commenter's suggestion under consideration.

After consideration of the public comments we received, we are finalizing our proposal to remove the following clinical process/cancer specific treatment measures from the PCHQR Program beginning with the FY 2020 program year because they are topped-out:

- Adjuvant Chemotherapy is Considered or Administered Within 4 Months (120 Days) of Diagnosis to Patients Under the Age of 80 with AJCC III (Lymph Node Positive) Colon Cancer (PCH–01/NQF #0223);

• Combination Chemotherapy is Considered or Administered Within 4 Months (120 Days) of Diagnosis for Women Under 70 with AJCC T1c, or Stage II or III Hormone Receptor Negative Breast Cancer (PCH–02/NQF #0559); and

• Adjuvant Hormonal Therapy (PCH–03/NQF #0220).

4. New Quality Measures Beginning With the FY 2020 Program Year

a. Considerations in the Selection of Quality Measures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53556), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50837 through 50838), and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50278), we indicated that we take a number of principles into consideration when developing and selecting measures for the PCHQR Program, and that many of these principles are modeled on those we use for measure development and selection under the Hospital IQR Program. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20077), we did not propose any changes to the principles we consider when developing and selecting measures for the PCHQR Program.

Section 1866(k)(3)(A) of the Act requires that any measure specified by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act (the NQF is the entity that currently holds this contract). Section 1866(k)(3)(B) of the Act provides an exception under which, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization. Using the principles for measure selection in the PCHQR Program, we proposed four new measures, described below.

b. New Quality Measures Beginning With the FY 2020 Program Year

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20077 through 20081), beginning with the FY 2020 PCHQR program year, we proposed to adopt two clinical process measures and two intermediate clinical outcome quality measures. These measures meet the requirement under section 1866(k)(3)(A) of the Act that measures specified for the PCHQR Program be endorsed by the entity with a contract under section 1890(a) of the Act (currently the NQF). Although there is no financial incentive or penalty associated with the PCHQR Program, we encourage participation to further the goal of improving the quality of care for the PCH patient population. The proposed measures are:

• Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (NQF #0210);

• Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life (NQF #0213);

• Proportion of Patients Who Died from Cancer Not Admitted to Hospice (NQF #0215); and

• Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days (NQF #0216).

In compliance with section 1890A(a)(2) of the Act, the proposed measures were included on a publicly available document entitled ''List of Measures under Consideration for December 1, 2016,'' [298] a list of quality and efficiency measures under consideration for use in various Medicare programs, and were reviewed by the MAP Hospital Workgroup. The MAP Hospital Workgroup supported the inclusion of these measures in the PCHQR Program in final recommendations it made in its February 2017 report to HHS and CMS for 2016 to 2017.[299] Additional details on MAP discussions of these measures may be found in the ''MAP Pre-Rulemaking Report: 2016 Recommendations on Measures Under Consideration by HHS,'' with additional discussion in the ''MAP 2017 Considerations for Implementing Measures in Federal Programs: Hospitals (Draft Report).'' [300] The sections below outline our rationale for proposing these measures.

(1) Background

The quality of end-of-life care has been identified by the NQF as an area of care that continues to need improvement.[301] End-of-life care may be defined as ''comprehensive care that addresses medical, emotional, spiritual, and social needs during the last stages of a person's terminal illness,'' [302] and may include palliative care. Palliative care is generally defined as multi-faceted, holistic care that anticipates, prevents, and alleviates suffering.[303] Both palliative and end-of-life care can be provided when a patient is receiving hospice services, but it is not necessary to be admitted to hospice to receive such care. The NQF notes that hospice is both a type of care team and a care philosophy, and is intended to enable patients to prepare for death while living as fully as possible.[304] The Institute of Medicine of the National Academies (IOM) has noted that while clinicians are encouraged to counsel patients about palliative care, which betters chances of maintaining a high quality of life when dying, ''too few patients and families receive this help in a timely manner.'' [305] In the same report, the IOM proposed a number of core components of quality end-of-life care. These proposals included offering a referral to hospice if a patient ''has a prognosis of 6 months or less'' and regular revision of a patient's care plan to address the patient's changing needs, as well as the changing needs of the family.[306]

In addition to all of the quality of care benefits of end-of-life care to patients and caregivers, there are financial cost benefits as well. In its Technical Report on palliative and end-of-life care, the NQF cited research indicating that the use of palliative care, including end-of-life care, results in various positive outcomes, including a reduction of

[298] Centers for Medicare and Medicaid Services, List of Measures under Consideration for December 1, 2016. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/Measures-under-Consideration-List-for-2016.pdf.*

[299] National Quality Forum. Measures Application Partnership Hospital Workgroup. MAP 2016–2017 Spreadsheet of Final Recommendations to HHS and CMS. Available at: *http://www.qualityforum.org/MAP_Hospital_Workgroup.aspx.*

[300] National Quality Forum. Measures Application Partnership Hospital Workgroup. MAP 2016–2017 Preliminary Recommendations. Available at: *http://www.qualityforum.org/MAP_Hospital_Workgroup.aspx.* National Quality Forum. Measures Application Partnership Hospital Workgroup. Draft for Comment, MAP 2017 Considerations for Implementing Measures in Federal Programs: Hospitals. Available at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[301] National Quality Forum, Technical Report. Palliative and End-of-Life Care 2015–2016. (December 23, 2016).

[302] National Quality Forum, Technical Report. Palliative and End-of-Life Care 2015–2016. (December 23, 2016).

[303] National Quality Forum, Technical Report. Palliative and End-of-Life Care 2015–2016. (December 23, 2016).

[304] National Quality Forum, Technical Report. Palliative and End-of-Life Care 2015–2016. (December 23, 2016).

[305] Committee on Approaching Death: Addressing Key End of Life Issues, Institute of Medicine: Dying in America: Improving Quality and Honoring Individual Preferences Near the End of Life. Washington DC, National Academies Press, 2015.

[306] Committee on Approaching Death: Addressing Key End of Life Issues, Institute of Medicine: Dying in America: Improving Quality and Honoring Individual Preferences Near the End of Life. Washington DC, National Academies Press, 2015.

costs.[307] For example, one study evaluated the impact of hospice enrollment at different time periods on Medicare expenditures, and found that regardless of when a patient was enrolled in hospice, such patients' subsequent Medicare costs were significantly lowered.[308]

Despite the benefits attributed to the use of palliative and end-of-life services and the increase in their availability, the NQF and others have noted that such services remain underutilized. By proposing to include two process measures and two intermediate clinical outcome measures related to end-of-life care in the PCHQR Program, our intent is to assess the quality of end-of-life care provided to patients in the PCH setting. We recognize that these measures may also be used in the broader population of all hospitals providing cancer care; therefore, as discussed in section IX.A.9.b. of the preamble of this final rule, we invited public comment on the future inclusion of these measures in the Hospital IQR Program. These four measures are described in more detail below.

Comment: Several commenters generally addressed all four measures. Several commenters supported the introduction of the end-of-life measures into the PCHQR measure set, but recommended that we also adopt measures that focus on care planning to ensure that patients are given opportunity to engage in meaningful end-of-life care discussions. Some commenters expressed concern that measuring end-of-life care processes and outcomes could result in unintended consequences and incentives to stint on necessary care, and believed that patient and family engagement is necessary to ensure that patient preferences are considered. Some commenters recommended that we update the measure specifications for all of the proposed measures to incorporate updates to the ICD–10 and CPT code lists. Finally, several commenters agreed that risk adjustment and risk stratification are not necessary for the end-of-life measures proposed.

Response: We appreciate the commenters' suggestions and concerns. We believe that the inclusion of the proposed measures in the program will lead to more, not less, patient and family engagement, because the measures draw attention to the need to understand and clarify patient wishes regarding end-of-life care. Evidence cited by the measure developers and in other research indicates that when death is imminent, providing less aggressive care can improve quality of life for patients. We believe that end-of-life care that adapts to patient experience and need does not result in stinted care, but instead reshapes that care pursuant to changing patient needs and incorporation of patient wishes. We note that these measures are a first step that seeks to broadly assess what is happening in PCHs at the end of life, and will provide a baseline picture of existing end-of-life care at those hospitals. We will continue to consider other measures for future introduction into the program that can complement the proposed measures, and we welcome input from stakeholders as we do so.

(2) Proportion of Patients Who Died From Cancer Receiving Chemotherapy in the Last 14 Days of Life (EOL-Chemo) Measure (NQF #0210)

Chemotherapy is typically used to treat cancer, but in patients with incurable cancer it may also be used with the goal of easing symptoms and improving survival.[309] One study estimated that 6.2 percent of cancer patients continue receiving chemotherapy close to the end of their lives (defined as within 2 weeks of death).[310] However, studies have shown that administering palliative chemotherapy to terminally ill cancer patients may not be beneficial, as it may be associated with higher rates of interventions such as cardiopulmonary resuscitation in the last week of life without any difference in survival.[311] Such patients may also be more likely to die in the intensive care unit (ICU), and less likely to die either at home or in the place where they had expressed preference to die.[312] In addition, research has shown that some patients may receive chemotherapy for treatment instead of palliative care at the end of life, even when treatment has been determined to be unnecessary.[313] While the impetus for continuing treatment may vary from case to case,[314] the available evidence indicates continuing to receive chemotherapy—for palliation or treatment—toward the end of a patient's illness is associated with increased hospitalization and may be associated decreased experience of care.

Researchers have also observed that patients receiving chemotherapy late into the course of a terminal illness tended to be referred to hospice later, resulting in lower quality of life, distress for caregivers, and increased cost.[315] They noted that their results could suggest that either less use chemotherapy at the end of life or more frequent end-of-life discussions could improve the quality of those patients' end-of-life care.[316] Another study of early engagement in palliative care in patients diagnosed with metastatic lung cancer found that patients who received palliative care and less chemotherapy survived longer, in addition to experiencing improvement in quality of life.[317] In this study, palliative care was integrated into standard oncologic care, and included an assessment of physical and psychosocial symptoms as well as care decision assistance.[318] Results from this study showed significantly higher quality of life in the patient cohort receiving palliative care compared to those receiving only the standard oncologic care.[319] In particular,

[307] NQF. Final Report, National Voluntary Consensus Standards: Palliative Care and End-of-Life Care—A Consensus Report. 2012.

[308] Kelley AS et al., Hospice Enrollment Saves Money for Medicare and Improves Care Quality Across a Number of Different Lengths-of-Stay, Health Affairs (March 2013)32:3;552–561.

[309] Wright A et al., Associations Between Palliative Chemotherapy and Adult Cancer Patients' End of Life Care and Place of Death: Prospective Cohort Study, BMJ 2014;348:g1219.

[310] Wright A et al., Associations Between Palliative Chemotherapy and Adult Cancer Patients' End of Life Care and Place of Death: Prospective Cohort Study, BMJ 2014;348:g1219.

[311] Wright A et al., Associations Between Palliative Chemotherapy and Adult Cancer Patients' End of Life Care and Place of Death: Prospective Cohort Study, BMJ 2014;348:g1219.

[312] Wright A et al., Associations Between Palliative Chemotherapy and Adult Cancer Patients' End of Life Care and Place of Death: Prospective Cohort Study, BMJ 2014;348:g1219.

[313] Mack JW et al., Patient Beliefs that Chemotherapy May be Curative and Care Received at the End of Life Among Patients with Metastatic Lung and Colorectal Cancer, Cancer (June 1, 2015)121:11;1891–1897.

[314] Mack JW et al., Patient Beliefs that Chemotherapy May be Curative and Care Received at the End of Life Among Patients with Metastatic Lung and Colorectal Cancer, Cancer (June 1, 2015)121:11;1891–1897.

[315] Wright A et al., Associations Between Palliative Chemotherapy and Adult Cancer Patients' End of Life Care and Place of Death: Prospective Cohort Study, BMJ 2014;348:g1219.

[316] Wright A et al., Associations Between Palliative Chemotherapy and Adult Cancer Patients' End of Life Care and Place of Death: Prospective Cohort Study, BMJ 2014;348:g1219.

[317] Committee on Approaching Death: Addressing Key End of Life Issues, Institute of Medicine: Dying in America: Improving Quality and Honoring Individual Preferences Near the End of Life. Washington DC, National Academies Press, 2015 (citing Temel JC et al. Early Palliative Care for Patients with Metastatic Non-Small-Cell Lung Cancer. NEJM. 2010; 363:733–742).

[318] Temel JC et al. Early Palliative Care for Patients with Metastatic Non-Small-Cell Lung Cancer. NEJM. 2010; 363:733–742.

[319] Temel JC et al. Early Palliative Care for Patients with Metastatic Non-Small-Cell Lung Cancer. NEJM. 2010; 363:733–742.

clinically meaningful improvements in quality of life and mood were noted.[320]

The proposed EOL-Chemo measure addresses the NQS Communication and Care Coordination and Affordable Care domains, and aligns with the CMS Quality Strategy goals of strengthening person and family engagement as partners in their care, and promoting effective communication and coordination of care. The proposed measure is a process measure that evaluates the proportion of patients who died from cancer who received chemotherapy in the last 14 days of life. Similar to the other three end-of-life measures we proposed, this proposed measure seeks to assess the use of chemotherapy at the end-of-life, a practice advanced with the intent to alleviate disease symptoms but which has been shown to also be associated with reduced quality of life and increased costs. This measure was finalized for use in the Merit-based Incentive Payment System (MIPS) in the FY 2017 MIPS final rule with comment period (81 FR 77672). By introducing this measure here, we are seeking to evaluate how often chemotherapy is administered near the end of life in PCHs.

The proposed EOL-Chemo measure cohort includes all Medicare beneficiaries who died of cancer and who received chemotherapy at a PCH within the last 14 days of their lives. The proposed measure uses Medicare administrative claims data to derive the numerator and denominator. The numerator for this measure is defined as cancer patients who received chemotherapy (regardless of whether for treatment or palliative purposes) in the last fourteen days of life. The denominator is defined as patients who died from cancer. Patients for whom numerator or denominator data cannot be identified will not be included in the calculation. The measure specifications contain no exclusions, risk adjustments or risk stratifications because the measure is intended to evaluate the quality of care provided to all cancer patients at the end of life. The measure will be calculated as the numerator divided by the denominator. Measure specifications for the proposed EOL-Chemo measure can be accessed on the NQF's Web site at: *http://www.qualityforum.org/Publications/2016/12/Palliative_and_End-of-Life_Care_2015-2016.aspx*.

We invited public comment on our proposal to adopt the Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (NQF #0210) measure for the FY 2020 program year and subsequent years.

Comment: Many commenters supported the introduction of the EOL-Chemo measure into the PCHQR Program. Commenters stated that the measure will improve care for cancer patients by encouraging providers to have difficult but necessary conversations with their patients; that it addresses treatment that could lead to unnecessary and futile care; that in concert with the other end-of-life measures proposed, this measure will promote accountability and drive improvement; and because it addresses a measurement gap. Commenters also noted that the measure was recently re-endorsed by the NQF.

Response: We thank the commenters for their support.

Comment: Several commenters recommended modification of the measure specifications to incorporate exclusions for patient preference, patients in clinical trials, and palliative chemotherapy, and urged recognition in reporting that a performance rate of zero is not the goal.

Response: The measure is intended to gather information on the proportion of patients who receive chemotherapy close to the end of life regardless of the purpose of that chemotherapy and, to that end, does not distinguish between curative and palliative chemotherapy, or patients receiving chemotherapy as part of a clinical trial. We appreciate that commenters find it important to distinguish between chemotherapy used for palliative purposes as opposed to curatively, as well as the fact that some patients may choose to continue to receive curative or experimental chemotherapy until the end of life, perhaps despite medical advice. We do not believe, however, that it would be appropriate to modify measure specifications during the rule process without sufficient data analysis and clinical review to assess appropriateness for the measures. As with all measures adopted for the PCHQR Program, we will monitor the measure and continue to assess its use in the program as specified over time. We agree that a performance rate of zero is not a reasonable goal, and note this is not the intent of the measure. We will evaluate ways to address this as part of publicly reporting measure data in the future. After consideration of the public comments we received, we are finalizing our proposal to adopt the Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (NQF #0210) measure for the FY 2020 program year and subsequent years.

(3) Proportion of Patients Who Died From Cancer Admitted to the ICU in the Last 30 Days of Life (EOL–ICU) Measure (NQF #0213)

A number of research studies have determined that cancer care can become more aggressive at the end of life, which can result in a lower quality of care and lower quality of life.[321] Care defined as ''aggressive'' may include the ''possible misuse of treatment resulting in high rates of emergency room visits, hospitalization, or ICU stays for terminal patients'' in addition to overuse of chemotherapy close to death and the underuse of hospice.[322] In a retrospective study of patients with advanced lung cancer, researchers found that between 1993 and 2002, the number of patients being admitted to the ICU near death increased, and while in the ICU, one in four of those patients received mechanical ventilation, despite the likelihood that neither intervention would necessarily have effect on the advanced cancer.[323] In this study, two-thirds of the patients died within a month of their admission to the ICU, which the authors interpreted as demonstrating that ICU admission in the context of advanced lung cancer was potentially ineffective.[324] The authors noted other studies that showed that in-hospital mortality during ICU admissions exact a toll on patients and families in terms of ''financial cost, emotional burden, and failed expectations.'' [325] The impact of ICU admission at the end of life is also observed amongst caregivers, who report excellent end-of-life care less often for patients admitted to the ICU within 30 days of death compared to those who are not.[326]

[320] Temel JC et al. Early Palliative Care for Patients with Metastatic Non-Small-Cell Lung Cancer. NEJM. 2010; 363:733–742.

[321] Barbera L et al., Quality of End-of-Life Cancer Care in Canada: A Retrospective Four-Province Study Using Administrative Health Care Data, Oncology (October 2015)22:5;341–355; Earle CC et al. Aggressiveness of Cancer Care Near the End of Life: Is It a Quality-of-Care Issue? Journal of Clinical Oncology. 2008; 26:23, 3860–3866.

[322] Earle CC et al. Aggressiveness of Cancer Care Near the End of Life: Is It a Quality-of-Care Issue? Journal of Clinical Oncology. 2003; 26:23, 3860–3866.

[323] Sharma G et al., Trends in End-of-Life ICU Use Among Older Adults with Advanced Lung Cancer, Chest (January 2008)133:1;72–78.

[324] Sharma G et al., Trends in End-of-Life ICU Use Among Older Adults with Advanced Lung Cancer, Chest (January 2008)133:1;72–78.

[325] Sharma G et al., Trends in End-of-Life ICU Use Among Older Adults with Advanced Lung Cancer, Chest (January 2008)133:1;72–78.

[326] Wright AA et al., Family Perspectives on Aggressive Cancer Care Near the End of Life, JAMA (2016)315:3;284–292.

Patients who are not admitted to the ICU or involved in other aggressive mechanisms of care in their final week of life have been shown to experience a higher quality of life via less physical and emotional distress.[327] Researchers have theorized that while patients who die at home are able to have care that focuses on symptom management and comfort; hospitals and ICUs focus instead on keeping the patient alive.[328]

ICU admission at the end of life is also costly,[329] with ICU admissions identified as one of the ''key drivers of resource use and expenditures.'' [330] Studies of claims data indicate that aggressiveness of care given to Medicare beneficiaries with cancer at the end of life continues to increase, with nearly 25 percent of Medicare expenditures in the last month of such beneficiaries' lives, despite limited evidence that such an intervention improves patient outcomes.[331]

The proposed EOL–ICU measure addresses the NQS Communication and Care Coordination and Affordable Care domains, and addresses several CMS Quality Strategy goals: making care safer by reducing harm caused in the delivery of care; strengthening person and family engagement as partners in their care; and promoting effective communication and coordination of care. The proposed EOL–ICU measure is an intermediate clinical outcome measure that assesses whether cancer patients were admitted to the ICU in the last 30 days of their lives. As with the other three proposed end-of-life measures discussed in section IX.B.4.b. of the preamble of this final rule, this proposed measure seeks to evaluate the end-of-life care provided to patients at PCHs. In particular, we seek to assess the frequency of end-of-life admissions to the ICU in this setting, as the research has shown that interventions provided in the ICU to patients with irreversible disease can be futile and may negatively impact patients' quality of life. We recognize, however, that in some cases ICU admissions may be appropriate, and note that this measure broadly assesses how many patients are admitted to the ICU close to death, without excluding admissions for specific reasons.

The proposed EOL–ICU measure cohort includes Medicare beneficiaries who are PCH patients who died of cancer and who were admitted to the ICU within the last thirty days of their lives. This proposed measure uses Medicare administrative claims data to derive the numerator and denominator. The numerator for this measure is defined as the number of patients who died from cancer and who were admitted to the ICU in the last 30 days of life. The denominator is defined as patients who died from cancer. The measure specifications do not contain exclusions from the denominator and do not provide for risk adjustment or risk stratification in order to assess the quality of care provided to all cancer patients at the end of life. The rate of ICU admissions in the last 30 days of life will be calculated from the numerator divided by the denominator. Measure specifications for the proposed EOL–ICU measure can be accessed on the NQF's Web site at: *http://www.qualityforum.org/Publications/2016/12/Palliative_and_End-of-Life_Care_2015-2016.aspx*.

We invited public comment on our proposal to adopt the Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life (NQF #0213) measure for the FY 2020 program year and subsequent years.

Comment: Many commenters supported the introduction of the EOL–ICU measure into the PCHQR Program. Commenters expressed that the measure will improve care for cancer patients by encouraging providers to have difficult but necessary conversations with their patients as well as allowing PCHs to identify where patients need additional supportive care; that it addresses treatment that could lead to unnecessary and futile care; that in concert with the other end-of-life measures proposed, this measure will promote accountability and drive improvement; and because it addresses a measurement gap. Commenters also noted that the measure was recently re-endorsed by the NQF and that the measure aligns with NQF's goal to improve end-of-life care.

Response: We thank the commenters for their support.

Comment: Several commenters recommended modification of the measure specifications to incorporate exclusions for bone marrow transplants with curative intent as well as exclusions for other patient characteristics. One commenter recommended against public reporting of the EOL–ICU measure or introducing the measure into quality programs tied to payment until adjustments to the specifications are made to account for patient characteristics.

Response: We thank the commenters for these recommendations. The measure is intended to gather information on the proportion of patients admitted to the ICU close to the end of life and, to that end, does not distinguish between reasons for admission because the measure's goal is to assess such admissions overall for the cancer population regardless of reason for admission to the ICU. As the data is reported, we can determine whether there is a need to further evolve the program and measure specifications to account or exclude for specific reasons for admission. We do not believe, however, that it would be appropriate to modify measure specifications during the rule process without sufficient data analysis and clinical review to assess appropriateness for the measures. Finally, we note that the PCHQR Program is not tied to payment.

Comment: One commenter recommended that PCHs be provided with confidential performance data that stratifies rates between ICU admission at a PCH as compared to that at non-PCH providers.

Response: We continue to evaluate ways to report performance data that is meaningful not only to providers for their own quality improvement but also to patients, so that they can make informed choices about their healthcare providers. At the present time, we are unable to provide reports such as the one recommended above due to the operational concerns associated with collecting and reporting this data to PCHs. However, we welcome suggestions from providers as to ways to provide meaningful data to help them improve their performance.

After consideration of the public comments we received, we are finalizing our proposal to adopt the Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life (NQF #0213) measure for the FY 2020 program year and subsequent years.

[327] Zhang B et al., Factors Important to Patients' Quality-of-Life at the End-of-Life, Arch. Intern. Med (August 13, 2012)172:15;1133–1142; Wright AA et al., Place of Death: Correlations with Quality of Life of Patients with Cancer and Predictors of Bereaved Caregivers' Mental Health, J Clin Oncol (October 10, 2010)28:29;4457–4464.

[328] Wright AA et al., Place of Death: Correlations with Quality of Life of Patients with Cancer and Predictors of Bereaved Caregivers' Mental Health, J Clin Oncol (October 10, 2010)28:29;4457–4464.

[329] Wright AA et al., Place of Death: Correlations with Quality of Life of Patients with Cancer and Predictors of Bereaved Caregivers' Mental Health, J Clin Oncol (October 10, 2010)28:29;4457–4464.

[330] Langton JL et al., Retrospective Studies of End-of-Life Resource Utilization and Costs in Cancer Care Using Health Administrative Data: A Systematic Review, Palliative Medicine (2014)28:10;1167–1196.

[331] Wright AA et al. Place of Death: Correlations with Quality of Life of Patients with Cancer and Predictors of Bereaved Caregivers' Mental Health. Journal of Clinical Oncology. (2010)28:4457–4464.

(4) Proportion of Patients Who Died from Cancer Not Admitted to Hospice (EOL-Hospice) Measure (NQF #0215)

A number of research studies have determined that cancer care can become more aggressive at the end of life, which can result in a lower quality of care and lower quality of life.[332] Such aggressive care has been identified to include the underutilization of hospice,[333] which is either lack of referral or late referral to hospice services.[334] Patients with advanced cancer who die while admitted to the hospital have been shown to have lower quality of life than those who die at home with hospice services.[335]

By contrast, studies have shown that cancer patients enrolled in hospice were hospitalized less frequently and received fewer procedures than those who were not receiving hospice care.[336] In addition, cancer patients who were enrolled in hospice 5 to 8 weeks prior to their deaths demonstrated significant cost savings, with savings decreasing as the time period enrolled shortens.[337] Researchers theorize that one reason aggressive or ''injudicious'' treatment occurs at the end of life is that end-of-life discussions are not being held with patients, and note that it is ''the physician's responsibility to counsel patients and their families and . . . focus on the need for effective palliative care as patients approach the end of life.'' [338]

The proposed EOL-Hospice measure addresses the NQS Communication and Care Coordination and Affordable Care domains, as well as the CMS Quality Strategy goals of strengthening person and family engagement as partners in their care and promoting effective communication and coordination of care. The proposed measure is a process measure that assesses the proportion of patients who died from cancer who were not admitted to hospice. This measure evaluates whether or not patients were admitted to hospice, and then ties in to the following measure (EOL–3DH), which evaluates whether patients who were admitted to hospice were admitted to hospice late in the course of their illness, defined as within 3 days of their death. We discuss this proposed follow-on measure, EOL–3DH, in more detail below in section IX.B.4.b.(5) of the preamble of this final rule. In summary, EOL-Hospice seeks to evaluate, simply, whether patients were admitted to hospice or not; the proposed follow-on measure EOL–3DH will then assess whether those patients admitted to hospice were admitted in a timely fashion to derive maximum benefit from hospice services. We do not expect PCHs to achieve perfect rates on the EOL-Hospice measure because we understand that some patients may refuse hospice, or that there may be additional intervening events or circumstances that impact whether or not a patient is admitted to hospice.

The proposed EOL-Hospice measure cohort includes Medicare beneficiaries who are PCH patients who died of cancer. The proposed measure uses Medicare administrative claims data to derive the numerator and denominator. The numerator in this proposed measure is defined as the proportion of PCH patients not enrolled in hospice. The denominator is defined as patients who died from cancer. The measure specifications contain no denominator exclusions nor any risk adjustment or risk stratification. The proposed measure is calculated by dividing the numerator by the denominator. Measure specifications for the proposed EOL-Hospice measure can be accessed on the NQF's Web site at: *http://www.qualityforum.org/Publications/2016/12/Palliative_and_End-of-Life_Care_2015-2016.aspx.*

We invited public comment on our proposal to adopt the Proportion of Patients Who Died from Cancer Not Admitted to Hospice (NQF #0215) measure for the FY 2020 program year and subsequent years.

Comment: Many commenters supported the introduction of the EOL-Hospice measure into the PCHQR Program. Commenters stated that the measure will improve care for cancer patients by encouraging providers to have difficult but necessary conversations with their patients as well as allowing earlier referrals to hospice care. Commenters noted that hospice referrals often come too late to be of benefit to patients, and that the measure may help PCHs identify opportunities to ensure appropriate care transitions and planning. Commenters also expressed that the measure addresses treatment that could lead to unnecessary and futile care; that in concert with the other end-of-life measures proposed, this measure will promote accountability and drive improvement; and because it addresses a measurement gap. Commenters also noted that the measure was recently re-endorsed by the NQF and that the measure aligns with NQF's goal to improve end-of-life care.

Response: We thank the commenters for their support.

Comment: One commenter recommended adoption of the EOL-Hospice measure with modification of the measure specifications to include hospital-based palliative care services into the measure numerator. Another commenter recommended expansion of the measure to include such services because the ability of palliative care services to provide symptom management.

Response: We appreciate commenters' recommendations. At this point, we are interested in assessing whether or not patients in PCHs are admitted to hospice prior to death because patient admission to hospice has been shown to be an indicator of the aggressiveness of care at the end of life and whether discussions are being held with patients to discuss choice and preference regarding care at the end of life. We believe that pairing this measure with the EOL–3DH outcome measure, discussed below, provides additional insight into hospice admission at PCHs. We recognize the importance of palliative care services in alleviating symptoms during the disease process, and welcome recommendations as to additional measures related to palliative care for possible incorporation into the PCHQR Program in the future.

Comment: One commenter did not support the introduction of the EOL-Hospice measure. The commenter instead recommended the adoption of a process measure that evaluates if and when terminally ill patients are timely given the opportunity to consider hospice.

Response: We appreciate the commenter's concern, and agree that it is important to gauge whether and when patients are alerted to their prognosis and given an opportunity to make decisions regarding their end-of-life care. We intend to take under advisement the commenter's suggestion

[332] Barbera L et al., Quality of End-of-Life Cancer Care in Canada: A Retrospective Four-Province Study Using Administrative Health Care Data, Oncology (October 2015)22:5;341–355; Earle CC et al. Aggressiveness of Cancer Care Near the End of Life: Is It a Quality-of-Care Issue? Journal of Clinical Oncology. 2008; 26:23, 3860–3866.

[333] Earle CC et al. Aggressiveness of Cancer Care Near the End of Life: Is It a Quality-of-Care Issue? Journal of Clinical Oncology. 2003; 26:23, 3860–3866.

[334] Earle CC et al. Aggressiveness of Cancer Care Near the End of Life: Is It a Quality-of-Care Issue? Journal of Clinical Oncology. 2003; 26:23, 3860–3866.

[335] Wright AA et al., Place of Death: Correlations with Quality of Life of Patients with Cancer and Predictors of Bereaved Caregivers' Mental Health, J Clin Oncol (October 10, 2010)28:29;4457–4464.

[336] Obermeyer Z et al., Association Between the Medicare Hospice Benefit and Health Care Utilization and Costs for Patients with Poor-Prognosis Cancer, JAMA (2014)312:18;1888–1896.

[337] Obermeyer Z et al., Association Between the Medicare Hospice Benefit and Health Care Utilization and Costs for Patients with Poor-Prognosis Cancer, JAMA (2014)312:18;1888–1896.

[338] Earle CC et al. Aggressiveness of Cancer Care Near the End of Life: Is It a Quality-of-Care Issue? Journal of Clinical Oncology. 2003; 26:23, 3860–3866.

to adopt a process measure assessing if and when a terminally ill cancer patient is given an opportunity to consider hospice; however, we would not view such a measure as an alternative to the proposed EOL-Hospice measure. We believe that the proportion of patients admitted to hospice is an important metric, and is particularly valuable when considered alongside the proposed EOL–3DH measure, which assesses the proportion of cancer patients who died after being admitted to hospice for less than three days.

After consideration of the public comments we received, we are finalizing our proposal to adopt the Proportion of Patients Who Died From Cancer Not Admitted to Hospice (NQF #0215) measure for the FY 2020 program year and subsequent years.

(5) Proportion of Patients Who Died From Cancer Admitted to Hospice for Less Than 3 Days (EOL–3DH) Measure (NQF #0216)

Older studies of patient cohorts from the mid-1990s have shown that, though there was an increasing trend to admit cancer patients to hospice, the number of patients admitted close to death was also increasing, about which the authors surmised that hospice care was not being used to mitigate symptoms but only to manage death.[339] Patients with cancer have been identified as the largest users of hospice, but are also the cohort with the highest rates of hospice stays of less than 3 days.[340]

In one study involving cancer patients' family members, patients' loved ones were more likely to report that the patients received excellent end-of-life care when hospice was initiated earlier than three days prior to death.[341] The researchers indicated that enhancing counseling of patients and families and early referral to palliative care services could result in more ''preference-sensitive care for patients'' and overall improvement in the quality of care cancer patients receive at the end of life.[342] Because this and other research indicates that earlier discussion with patients about palliative care can positively impact the care received at the end of life, including timely admission to hospice, we believe including the proposed EOL–3DH measure in the measure set will incentivize timely discussions and admissions to hospice within the PCH setting. We believe that the emphasis on timely admission to hospice may lead to improved quality of care for cancer patients at PCHs.

The proposed EOL–3DH measure addresses the NQS Communication and Care Coordination domain. It also addresses two CMS Quality Strategy goals: Strengthening person and family engagement as partners in their care and promoting effective communication and coordination of care. The proposed EOL–3DH measure is an intermediate clinical outcome measure that assesses the proportion of patients who died from cancer who were admitted to hospice late in the course of their illness, within 3 days of their death. The measure ties in to the proposed process measure (EOL-Hospice) we discuss in section IX.B.4.b.(4) of the preamble of this final rule, above, and assesses whether, if patients were admitted to hospice, they were admitted prior to or when death was immediately imminent. As discussed, research has shown that the longer patients receive hospice services before the end of life, the more improvements in their quality of life and mood are observed.

The proposed EOL–3DH measure cohort includes Medicare beneficiaries who are PCH patients that died of cancer and were admitted to hospice within the last 3 days of their lives. The proposed measure uses Medicare administrative claims data to derive the numerator and denominator. The numerator is defined as the number of patients who died from cancer and spent fewer than 3 days in hospice. The denominator is defined as the number of patients who died from cancer and were admitted to hospice. There are no exclusions from the denominator in the measure specifications, nor risk adjustment or risk stratification, because the goal of the measure is to assess the quality of care provided to all cancer patients at the end of life. Measure specifications for the proposed EOL–3DH measure can be accessed on the NQF's Web site at: *http://www.qualityforum.org/Publications/2016/12/Palliative_and_End-of-Life_Care_2015-2016.aspx.*

We invited public comment on our proposal to adopt the Proportion of Patients Who Died From Cancer Admitted to Hospice for Less Than 3 Days (NQF #0216) measure for the FY 2020 program year and subsequent years.

Comment: Many commenters supported the introduction of the EOL–3DH measure into the PCHQR Program. Commenters stated that the measure will improve care for cancer patients by encouraging providers to have difficult but necessary conversations with their patients, promoting patient and family engagement in decision-making, as well as allowing earlier referrals to hospice care. Commenters noted that hospice referrals often come too late to be of benefit to patients, and that the measure may help PCHs identify opportunities to ensure appropriate care transitions and planning. Commenters also expressed that the measure addresses treatment that could lead to unnecessary and futile care; that in concert with the other proposed end-of-life measures, this measure will promote accountability and drive improvement; and because it addresses a measurement gap. Commenters also noted that the measure was recently re-endorsed by the NQF and that the measure aligns with NQF's goal to improve end-of-life care.

Response: We thank the commenters for their support.

Comment: One commenter recommended expansion of the measure to include palliative care services because of the ability of such services to provide symptom management. Another commenter recommended risk adjustment of the measure for social risk factors and comorbidities, such as dementia, that could impact timely admission to hospice.

Response: We appreciate commenters' recommendations. At this time, we are interested in adopting the EOL–3DH outcome measure because it will enable us to assess current hospice admitting practices at PCHs. We recognize the importance of palliative care services in alleviating symptoms during the disease process, and we welcome recommendations as to additional measures related to palliative care for possible incorporation into the PCHQR Program in the future. We also welcome recommendations as to other aspects of the measure specifications that could be revised in the future, such as consideration of comorbidities that could delay timely admission, or additional measures that address issues related to timely admission to hospice, for future rulemaking.

After consideration of the public comments we received we are finalizing our proposal to adopt the Proportion of Patients Who Died From Cancer Admitted to Hospice for Less Than 3 Days (NQF #0216) measure for the FY

[339] Earle CC et al., Aggressiveness of Cancer Care Near the End of Life: Is It a Quality-of-Care Issue? Journal of Clinical Oncology. August 2008; 26:23; 3860–3866; Earle CC et al., Trends in the Aggressiveness of Cancer Care Near the End of Life, Journal of Clinical Oncology 22 no. 2 (January 2004) 315–321.

[340] Obermeyer Z et al., Association Between the Medicare Hospice Benefit and Health Care Utilization and Costs for Patients with Poor-Prognosis Cancer, JAMA (2014)312:18;1888–1896.

[341] Wright AA et al., Family Perspectives on Aggressive Cancer Care Near the End of Life, JAMA (2016)315:3;284–292.

[342] Wright AA et al., Family Perspectives on Aggressive Cancer Care Near the End of Life, JAMA (2016)315:3;284–292.

2020 program year and subsequent years.

c. Summary of Previously Finalized and Newly Finalized PCHQR Program Measures for the FY 2020 Program Year and Subsequent Years

In summary, the previously finalized and newly finalized measures for the PCHQR Program for the FY 2020 program year and subsequent years are listed in the table below.

PREVIOUSLY FINALIZED AND NEWLY FINALIZED PCHQR MEASURES FOR THE FY 2020 PROGRAM YEAR AND SUBSEQUENT YEARS

Short name	NQF number	Measure name
Safety and Healthcare-Associated Infection (HAI)		
CLABSI	0139	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection Outcome Measure
CAUTI	0138	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infections Outcome Measure
SSI	0753	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure [currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery]
CDI	1717	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure
MRSA	1716	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* Bacteremia Outcome Measure
HCP	0431	Influenza Vaccination Coverage Among Healthcare Personnel
Clinical Process/Oncology Care Measures		
N/A	0382	Oncology: Radiation Dose Limits to Normal Tissues
N/A	0383	Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology
N/A	0384	Oncology: Medical and Radiation—Pain Intensity Quantified
N/A	0390	Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Prostate Cancer Patients
N/A	0389	Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients
EOL-Chemo	0210	Proportion of Patients Who Died From Cancer Receiving Chemotherapy in the Last 14 Days of Life*
EOL-Hospice	0215	Proportion of Patients Who Died From Cancer Not Admitted to Hospice*
Intermediate Clinical Outcome Measures		
EOL–ICU	0213	Proportion of Patients Who Died From Cancer Admitted to the ICU in the Last 30 Days of Life*
EOL–3DH	0216	Proportion of Patients Who Died From Cancer Admitted to Hospice for Less Than Three Days*
Patient Engagement/Experience of Care		
HCAHPS	0166	HCAHPS
Clinical Effectiveness Measure		
EBRT	1822	External Beam Radiotherapy for Bone Metastases
Claims Based Outcome Measure		
N/A	N/A	Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy

±We note that the previously finalized measures finalized for removal in this final rule are not included in this table. These measures are: (1) Adjuvant Chemotherapy is Considered or Administered Within 4 Months (120 Days) of Diagnosis to Patients Under the Age of 80 with AJCC II (Lymph Node Positive) Colon Cancer; (2) Combination Chemotherapy is Considered or Administered Within 4 Months (120 Days) of Diagnosis for Women Under 70 with AJCC T1c, or Stage II or III Hormone Receptor Negative Breast Cancer; and (3) Adjuvant Hormonal Therapy.

*This measure is finalized for adoption for the FY 2020 program year in section IX.B.4.b of the preamble of this final rule.

5. Accounting for Social Risk Factors in the PCHQR Program

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20082 through 20083), we discussed the issue of accounting for social risk factors in the PCHQR Program. We understand that social risk factors such as income, education, race and ethnicity, employment, disability, community resources, and social support (certain factors of which are also sometimes referred to as socioeconomic status (SES) factors or socio-demographic status (SDS) factors) play a major role in health. One of our core objectives is to improve beneficiary outcomes including reducing health disparities, and we want to ensure that all beneficiaries, including those with social risk factors, receive high quality care. In addition, we seek to ensure that the quality of care furnished by providers and suppliers is assessed as fairly as possible under our programs while

ensuring that beneficiaries have adequate access to excellent care.

We have been reviewing reports prepared by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) [343] and the National Academies of Sciences, Engineering, and Medicine on the issue of measuring and accounting for social risk factors in CMS' quality measurement and payment programs, and considering options on how to address the issue in these programs. On December 21, 2016, ASPE submitted a Report to Congress on a study it was required to conduct under section 2(d) of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. The study analyzed the effects of certain social risk factors of Medicare beneficiaries on quality measures and measures of resource use used in one or more of nine Medicare value-based purchasing programs.[344] The report also included considerations for strategies to account for social risk factors in these programs. In a January 10, 2017 report released by the National Academies of Sciences, Engineering, and Medicine, that body provided various potential methods for measuring and accounting for social risk factors, including stratified public reporting.[345]

As noted in the FY 2017 IPPS/LTCH PPS final rule, the NQF undertook a 2-year trial period in which certain new measures, measures undergoing maintenance review, and measures endorsed with the condition that they enter the trial period were assessed to determine whether risk adjustment for selected social risk factors is appropriate for these measures. This trial entailed temporarily allowing inclusion of social risk factors in the risk-adjustment approach for these measures. We await the recommendations of the NQF trial on risk adjustment for quality measures.

As we continue to consider the analyses and recommendations from these reports and await the results of the NQF pilot on risk adjustment for quality measures, we are continuing to work with stakeholders in this process. As we have previously communicated, we are concerned about holding providers to different standards for the outcomes of their patients with social risk factors because we do not want to mask potential disparities or minimize incentives to improve the outcomes for disadvantaged populations. Keeping this concern in mind, while we sought input on this topic previously, we continue to seek public comment on whether we should account for social risk factors in the PCHQR Program, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors. Examples of methods include: Confidential reporting to providers of measure rates stratified by social risk factors; public reporting of stratified measure rates; and potential risk adjustment of a particular measure as appropriate based on data and evidence.

In addition, in the proposed rule, we sought public comment on which social risk factors might be most appropriate for reporting stratified measure scores and/or potential risk adjustment of a particular measure. Examples of social risk factors include, but are not limited to, dual eligibility/low-income subsidy, race and ethnicity, and geographic area of residence. We also sought comments on which of these factors, including current data sources where this information would be available, could be used alone or in combination, and whether other data should be collected to better capture the effects of social risk. We also welcomed comment on operational considerations. Of note, implementing any of the above methods would be taken into consideration in the context of how this and other CMS programs operate (for example, data submission methods, availability of data, statistical considerations relating to reliability of data calculations, among others).

We received several comments in response to our request for public comment on whether we should account for social risk factors in the PCHQR Program and if so, what method or combination of methods would be most appropriate for accounting for social risk factors.

Comment: Commenters were generally supportive of implementing an approach to account for social risk factors in the PCHQR Program. Commenters encouraged evaluation of each measure for applicability of adjustment for social risk factors, with considerations given to type and purpose of measure and whether or not a measure is reported publicly. Commenters also urged careful balancing of the need to risk adjust for social risk factors with the potential burden of collecting more data to perform such risk adjustment.

Response: We appreciate the comments and interest in this topic. As we have previously stated, we are concerned about holding providers to different standards for the outcomes of their patients with social risk factors, because we do not want to mask potential disparities or minimize incentives to improve outcomes for disadvantaged populations. We believe that the path forward should incentivize improvements in health outcomes for disadvantaged populations while ensuring that beneficiaries have access to excellent care. We intend to consider all suggestions as we continue to assess each measure and the overall program. We appreciate that some commenters recommended risk adjustment as a strategy to account for social risk factors, while others noted the potential increased burden of collecting additional data for risk adjustment purposes.

We will consider all suggestions as we continue to assess each measure and the overall program. We intend to conduct further analyses on the impact of strategies such as measure-level risk adjustment and measure stratification by social risk factors, including the options suggested by commenters. As we consider the feasibility of collecting patient-level data and the impact of strategies to account for social risk factors through further analysis, we will continue to evaluate the reporting burden on providers. Future proposals would be made after further research and continued stakeholder engagement.

6. Possible New Quality Measure Topics for Future Years

a. Background

We discussed future quality measure topics and quality measure domain areas in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50280), the FY 2016 IPPS/LTCH PPS final rule (80 FR4979), and the FY 2017 IPPS/LTCH PPS final rule (81 FR 25211). Specifically, we discussed public comment and suggestions for measure topics addressing the following CMS Quality Strategy domains: (1) Making care affordable; (2) communication and care coordination; and (3) working with communities to promote best practices of healthy living. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20083), we welcomed public comment and specific suggestions for measure topics that we should consider for future rulemaking, including considerations related to risk adjustment and the inclusion of social risk factors in risk adjustment for any individual performance measures.

[343] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[344] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[345] National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20083 through 20084), we also sought public comment on six measures for potential future inclusion in the PCHQR Program:

- Localized Prostate Cancer: Vitality;
- Localized Prostate Cancer: Urinary Incontinence;
- Localized Prostate Cancer: Urinary Frequency, Obstruction, and/or Irritation;
- Localized Prostate Cancer: Sexual Function;
- Localized Prostate Cancer: Bowel Function; and
- 30 Day Unplanned Readmissions for Cancer Patients.

These measures are discussed in more detail below.

b. Localized Prostate Cancer: Vitality; Localized Prostate Cancer: Urinary Incontinence; Localized Prostate Cancer: Urinary Frequency, Obstruction, and/or Irritation; Localized Prostate Cancer: Sexual Function; and Localized Prostate Cancer: Bowel Function

The Localized Prostate Cancer measures are five related, patient-reported outcome measures drawn from the Expanded Prostate Inventory Composite (EPIC), which is a survey intended to gather input from patients on their experience. The survey questions are intended to be administered to all non-metastatic prostate cancer patients undergoing radiation or surgical treatment for prostate cancer at the reporting facility (denominator); the numerator is patients with clinically significant changes in each of the listed areas from baseline to follow-up. The goal of the measurement is to identify issues of variation, suboptimal performance, and disparities in care. This measurement aligns with recent initiatives to include patient-reported outcomes and experience of care into quality reporting programs, as well as to incorporate more outcome measures generally. Patient-centered experience measures are also a component of the 2016 CMS Quality Strategy, which emphasizes patient-centered care by rating patient experience as a means for empowering patients and improving the quality of their care and care experience.[346]

These measures were included on the publicly available document entitled ''List of Measures under Consideration for December 1, 2016'' [347] but were not reviewed by the MAP. We anticipate that they will be included on a future list of measures under consideration for MAP review. For further information on these measures, we refer readers to the discussion from the Measures Application Partnership's Hospital Workgroup Discussion at: *http://public.qualityforum.org/MAP/MAP%20Hospital%20Workgroup/2016-2017%20Hospital%20MAP/MAP_Hospital_Workgroup_Discussion_Guide.html#MUC16-375PCHQ.* We requested public comment on the possible inclusion of these measures in future years of the program.

Comment: A number of commenters expressed support for the future introduction of the five Localized Prostate Cancer measures. Commenters noted the importance to patients of measures that assess quality of life as well as the ability of the measures to support meaningful comparisons between providers. Commenters stated that such measures will enable patients to make informed decisions as they will have available quality of care information. A commenter also stated that the measures would improve communications between hospitals and patients.

Response: We appreciate the commenters' support and views on these potential measures.

Comment: One commenter supported the future introduction of the measures and asked whether the tool mentioned as the means for collection, the Expanded Prostate Inventory Composite, would be the only mechanism for documenting patient-reported outcomes.

Response: We thank the commenter for its support. We welcome recommendations and stakeholder input into different mechanisms for collection of patient-reported outcomes and will take such suggestions into consideration for future rulemaking. These measures are being developed based on a single data collection tool, although we understand that there may be several other tools that could potentially collect this information. We will continue to monitor the measures' development and testing to determine the best means of data collection for these measures.

Comment: One commenter asked whether the tool mentioned as the means for collection, the Expanded Prostate Inventory Composite, would support the move to electronic quality reporting.

Response: At this time, we cannot say with certainty whether the particular tool described in the measure specifications would support the move to electronic quality reporting. We thank the commenter for the inquiry and will take this under consideration as we continue to consider these and other measures for possible inclusion in the PCHQR Program in the future.

We thank the commenters and we will consider their views as we develop further measures for use in the PCHQR Program.

c. 30-Day Unplanned Readmissions for Cancer Patients

The 30-Day Unplanned Readmissions for Cancer Patients measure would measure the number of hospital-specific 30-day unscheduled and potentially avoidable readmissions following hospitalization among diagnosed malignant cancer patients. The measure numerator is the total number of unscheduled readmissions within 30 days of index admission. The measure denominator is total PCH admissions within the reporting year for patients, aged 18 years or older, who were discharged alive from the facility with an active malignant cancer diagnosis.

For further information on this measure, we refer readers to the AHRQ National Quality Measure Clearinghouse at: *https://www.qualitymeasures.ahrq.gov/summaries/summary/50490/cancer-30day-unplanned-readmission-rate-for-cancer-patients.* We requested public comment on the possible inclusion of this measure in future years of the program.

Comment: Several commenters generally supported the future inclusion of a 30-day, unplanned readmissions measure for cancer patients, noting that until recently no such measure existed and that the potential measure would take steps toward addressing a gap in the measurement of cancer care. One commenter supported the introduction of a measure even without NQF endorsement, stating that it believed the measure meets the criteria for introduction into the PCHQR Program without endorsement. Another commenter noted that the measure has been shown to demonstrate reliability and validity, and that the measure is currently in use in several of the PCHs for hospital-specific, non-Medicare performance improvement or payment programs. Finally, a commenter noted that the measure incorporates risk adjustment in a way that carefully distinguishes preventable from non-preventable readmissions in cancer patients.

[346] CMS Quality Strategy 2016. Available at: *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/qualityinitiativesgeninfo/downloads/cms-quality-strategy.pdf.*

[347] Centers for Medicare and Medicaid Services, List of Measures under Consideration for December 1, 2016. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/Measures-under-Consideration-List-for-2016.pdf.*

Response: We thank the commenters for their support.

Comment: One commenter supported the future adoption of the measure and encouraged additional consideration and evaluation of a measure that would report a five-year survival rate for cancer.

Response: We appreciate the support for the potential readmissions measure, and we will take the suggestion to adopt a survival rate measure into consideration for future rulemaking.

We thank the commenters and we will consider their views as we develop further measures for use in the PCHQR Program.

7. Maintenance of Technical Specifications for Quality Measures

We maintain technical specifications for the PCHQR Program measures, and we periodically update those specifications. The specifications may be found on the QualityNet Web site at: *https://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228774479863.*

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50281), we adopted a policy under which we use a subregulatory process to make nonsubstantive updates to measures used for the PCHQR Program. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20084), we did not propose any changes to this policy.

8. Public Display Requirements

a. Background

Under section 1866(k)(4) of the Act, we are required to establish procedures for making the data submitted under the PCHQR Program available to the public. Such procedures must ensure that a PCH has the opportunity to review the data that are to be made public with respect to the PCH prior to such data being made public. Section 1866(k)(4) of the Act also provides that the Secretary must report quality measures of process, structure, outcome, patients' perspective on care, efficiency, and costs of care that relate to services furnished in such hospitals on the CMS Web site. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57191 through 57192), we listed our finalized public display requirements. The measures we have finalized for public display are shown in the table below.

PREVIOUSLY FINALIZED PUBLIC DISPLAY REQUIREMENTS

Summary of previously finalized public display requirements	
Measures	Public reporting
• Adjuvant Chemotherapy is Considered or Administered Within 4 Months (120 days) of Diagnosis to Patients Under the Age of 80 with AJCC III (lymph node positive) Colon Cancer (NQF #0223)×.	2014 and subsequent years.
• Combination Chemotherapy is Considered or Administered Within 4 Months (120 days) of Diagnosis for Women Under 70 with AJCC T1cN0M0, or Stage IB—III Hormone Receptor Negative Breast Cancer (NQF #0559)×.	
• Adjuvant Hormonal Therapy (NQF #0220)×	2015 and subsequent years.
• Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382)*	2016 and subsequent years.
• Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology (NQF #0383).	
• Oncology: Medical and Radiation—Pain Intensity Quantified (NQF #0384).	
• Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Prostate Cancer Patients (NQF #0390).	
• Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients (NQF #0389).	
• HCAHPS (NQF #0166).	
• CLABSI (NQF #0139)**	Deferred.
• CAUTI (NQF #0138)**.	
• External Beam Radiotherapy for Bone Metastases (NQF #1822)***	Beginning at the first opportunity in 2017 and for subsequent years.

*Update newly finalized for display for the FY 2019 program year and subsequent years in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57192)—expanded cohort will be displayed as soon as feasible.
**Deferral finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57192).
***Measure newly finalized for public display in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57192).
×Measure finalized for removal beginning the FY 2020 program year in section IX.B.3.b of the preamble of this final rule.

As we strive to publicly display data as soon as possible on a CMS Web site, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57191 through 57192), we finalized an update to our public display polices. We believe it is best to not specify in rulemaking the exact timeframe during the year for publication as doing so may prevent earlier publication. Therefore, we finalized our policy to make these data available as soon as it is feasible during the year, starting with the first year for which we are publishing data for each measure. We will continue to propose in rulemaking the first year for which we intend to publish data for each measure. We intend to make the data available on at least a yearly basis.

As stated above, we are required to give PCHs an opportunity to review their data before the data are made public. Because we will make the data for this program available as soon as possible, and the timeframe for this publication may change year to year, we will not propose to specify in rulemaking the exact dates for review. However, in that final rule, we stated that the time period for review would be approximately 30 days in length. We will announce the exact timeframes on a CMS Web site and/or on our applicable listservs. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20084), we did not propose any changes to this policy.

b. Deferment of Public Display of Two Measures

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50281 through 50282), we finalized public display of the CLABSI and CAUTI measures beginning no later than 2017 and subsequent years. However, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57192), we finalized a proposal to continue to defer public reporting of the CLABSI and CAUTI measures pending ongoing collaboration with the CDC to identify an appropriate timeframe for public reporting and the analytic methods that

will be used to summarize the CLABSI and CAUTI data for public reporting purposes. We continue to collaborate with the CDC on these issues and continue to defer the public reporting of these two measures accordingly.

9. Form, Manner, and Timing of Data Submission

a. Background

Section 1866(k)(2) of the Act requires that, beginning with the FY 2014 PCHQR program year, each PCH must submit to the Secretary data on quality measures specified under section 1866(k)(3) of the Act in a form and manner, and at a time, as specified by the Secretary. There are no financial incentives or penalties associated with the PCHQR Program.

Data submission requirements and deadlines for the PCHQR Program are generally posted on the QualityNet Web site at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772864228.*

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20085), we did not propose any changes to previously finalized data submission requirements.

b. Reporting Requirements for the Newly Finalized Measures

As further described above, we are finalizing the adoption of four new measures beginning with the FY 2020 program year: Proportion of Patients Who Died From Cancer Receiving Chemotherapy in the Last 14 Days of Life (NQF #0210); Proportion of Patients Who Died From Cancer Admitted to the ICU in the Last 30 Days of Life (NQF #0213); Proportion of Patients Who Died From Cancer Not Admitted to Hospice (NQF #0215); and Proportion of Patients Who Died From Cancer Admitted to Hospice for Less Than Three Days (NQF #0216). All four measures are claims-based measures. Therefore, there will be no separate data submission requirements for PCHs related to these measures as CMS will calculate the measures from data submitted for reimbursement purposes. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20085), we proposed to calculate these measures on a yearly basis because we will be calculating them using Medicare administrative claims data. Specifically, we proposed that the data collection period would be from July 1 of the year 3 years prior to the program year to June 30 of the year 2 years prior to the program year. Thus, for the FY 2020 program year, we would collect data from July 1, 2017 through June 30, 2018.

We invited public comment on this proposal.

Comment: One commenter supported the proposed time period for the reporting of the EOL–ICU measure data specifically, while another commenter recommended against public reporting of the EOL–ICU measure until adjustments are made to the measure specifications to account for patient characteristics.

Response: We thank the commenters for their thoughts. However, we do not plan on altering the measure specifications to account for patient characteristics because the measure is intended to assess the overall proportion of patients receiving chemotherapy within fourteen days of the end of life and provide a broad picture of end-of-life care.

Comment: One commenter sought further direction on the plans for the public reporting of the new end-of-life measures.

Response: We thank the commenter for expressing the request for additional direction, and note that further information will be available on QualityNet in the future. We strive to make data available as soon as it is feasible during the year, starting with the first year for which we are publishing data for each measure, and therefore believe it is best to not specify in rulemaking the exact timeframe during the year for publication as doing so may prevent earlier publication.

After consideration of the public comments we received we are finalizing the data collection period, as proposed, from July 1 of the year 3 years prior to the program year to June 30 of the year 2 years prior to the program year. Thus, for the FY 2020 program year, we will collect data for the four new measures from July 1, 2017 through June 30, 2018.

10. Extraordinary Circumstances Exceptions (ECE) Policy Under the PCHQR Program

a. Background

In our experience with other quality reporting and performance programs, we have noted occasions when providers have been unable to submit required quality data due to extraordinary circumstances that are not within their control (for example, natural disasters). We do not wish to increase their burden unduly during these times. Therefore, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50848), we finalized our policy that, for the FY 2014 program year and subsequent years, PCHs may request and we may grant exceptions (formerly referred to as waivers)[348] with respect to the reporting of required quality data when extraordinary circumstances beyond the control of the PCH warrant. The PCH may request a reporting extension or a complete exception from the requirement to submit quality data for one or more quarters. Under our current policy, PCHs can submit a request form to CMS with the following information:

- The PCH's CCN;
- The PCH's name;
- Contact information for the PCH's CEO and any other designated personnel, including name, email address, telephone number, and mailing address (the address must be a physical address, not a post office box);
- The PCH's reason for requesting an extension or exception;
- Evidence of the impact of extraordinary circumstances, including but not limited to photographs, newspaper and other media articles; and
- A date when the PCH will again be able to submit PCHQR Program data, and a justification for the proposed date.

In addition, we finalized that the form must be signed by the PCH's CEO or designee and submitted within 30 days of the date that the extraordinary circumstances occurred. Lastly, we finalized that following the receipt of the request form, we would: (1) Provide a written acknowledgement; and (2) provide a formal response notifying the PCH of our decision.

We also clarified that the above policy does not preclude us from granting exceptions (including extensions) to PCHs that have not requested them when we determine that an extraordinary circumstance has affected an entire region or locale. We stated that if we make the determination to grant such an exception, we would communicate this decision through routine communication channels.

b. Modifications to the ECE Policy

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20085 through 20086), we proposed to modify the ECE policy for the PCHQR Program by: (1) Extending the deadline for a PCH to submit a request for an extension or exception from 30 days following the date that the extraordinary circumstance occurred to 90 days following the date that the extraordinary circumstance occurred; and (2) allowing CMS to grant an exception or extension due to CMS data system issues which affect data submission. These proposed

[348] ECEs were originally referred to as ''waivers.'' This term was changed to ''exceptions'' in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50286).

modifications will better align our ECE policy with that adopted for the Hospital IQR Program (76 FR 51651 through 51652, 78 FR 50836 through 50837, and 81 FR 57181 through 57182), the Hospital OQR Program (77 FR 68489 and 81 FR 79795), as well as other quality reporting programs that already have such policies in place or have proposed to modify their policies to achieve alignment. We proposed that these modifications would apply beginning in FY 2018 as related to extraordinary circumstances that occur on or after October 1, 2017.

We also believe that it is important for facilities to receive timely feedback regarding the status of ECE requests. We strive to complete our review of each ECE request as quickly as possible. However, we recognize that the number of requests we receive, and the complexity of the information provided impacts the actual timeframe to make ECE determinations. Therefore, to ensure transparency and understanding of our process, we are also taking this opportunity to clarify that we will strive to provide our response to an ECE request within 90 days of receipt.

(1) ECE Request Submission Deadline

In the past, we have allowed facilities to submit an ECE request form within 30 calendar days following the occurrence of an extraordinary circumstance that causes hardship and prevents them from providing data. In certain circumstances, however, it may be difficult for facilities to timely evaluate the impact of a certain extraordinary circumstance within 30 calendar days. We believe that extending the deadline to 90 calendar days would allow PCHs more time to determine whether it is necessary and appropriate to submit an ECE request and to provide a more comprehensive account of the extraordinary circumstance in their ECE request form to CMS. For example, if a PCH has suffered damage due to a hurricane on June 1, it would have until August 30 to submit an ECE form via the QualityNet Secure Portal, mail, email, or secure fax as instructed on the ECE form.

We invited public comments on this proposal.

Comment: Commenters generally supported the proposed amendments to the ECE policy to align with other quality reporting programs. One commenter specifically noted that providing additional time to request an extension or exception after an extraordinary event will enable PCHs to focus on patient needs and service recovery.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal to extend the deadline for a PCH to submit a request for an extension or exception from 30 days following the date that the extraordinary circumstance occurred to 90 days following the date that the extraordinary circumstance occurred.

(2) Exceptions or Extensions Due to CMS Data System Issues

Although we do not anticipate this situation will happen often, there may be times where CMS experiences issues with its data systems that directly affect facilities' abilities to submit data. In these circumstances, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20086), we proposed to grant exceptions or extensions to one or more data reporting requirements. If we make the determination to grant exceptions or extensions to PCHs on this basis, we proposed to communicate this decision through routine communication channels.

We invited public comment on this proposal.

Comment: Commenters generally supported the proposed amendments to the ECE policy to align with other quality reporting programs. One comment specifically noted that modifying the policy to allow an exception for CMS data system issues will avoid unfairly penalizing PCHs for circumstances outside of their control.

Response: We thank the commenters for their responses and comments. Regarding our proposal to modify the ECE policy to allow an exception for CMS data system issues, we wish to clarify that if CMS does not proactively notify PCHs that it plans to provide an exception to the policy after a data system issue, PCHs may still submit a request for an exception for CMS consideration.

After consideration of the public comments we received, we are finalizing our proposal to allow CMS to grant an exception or extension due to CMS data system issues which affect data submission.

C. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

1. Background and Statutory Authority

Section 3004(a) of the Affordable Care Act amended section 1886(m) of the Act by adding paragraph (5), requiring the Secretary to establish the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). This program applies to all hospitals certified by Medicare as LTCHs. Beginning with the FY 2014 LTCH QRP, the Secretary is required to reduce any annual update to the LTCH PPS standard Federal rate for discharges occurring during such fiscal year by 2 percentage points for any LTCH that does not comply with the requirements established by the Secretary. Specifically, section 1886(m)(5) of the Act requires that beginning with the FY 2014 LTCH QRP, each LTCH submit data on quality measures specified by the Secretary in a form and manner, and at a time, specified by the Secretary. For more information on the statutory history of the LTCH QRP, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50286).

When we use the term ''FY [year] LTCH QRP,'' we are referring to the fiscal year for which the LTCH QRP requirements applicable to that fiscal year must be met for an LTCH to receive the full annual update when calculating the payment rates applicable to it for that fiscal year.

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185) amended Title XVIII of the Act, in part, by adding a new section 1899B of the Act that requires the Secretary to establish new data reporting requirements for certain post-acute care (PAC) providers, including LTCHs. Specifically, sections 1899B(a)(1)(A)(ii) and (iii) of the Act require LTCHs, inpatient rehabilitation facilities (IRFs), skilled nursing facilities (SNFs), and home health agencies (HHAs), under the provider-type's respective quality reporting program (which, for LTCHs, is found at section 1886(m)(5) of the Act), to report data on quality measures specified under section 1899B(c)(1), with respect to at least five domains, and data on resource use and other measures specified under section 1899B(d)(1) of the Act with respect to at least three domains. Section 1899B(a)(1)(A)(i) of the Act further requires each of these PAC provider-types to report under its respective quality reporting program standardized patient assessment data in accordance with subsection (b) for at least the quality measures specified under subsection (c)(1) and that is with respect to five specific categories: functional status; cognitive function and mental status; special services, treatments, and interventions; medical conditions and co-morbidities; and impairments. Section 1899B(a)(1)(B) requires that all of the data that must be reported in accordance with section 1899B(a)(1)(A) of the Act be standardized and interoperable to allow for the exchange

of the information among PAC providers and other providers and the use of such data in order to enable access to longitudinal information and to facilitate coordinated care. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49723 through 49724) for additional information on the IMPACT Act and its applicability to LTCHs.

2. General Considerations Used for Selection of Quality Measures for the LTCH QRP

a. Background

We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49728) for a detailed discussion of the considerations we apply in measure selection for the LTCH QRP, such as alignment with the CMS Quality Strategy,[349] which incorporates the three broad aims of the National Quality Strategy.[350]

As part of our consideration for measures for use in the LTCH QRP, we review and evaluate measures that have been implemented in other programs and take into account measures that have been endorsed by NQF for provider settings other than the LTCH setting. We have previously adopted measures with the term ''Application of'' in the names of those measures. We have received questions pertaining to the term ''application'' and want to clarify that when we refer to a measure as an ''application of'' the measure, we mean that the measure will be used in the LTCH setting, rather than the setting for which it was endorsed by the NQF. For example, in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49736 through 49739) we adopted a measure entitled, an Application of Percent of Residents Experiencing One or More Falls With Major Injury (Long Stay) (NQF #0674), which is currently endorsed for the nursing home setting but not for the LTCH setting. For such measures, we intend to seek NQF endorsement for the LTCH setting, and if the NQF endorses one or more of them, we will update the title of the measure to remove the reference to ''application.''

We received several comments generally related to the proposed measures, the IMPACT Act, NQF endorsement, the NQF MAP review process, and the use of technical expert panels (TEPs), which are summarized and discussed below.

Comment: Several commenters expressed support for the goals and objectives of the IMPACT Act. One commenter supported the continued additions and modifications to the LTCH QRP as mandated by the IMPACT Act, stating that regulatory changes from the LTCH QRP have not only required LTCHs to focus more on care processes and data collection, but have also promoted a shift in provider focus toward improved care quality, increased transparency, and enhanced provider accountability. Another commenter stated that, even though it supports CMS' effort under the IMPACT Act, additional time may be necessary to fully implement all changes as outlined in the final rule.

Response: We appreciate the commenters' support for the continued additions and modifications to the LTCH QRP, particularly the support for modifications required by the IMPACT Act. We strive to put patients first, ensuring that they can make decisions about their own healthcare along with their clinicians. We want to ensure innovative approaches to improve quality, accessibility, and affordability while paying particular attention to improving clinicians' and beneficiaries' experience when interacting with CMS programs. To that end, we believe that a focus on data collection and quality measurement leads to improved care processes, facilitation of care coordination, and, ultimately, improved patient outcomes. However, we are also sensitive to LTCHs' needs for sufficient time to implement the requirements pertaining to the LTCH QRP, and we aim to be responsive to these needs to the extent feasible and appropriate.

Comment: Several commenters expressed concern that quality measures proposed for the LTCH QRP lack NQF endorsement for the LTCH setting. One commenter noted that NQF endorsement for the LTCH setting reflects that the NQF has determined the measure to be appropriately modified for the LTCH setting, which is unique from other PAC settings due to the complexity of LTCH patient needs. A few commenters recommended that CMS obtain NQF endorsement for the LTCH setting through NQF review using the Consensus Development Process, a formal peer-review process providing input on performance measures, before proposing quality measures for the LTCH QRP. Commenters further recommended that CMS refrain from implementing measures in the LTCH QRP until the measures receive NQF endorsement for the LTCH setting.

Response: We acknowledge the commenters' recommendation that proposed measures receive NQF endorsement in the LTCH setting prior to implementation. We would like to note that we consider and propose measures that have been endorsed by the NQF whenever possible. However, when this is not feasible because there is not an NQF endorsed measure that addresses quality gaps identified in the program, we believe it is appropriate to specify a measure for the LTCH QRP that is not NQF-endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization, as is the case for the proposed measures, and we have considered but have not been able to identify other feasible measures that are endorsed or adopted by a consensus organization. We plan to submit measures within our program for endorsement as soon as feasible.

Comment: Several commenters expressed concern that quality measures proposed for the LTCH QRP may not be fully supported by the MAP. Commenters recommended that CMS obtain full support by the MAP before proposing quality measures for the LTCH QRP.

Response: We acknowledge that the NQF-convened MAP serves a critical function in evaluating measures under consideration and providing recommendations for measure implementation prior to rulemaking though MAP support is not a requirement for a measure to be proposed or finalized. However, as the MAP's role is to maintain transparency for the public and encourage public engagement throughout the measure development process, we value the MAP's input and take into consideration all input received.

We would like to clarify that the MAP recommended ''conditional support for rulemaking'' and ''encouraged continued development'' for the proposed measures for the LTCH QRP. According to the MAP, the term ''conditional support for rulemaking'' is applied when a measure is fully developed and tested and meets MAP assessment criteria; however should meet a condition specified by MAP before it can be supported for implementation. Measures that are conditionally supported are not expected to be resubmitted to MAP. The term ''encourage continued development'' is applied when a measure addresses a critical program objective or promotes alignment. In contrast, the MAP uses the phrase ''do not support'' when it does not support the measure at all.

For the proposed measure, Changes in Skin Integrity Post-Acute Care: Pressure

[349] *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html.*

[350] *https://www.ahrq.gov/workingforquality/reports/2011-annual-report.html.*

Ulcer/Injury, the MAP Post-Acute Care/Long-Term Care (PAC/LTC) Workgroup met on December 14 and 15, 2016, and provided CMS a recommendation of ''support for rulemaking'' for use of the measure in the LTCH QRP. The MAP Coordinating Committee met on January 24 and 25, 2017, and provided a recommendation of ''conditional support for rulemaking'' for use of the proposed measure in the LTCH QRP. The MAP's conditions of support include as a part of measure implementation, that CMS provide guidance on the correct collection and calculation of the measure result. CMS intends to comply with all conditions recommended by the MAP and will engage in intensive training and guidance efforts to ensure appropriate calculation of the measure.

For the LTCH QRP ventilator weaning measures, Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay and Ventilator Liberation Rate, the MAP met on December 12, 2014 and again on December 14 and 15, 2015. For the Compliance with SBT by Day 2 of the LTCH Stay measure, the MAP encouraged continued development, acknowledging that there is evidence for interventions that improve ventilator care, that variation in quality of care exists among LTCHs, and that ventilator care is an important safety priority for LTCHs. Pursuant to MAP review and recommendations, we have continued to refine this proposed measure and these activities are described more fully below. For the Ventilator Liberation Rate measure, the MAP encouraged continued development, stating that this measure has high value potential for the LTCH QRP because successful weaning is important for improving quality of life and decreasing morbidity, mortality, and resource use among patients. We have continued to refine these measures and these activities are described more fully below. CMS has consistently used the MAP process to improve measures prior to rulemaking and implementation and to ensure continued enhancement of the LTCH QRP. We believe that the measures have been fully and robustly developed, and believe they are appropriate for implementation and should not be delayed.

Comment: Several commenters expressed concern that quality measures proposed for the LTCH QRP may not be fully supported by a TEP. Commenters recommended that CMS obtain full support by a TEP before proposing measures for the LTCH QRP. In addition, commenters requested that the TEPs that evaluate measures under consideration for the LTCH QRP include members who work in the LTCH setting.

Response: TEP members are a valuable part of the measure development process, and we would like to note that we take all TEP input into consideration as we develop and refine all quality measure work. When our measurement development contractors convene TEPs, they ensure we have a group of individuals that represents a wide range of clinical, consumer, and academic expertise in order to balance discipline and experience. Further, individuals are selected for TEPs because they are relevant subject matter experts who have knowledge of measure development and clinical expertise. For the LTCH QRP, selected TEP members typically include experts who work in the LTCH setting. We would like to note that the overarching purpose of a TEP is to obtain technical input on CMS work that is under development so that stakeholders can add input early in the development process.

Comment: A few commenters expressed concern regarding the intent of the IMPACT Act to facilitate care coordination and interoperability, stating there is currently a lack of comparability across PAC settings. One commenter expressed concern that data for assessment-based quality measures are collected on all patients in the LTCH setting, but collected only on Medicare Part A and Medicare Advantage patients/residents in the IRF and SNF settings, inhibiting cross-setting quality comparison. Another commenter noted that LTCHs are highly specialized acute care facilities that differ from other PAC settings in several key areas, including patient acuity levels, average length of patient stay, and regulatory requirements, making cross-setting comparison difficult. The commenter requested that CMS exercise care in the development of methods for and interpretation of findings related to differences across PAC settings. Another commenter noted some measures proposed for the LTCH QRP were not proposed in other PAC settings. The commenter suggested CMS implement all proposed LTCH QRP measures in every PAC setting and implement future PAC QRP measures in every PAC setting.

Response: Our intent is to develop standardized measures that can be collected across the LTCH, IRF, SNF, and HHA settings. However, we also recognize that each of these PAC settings is different in terms of patient mix, including complexity of care needed, therapies required, and length of stay. For this reason, we believe that in addition to adopting cross-setting measures that apply to all four settings, it is appropriate to adopt measures specific to each individual PAC setting that address a quality issue unique to that setting.

Comment: Several commenters expressed concern regarding the increasing burden of reporting data under the current LTCH QRP. One commenter noted that reporting the proposed new data elements and related sub-elements will require additional facility clinical staff time, which may take time away from patient care. One commenter expressed concern that the value of data collection under the LTCH QRP is unsubstantiated. Another commenter stated that the reported data goes unused. One commenter encouraged CMS to reconsider the necessity of the new data elements and requested additional clarification regarding these elements and reporting requirements.

Response: We appreciate commenters' concerns regarding burden due to the LTCH QRP data collection requirements. We also appreciate the importance of avoiding undue burden on providers and will continue to evaluate and avoid any unnecessary burden associated with the implementation of the LTCH QRP. We will also continue to work with stakeholders to explore ways to decrease burden as our shared goal is to focus on improving patient care. In response to these concerns regarding burden, and as we discuss further below, we have decided not to finalize a number of the proposed standardized patient assessment data elements.

Comment: A commenter thanked CMS for the opportunity to comment on measures proposed for the LTCH QRP but expressed concern that complete measure specifications were not available for all proposed measures. The commenter requested that CMS provide an additional opportunity for public comment when complete measure specifications are available for all proposed measures. Another commenter expressed concern that complete specifications and appropriate crosswalks were not provided for all proposed measures, noting that these materials assist staff to appropriately implement measures and utilize data to improve patient care. The commenter requested that CMS make crosswalks available prior to measure implementation, within the final rule or in a separate publication.

Response: We posted complete measure specifications for each proposed measure at the same time that we issued the proposed rule, and those

specifications can be viewed at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*. With the final rule, in accordance with our usual posting process, we will post all final measure specifications and associated measure documentation at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*.

We interpret the commenter's concern about crosswalks to be related to crosswalks from ICD–10 codes to LTCH CARE Data Set items. We refer readers to section IX.C.11.d. of the preamble of this final rule where we respond to similar issues.

b. Accounting for Social Risk Factors in the LTCH QRP

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20086 through 20087), we discussed accounting for social risk factors in the LTCH QRP. We stated that we consider related factors that may affect measures in the LTCH QRP. We understand that social risk factors such as income, education, race and ethnicity, employment, disability, community resources, and social support (certain factors of which are also sometimes referred to as socioeconomic status (SES) factors or socio-demographic status (SDS) factors) play a major role in health. One of our core objectives is to improve beneficiary outcomes including reducing health disparities, and we want to ensure that all beneficiaries, including those with social risk factors, receive high quality care. In addition, we seek to ensure that the quality of care furnished by providers and suppliers is assessed as fairly as possible under our programs while ensuring that beneficiaries have adequate access to excellent care.

We have been reviewing reports prepared by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) [351] and the National Academies of Sciences, Engineering, and Medicine on the issue of measuring and accounting for social risk factors in CMS' quality measurement and payment programs, and considering options on how to address the issue in these programs. On December 21, 2016, ASPE submitted a Report to Congress on a study it was required to conduct under section 2(d) of the IMPACT Act. The study analyzed the effects of certain social risk factors of Medicare beneficiaries on quality measures and measures of resource use used in one or more of nine Medicare value-based purchasing programs.[352] The report also included considerations for strategies to account for social risk factors in these programs. In a January 10, 2017 report released by The National Academies of Sciences, Engineering, and Medicine, that body provided various potential methods for measuring and accounting for social risk factors, including stratified public reporting.[353]

In addition, the NQF undertook a 2-year trial period in which new measures, measures undergoing maintenance review, and measures endorsed with the condition that they enter the trial period were assessed to determine whether risk adjustment for selected social risk factors was appropriate for these measures. A measure from the LTCH QRP was addressed in this trial (All-Cause Unplanned Readmission Measure for 30-Days Post-Discharge from LTCHs (NQF #2512)). This trial entailed temporarily allowing inclusion of social risk factors in the risk-adjustment approach for these measures. The trial has concluded, and NQF will issue recommendations on the future inclusion of social risk factors in risk adjustment for quality measures.

As we continue to consider the analyses and recommendations from these reports and await the recommendations of the NQF trial on risk adjustment for quality measures, we are continuing to work with stakeholders in this process. As we have previously communicated, we are concerned about holding providers to different standards for the outcomes of their patients with social risk factors because we do not want to mask potential disparities or minimize incentives to improve the outcomes for disadvantaged populations. Keeping this concern in mind, while we sought input on this topic previously, we continue to seek public comment on whether we should account for social risk factors in measures in the LTCH QRP, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors. Examples of methods include: Confidential reporting to providers of measure rates stratified by social risk factors; public reporting of stratified measure rates; and potential risk adjustment of a particular measure as appropriate based on data and evidence.

In addition, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20086 through 20087), we sought public comment on which social risk factors might be most appropriate for reporting stratified measure scores and/or potential risk adjustment of a particular measure. Examples of social risk factors include, but are not limited to, dual eligibility/low-income subsidy, race and ethnicity, and geographic area of residence. We also sought comments on which of these factors, including current data sources where this information would be available, could be used alone or in combination, and whether other data should be collected to better capture the effects of social risk. We will take commenters' input into consideration as we continue to assess the appropriateness and feasibility of accounting for social risk factors in the LTCH QRP. We note that any such changes would be proposed through future notice and comment rulemaking.

We look forward to working with stakeholders as we consider the issue of accounting for social risk factors and reducing health disparities in CMS programs. Of note, implementing any of the above methods would be taken into consideration in the context of how this and other CMS programs operate (for example, data submission methods, availability of data, statistical considerations relating to reliability of data calculations, among others), so we also sought comment on operational considerations. CMS is committed to ensuring that its beneficiaries have access to and receive excellent care, and that the quality of care furnished by providers and suppliers is assessed fairly in CMS programs.

Comment: We received several comments in response to our request for public comment on whether we should account for social risk factors in the LTCH QRP. Some commenters expressed appreciation for the agency's efforts and ongoing consideration of this issue. Commenters were generally supportive of accounting for social risk factors for LTCH QRP quality measures. Many commenters expressed concerns that not adjusting for social risk factors may lead to the appearance of low quality of care for LTCHs that treat more underserved patients. Some commenters noted that lack of adjustment for social risk factors may impact beneficiaries' access to care. A few commenters encouraged CMS to consider the results

[351] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[352] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[353] National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

of NQF's SES trial period and closely monitor recommendations from the NQF Disparities Standing Committee.

A few commenters expressed concerns with accounting for social risk factors. One commenter noted that adjusting for social risk factors may mask potential disparities and create disincentives to improve outcomes for vulnerable populations. Similarly, another commenter cautioned that the misapplication of social risk factors in the calculation of measures may create unintended consequences for disadvantaged groups.

Regarding the methodology for risk adjustment, some commenters made specific recommendations regarding the type of risk adjustment to be used. Commenters suggested approaches for CMS to consider, such as reporting of performance stratified by certain social risk factors. A few commenters drew attention to how adjustment should be conducted on a measure-specific basis, as different social risk factors affect different outcomes. One commenter recommended that quality measures reflecting processes within the control of a provider, such as pressure ulcer incidence, not be stratified by SES factors. Other commenters recommended adjusting for social risk factors, specifically for resource use measures assessing potentially preventable readmissions, discharge to community, and Medicare spending per beneficiary. Several commenters recommended conducting additional testing and evaluating this on a measure by measure basis.

In addition to support for CMS' suggested categories of race/ethnicity, dual eligibility status, and geographical location, specific, commenters suggested social risk factors for consideration, including patient-level factors like caregiver availability, disability, income, education, presence of pre-morbid assistance, and health care literacy. Commenters also suggested community resources and other factors such as access to adequate housing, medications, food, transportation, and availability of primary care. Some commenters also recommended specific data sources, such as administrative data for dual eligibility or US census data to derive SES or SDS data. A few commenters supported data collection of SES or SDS elements by LTCHs or patient-reported information. One commenter suggested formal assessment of caregiver capacity to facilitate discharge planning. Another commenter suggested the use of confidential patient-reported data to determine social risk.

There were a few comments discussing confidential and public reporting of data adjusted for social risk factors. Some commenters supported either statistical risk-adjustment or stratifying performance for public reporting. One commenter suggested that confidential feedback reports could include unadjusted performance.

Response: As we have previously stated, we are concerned about holding providers to different standards for the outcomes of their patients with social risk factors, because we do not want to mask potential disparities. We believe that the path forward should incentivize improvements in health outcomes for disadvantaged populations while ensuring that beneficiaries have adequate access to excellent care. We will consider all suggestions as we continue to assess each measure and the overall program. We intend to explore options including but not limited to measure stratification by social risk factors in a consistent manner across programs, informed by considerations of stratification methods described in section IX.A.13. of the preamble of this final rule. We thank commenters for this important feedback and will continue to consider options to account for social risk factors that would allow us to view disparities and potentially incentivize improvement in care for patients and beneficiaries. We are considering providing feedback to providers on outcomes for individuals with social risk factors in confidential reports.

3. Collection of Standardized Patient Assessment Data Under the LTCH QRP

a. Definition of Standardized Patient Assessment Data

Section 1886(m)(5)(F)(ii) of the Act requires that, for fiscal year 2019 (beginning October 1, 2018) and each subsequent year, LTCHs report standardized patient assessment data required under section 1899B(b)(1) of the Act. For purposes of meeting this requirement, section 1886(m)(5)(F)(iii) of the Act requires an LTCH to submit the standardized patient assessment data required under section 1899B(b)(1) of the Act using the standard instrument in a time, form, and manner specified by the Secretary.

Section 1899B(b)(1)(B) of the Act describes standardized patient assessment data as data required for at least the quality measures described in section 1899B(c)(1) of the Act and that is with respect to the following categories:

- Functional status, such as mobility and self-care at admission to a PAC provider and before discharge from a PAC provider;
- Cognitive function, such as ability to express ideas and to understand and mental status, such as depression and dementia;
- Special services, treatments and interventions such as the need for ventilator use, dialysis, chemotherapy, central line placement and total parenteral nutrition;
- Medical conditions and comorbidities such as diabetes, congestive heart failure and pressure ulcers;
- Impairments, such as incontinence and an impaired ability to hear, see or swallow; and
- Other categories deemed necessary and appropriate.

As required under section 1899B(b)(1)(A) of the Act, the standardized patient assessment data must be reported at least with respect to LTCH admissions and discharges, but the Secretary may require the data to be reported more frequently. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20087 through 20088), we proposed to define the standardized patient assessment data that LTCHs must report to comply with section 1886(m)(5)(F)(ii) of the Act, as well as the requirements for the reporting of these data. The collection of standardized patient assessment data is critical to our efforts to drive improvement in health care quality across the four PAC settings to which the IMPACT Act applies. We intend to use these data for a number of purposes, including facilitating their exchange and longitudinal use among health care providers to enable high quality care and outcomes through care coordination, as well as for quality measure calculation and identifying comorbidities that might increase the medical complexity of a particular admission.

LTCHs are currently required to report patient assessment data through the Long-Term Care Hospital Continuity Assessment Record and Evaluation Data Set (LTCH CARE Data Set or LCDS) by responding to an identical set of assessment questions using an identical set of response options (we refer to each solitary question/response option as a data element and we refer to a group of questions/responses as data elements), both of which incorporate an identical set of definitions and standards. The primary purpose of the identical questions and response options is to ensure that we collect a set of standardized data elements across LTCHs which can then be used for a number of purposes, including LTCH

payment and measure calculation for the LTCH QRP.

SNFs, IRFs, and HHAs are also required to report patient assessment data through their applicable PAC assessment instruments, and they do so by responding to identical assessment questions developed for their respective settings using an identical set of response options (which incorporate an identical set of definitions and standards). Like the LCDS, the questions and response options for each of these other PAC assessment instruments are standardized across the PAC provider type to which the PAC assessment instrument applies. However, the assessment questions and response options in the four PAC assessment instruments are not currently standardized with each other. As a result, questions and response options that appear on the LCDS cannot be readily compared with questions and response options that appear, for example, on the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF–PAI), the PAC assessment instrument used by IRFs. This is true even when the questions and response options are similar. This lack of standardization across the four PAC providers has limited our ability to compare one PAC provider type with another for purposes such as care coordination and quality improvement.

To achieve a level of standardization across SNFs, LTCHs, IRFs, and HHAs that enables us to make comparisons between them, we proposed to define ''standardized patient assessment data'' as patient assessment questions and response options that are identical in all four PAC assessment instruments, and to which identical standards and definitions apply.

Standardizing the questions and response options across the four PAC assessment instruments will also enable the data to be interoperable, allowing it to be shared electronically, or otherwise, between PAC provider types. It will enable the data to be comparable for various purposes, including the development of cross-setting quality measures, which may enhance provider and patient choice when selecting a post-acute care setting that will deliver the best outcome possible, and to inform payment models that take into account patient characteristics rather than setting, as described in the IMPACT Act.

We invited public comment on this proposed definition.

Comment: A commenter expressed support for the proposed definition of standardized patient assessment data.

Response: We thank the commenter for its support.

After consideration of the public comments we received, we are finalizing, as proposed, the definition of standardized patient assessment data for the LTCH QRP.

b. General Considerations Used for the Selection of Standardized Patient Assessment Data

As part of our effort to identify appropriate standardized patient assessment data for purposes of collecting under the LTCH QRP, we sought input from the general public, stakeholder community, and subject matter experts on items that would enable person-centered, high quality health care, as well as access to longitudinal information to facilitate coordinated care and improved beneficiary outcomes.

To identify optimal data elements for standardization, our data element contractor organized teams of researchers for each category, and each team worked with a group of advisors made up of clinicians and academic researchers with expertise in PAC. Information-gathering activities were used to identify data elements, as well as key themes related to the categories described in section 1899B(b)(1)(B) of the Act. In January and February 2016, our data element contractor also conducted provider focus groups for each of the four PAC provider types, and a focus group for consumers that included current or former PAC patients and residents, caregivers, ombudsmen, and patient advocacy group representatives. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data Focus Group Summary Report is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

Our data element contractor also assembled a 16-member TEP that met on April 7 and 8, 2016, and January 5 and 6, 2017, in Baltimore, Maryland, to provide expert input on data elements that are currently in each PAC assessment instrument, as well as data elements that could be standardized. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data TEP Summary Reports are available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

As part of the environmental scan, data elements currently in the four existing PAC assessment instruments were examined to see if any could be considered for proposal as standardized patient assessment data. Specifically, this evaluation included consideration of data elements in OASIS–C2 (effective January 2017); IRF–PAI, v1.4 (effective October 2016); LCDS, v3.00 (effective April 2016); and MDS 3.0, v1.14 (effective October 2016). Data elements in the standardized assessment instrument that we tested in the Post-Acute Care Payment Reform Demonstration (PAC PRD)—the Continuity Assessment Record and Evaluation (CARE)—were also considered. A literature search was also conducted to determine whether additional data elements to propose as standardized patient assessment data could be identified.

We also held four Special Open Door Forums (SODFs) on October 27, 2015; May 12, 2016; September 15, 2016; and December 8, 2016, to present data elements we were considering and solicit input. At each SODF, some stakeholders provided immediate input, and all were invited to submit additional comments via the CMS IMPACT Mailbox at: *PACQualityInitiative@cms.hhs.gov*.

We also convened a meeting with federal agency subject matter experts (SMEs) on May 13, 2016. In addition, a public comment period was open from August 12 to September 12, 2016, to solicit comments on detailed candidate data element descriptions, data collection methods, and coding methods. The IMPACT Act Public Comment Summary Report containing the public comments (summarized and verbatim) and our responses is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We specifically sought to identify standardized patient assessment data that we could feasibly incorporate into the LTCH, IRF, SNF, and HHA assessment instruments and that have the following attributes: (1) Being supported by current science; (2) testing well in terms of their reliability and validity, consistent with findings from the PAC PRD; (3) the potential to be shared (for example, through interoperable means) among PAC and other provider types to facilitate efficient care coordination and improved beneficiary outcomes; (4) the potential to inform the development of quality, resource use and other

measures, as well as future payment methodologies that could more directly take into account individual beneficiary health characteristics; and (5) the ability to be used by practitioners to inform their clinical decision and care planning activities. We also applied the same considerations that we apply with quality measures, including the CMS Quality Strategy which is framed using the three broad aims of the National Quality Strategy.

4. Policy for Retaining LTCH QRP Measures and Application of That Policy to Standardized Patient Assessment Data

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53614 through 53615), we adopted a policy that would allow any quality measure adopted for use in the LTCH QRP to remain in effect until the measure is removed, suspended, or replaced. For further information on how measures are considered for removal, suspension, or replacement, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53614 through 53615). In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20089), we proposed to apply this policy to the standardized patient assessment data that we adopt for the LTCH QRP.

We invited public comment on our proposal.

Comment: Some commenters expressed support for applying the CMS policy for retaining LTCH QRP measures to the standardized patient assessment data. Another commenter disagreed with applying the existing policy to standardized patient assessment data, and encouraged CMS to remove items with unsubstantiated value as soon as possible. The commenter also stated that CMS should alleviate the data collection burden on providers as soon as it is practicable.

Response: Standardized patient assessment data elements are used to collect data for quality measures. Therefore, standardized patient assessment elements that support such data collection follow the policy for quality measures that, once adopted, are retained until CMS determines that the quality measure should be removed. This determination is based on specific criteria for removal, suspension, or replacement. For any such removal, the public will be given a chance to comment through the notice-and-comment rulemaking process.

We understand the concerns raised by commenters to alleviate the data collection burden on providers resulting from the finalization of our standardized patient assessment data proposals. We strive to balance implementing the reporting requirements of standardized patient assessment data and responding to burden concerns.

After consideration of the public comments we received, we are finalizing our proposal, as proposed, to apply the policy for retaining LTCH QRP measures to the standardized patient assessment data that we adopt for the LTCH QRP.

5. Policy for Adopting Changes to LTCH QRP Measures and Application of That Policy for Adopting Changes to Standardized Patient Assessment Data

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53615 through 53616), we adopted a subregulatory process to incorporate updates to LTCH quality measure specifications that do not substantively change the nature of the measure. Under that policy, substantive changes to quality measures are proposed and finalized through rulemaking. For further information on what constitutes a substantive versus a nonsubstantive change and the subregulatory process we use to make nonsubstantive changes to measures, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53615 through 53616). In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20089), we proposed to apply this policy to the standardized patient assessment data that we adopt for the LTCH QRP.

We invited public comment on our proposal.

Comment: Several commenters supported CMS' subregulatory process for adopting nonsubstantive changes to LTCH QRP measures. One commenter expressed support for applying this approach to the standardized patient assessment data proposed for the LTCH QRP.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal, as proposed, to apply our policy for adopting changes to LTCH QRP measures to the standardized patient assessment data that we adopt for the LTCH QRP.

6. Quality Measures Currently Adopted for the LTCH QRP

The LTCH QRP currently has 17 adopted measures as outlined in the table below:

QUALITY MEASURES CURRENTLY ADOPTED FOR THE LTCH QRP

Short name	Measure name & data source
LTCH CARE Data Set	
Pressure Ulcers	Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678).
Patient Influenza Vaccine	Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680).
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).*
Functional Assessment	Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).
Application of Functional Assessment	Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).
Change in Mobility	Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital (LTCH) Patients Requiring Ventilator Support (NQF #2632).
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues—Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP).*
NHSN	
CAUTI	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection Outcome Measure (NQF #0138).
CLABSI	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection Outcome Measure (NQF #0139).

QUALITY MEASURES CURRENTLY ADOPTED FOR THE LTCH QRP—Continued

Short name	Measure name & data source
MRSA	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (NQF #1716).
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717).
HCP Influenza Vaccine	Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431).
VAE	National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure.*
Claims-based	
All-Cause Readmissions	All-Cause Unplanned Readmission Measure for 30-Days Post-Discharge from Long-Term Care Hospitals (LTCHs) (NQF #2512).
MSPB	Medicare Spending Per Beneficiary (MSPB)—Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP).*
DTC	Discharge to Community—Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP).*
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP).*

* Not currently NQF-endorsed for the LTCH setting.

We received comments about quality measures currently adopted for the LTCH QRP. The comments are summarized and discussed below.

Comment: A few commenters expressed views regarding Medicare Spending per Beneficiary—PAC LTCH QRP, a measure previously finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57199 through 57207). Commenters addressed the risk-adjustment approach, episode length, accounting for social risk factors, and potential for unintended consequences related to implementation of the measure. Some commenters encouraged CMS to utilize claims and patient assessment data to incorporate functional status into the risk-adjustment. One commenter recommended expanding the associated services period from 30 days to 180 days post-PAC discharge in order to enhance the measure's capacity to identify improvements in medically complex populations. Another commenter expressed concern that PAC providers' performance on this measure would focus on costs per patient, without fully accounting for patient outcomes, and that efficiency should not be based solely on the MSPB–PAC measures. This commenter also noted that this measure may result in limiting access to certain patients.

Response: Since no changes were proposed to the previously finalized measure, Medicare Spending per Beneficiary—PAC LTCH QRP, the comments received are outside the scope of the current rule. We addressed these issues in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57199 through 57207), and we refer the reader to that detailed discussion. We continue to believe that the measure specifications, including the risk-adjustment and episode length, are appropriate for this measure. With regard to comments related to accounting for social risk factors, we refer readers to section IX.C.2.b. of the preamble of this final rule.

Comment: A few commenters expressed views related to Discharge to Community—PAC LTCH QRP, a measure previously finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57207 through 57215). Commenters suggested excluding patients who died in the observation window following return to a community setting, distinguishing between a patient's return to home in the community versus home in a custodial nursing facility, assessing reliability and validity of the claims discharge status code used to calculate the measure, and accounting for social risk factors.

Response: Since no changes were proposed to the previously finalized Discharge to Community—PAC LTCH QRP measure, the comments received are outside the scope of the current rule. We addressed these issues in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57207 through 57215), and we refer readers to that rule for a detailed discussion of these issues. We also note that in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20098), we sought comment on the exclusion of baseline nursing facility residents as a potential future modification of the Discharge to Community—PAC LTCH QRP measure. We refer readers to section IX.C.9.a. of the preamble of this final rule for a discussion of this issue. With regard to comments related to social risk factors, we refer readers to section IX.C.2.b. of the preamble of this final rule.

Comment: A few commenters expressed views regarding the Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP, a measure previously finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57215 through 57219). Commenters expressed support for this measure, but encouraged further measure testing. They also suggested some modifications to the measure, such as excluding readmissions for conditions unrelated to the initial reason for LTCH admission and risk adjusting for certain patient characteristics, such as ''hospital dependent'' patients. Commenters also expressed views related to accounting for social risk factors.

Response: Since no changes were proposed to the previously finalized measure, Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP, comments received are outside the scope of the current rule. We addressed these issues in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57215 through 57219), and we refer the reader to that detailed discussion. We continue to believe that the measure specifications are appropriate for this measure. We also refer readers to section IX.C.2.b. of the preamble of this final rule for responses to comments received related to social risk factors for this measure.

Comment: We received a comment regarding the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) and Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measures. The commenter supported the continued inclusion of the previously adopted measure,

Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431), in the LTCH QRP. The commenter also supported CMS' proposal to extend the data collection period for the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure to allow for accurate calculation of the measure outcome.

Response: Since no changes were proposed to the previously finalized measures, Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) and Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431), the comments received are outside the scope of the current rule. We addressed these issues in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57227 through 57229) for the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure and in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53630 through 53631) for the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure. We refer readers to those rules for a detailed discussion. We continue to believe the inclusion of these influenza measures are important for the LTCH setting.

Comment: A commenter requested additional information regarding the Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and A Care Plan That Addresses Function (NQF #2631) and the Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and A Care Plan That Addresses Function (NQF #2631), measures previously finalized in the FY 2015 IPPS/LTCH PPS final rule and FY 2016 IPPS/LTCH PPS final rule, respectively. The commenter requested that CMS provide detailed examples for coding a patient's discharge functional goals, and suggested removing the gateway mobility item for both measures that have been previously finalized.

Response: Since no changes were proposed to the previously finalized measures, Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and A Care Plan That Addresses Function (NQF #2631) and Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and A Care Plan That Addresses Function (NQF #2631), the comments received are outside the scope of the current rule. We addressed these issues in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50291 through 50298) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49739 through 49747), respectively. We refer readers to those rules for a detailed discussion.

We also provide examples of coding goals in Section GG of the LTCH QRP Manual, which is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-CARE-Data-Set-and-LTCH-QRP-Manual.html*.

7. LTCH QRP Quality Measures Beginning With the FY 2020 LTCH QRP

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20090 through 20097), beginning with the FY 2020 LTCH QRP, in addition to the quality measures we are retaining under our policy described in section IX.C.4. of the preamble of this final rule, we proposed to remove the current pressure ulcer measure entitled Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) and replace it with a modified version of the measure entitled Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury and adopt two new measures (one process and one outcome) related to ventilator weaning. We also proposed to characterize the data elements described below as standardized patient assessment data under section 1899B(b)(1)(B) of the Act that must be reported by LTCHs under the LTCH QRP through the LTCH CARE Data Set.

The proposed measures are as follows:

- Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury
- Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay
- Ventilator Liberation Rate

The measures are described in more detail below.

a. Finalized Policy To Replace the Current Pressure Ulcer Quality Measure, Percent of Residents or Patients With Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), With a Modified Pressure Ulcer Measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury

(1) Measure Background

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20090 through 20092), we proposed to remove the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), from the LTCH QRP measure set and to replace it with a modified version of that measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, beginning with the FY 2020 LTCH QRP. The change in the measure name is to reduce confusion about the new modified measure. The modified version differs from the current version of the measure because it includes new or worsened unstageable pressure ulcers, including deep tissue injuries (DTIs), in the measure numerator. The proposed modified version of the measure also contains updated specifications intended to eliminate redundancies in the assessment items needed for its calculation and to reduce the potential for underestimating the frequency of pressure ulcers. The modified version of the measure would satisfy the IMPACT Act domain of skin integrity and changes in skin integrity.

(2) Measure Importance

As described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51754 through 51756), pressure ulcers are high-cost adverse events and an important measure of quality. For information on the history and rationale for the relevance, importance, and applicability of having a pressure ulcer measure in the LTCH QRP, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51748 through 51750) and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50861 through 50863).

We proposed to adopt a modified version of the current pressure ulcer measure because unstageable pressure ulcers, including DTIs, are similar to Stage 2, Stage 3, and Stage 4 pressure ulcers in that they represent poor outcomes, are a serious medical condition that can result in death and disability, are debilitating and painful, and are often an avoidable outcome of medical care.[354] [355] [356] [357] [358] [359] Studies

[354] Casey, G. (2013). ''Pressure ulcers reflect quality of nursing care.'' Nurs N Z 19(10): 20–24.

[355] Gorzoni, M.L. and S.L. Pires (2011). ''Deaths in nursing homes.'' Rev Assoc Med Bras 57(3): 327–331.

[356] Thomas, J.M., et al. (2013). ''Systematic review: Health-related characteristics of elderly hospitalized adults and nursing home residents associated with short-term mortality.'' J Am Geriatr Soc 61(6): 902–911.

[357] White-Chu, E.F., et al. (2011). ''Pressure ulcers in long-term care.'' Clin Geriatr Med 27(2): 241–258.

[358] Bates-Jensen BM. Quality indicators for prevention and management of pressure ulcers in vulnerable elders. Ann Int Med. 2001;135 (8 Part 2), 744–51.

[359] Bennet, G., Dealy, C., Posnett, J. (2004). The cost of pressure ulcers in the UK, *Age and Aging*, 33(3):230–235.

show that most pressure ulcers can be avoided and can also be healed in acute, post-acute, and long-term care settings with appropriate medical care.[360] Furthermore, some studies indicate that DTIs, if managed using appropriate care, can be resolved without deteriorating into a worsened pressure ulcer.[361] [362]

While there are few studies that provide information regarding the incidence of unstageable pressure ulcers in PAC settings, an analysis conducted by a contractor suggests the incidence of unstageable pressure ulcers varies according to the type of unstageable pressure ulcer and setting.[363] This analysis examined the national incidence of new unstageable pressure ulcers in LTCHs at discharge compared with admission using LTCH discharges from January through December 2015. The contractor found a national incidence of 1.15 percent of new unstageable pressure ulcers due to slough and/or eschar, 0.05 percent of new unstageable pressure ulcers due to non-removable dressing/device, and 1.01 percent of new DTIs. In addition, an international study spanning the time period 2006 to 2009 provides some evidence to suggest that the proportion of pressure ulcers identified as DTI has increased over time.[364] The study found DTIs increased by three fold, to nine percent of all observed ulcers in 2009, and that DTIs were more prevalent than either Stage 3 or 4 ulcers. During the same time period, the proportion of Stage 1 and 2 ulcers decreased, and the proportion of Stage 3 and 4 ulcers remained constant.

The inclusion of unstageable pressure ulcers, including DTIs, in the numerator of this measure is expected to increase measure scores and variability in measure scores, thereby improving the ability to discriminate among poor- and high-performing LTCHs. In the currently implemented pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), analysis using data from Quarter 1 through Quarter 4 2015 data reveals that the LTCH mean score is 1.95 percent; the 25th and 75th percentiles are 0.53 percent and 2.49 percent, respectively; and 12.11 percent of facilities have perfect scores. In the proposed measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, during the same time frame, the LTCH mean score is 3.73 percent; the 25th and 75th percentiles are 1.53 percent and 4.89 percent, respectively; and 5.46 percent of facilities have perfect scores.

(3) Stakeholder Feedback

Our measure development contractor sought input from subject matter experts, including Technical Expert Panels (TEPs), over the course of several years on various skin integrity topics and specifically those associated with the inclusion of unstageable pressure ulcers, including DTIs. Most recently, on July 18, 2016, a TEP convened by our measure development contractor provided input on the technical specifications of this quality measure, including the feasibility of implementing the proposed measure's updates across PAC settings. The TEP supported the updates to the measure across PAC settings, including the inclusion in the numerator of unstageable pressure ulcers due to slough and/or eschar that are new or worsened, new unstageable pressure ulcers due to a non-removable dressing or device, and new DTIs. The TEP also supported the use of different data elements for measure calculation. The TEP recommended supplying additional guidance to providers regarding each type of unstageable pressure ulcer. This support was in agreement with earlier TEP meetings, held on June 13 and November 15, 2013, which had recommended that CMS update the specifications for the pressure ulcer measure to include unstageable pressure ulcers in the numerator.[365] [366]

Exploratory data analysis conducted by our measure development contractor suggests that the addition of unstageable pressure ulcers, including DTIs, will increase the observed incidence and variation in the rate of new or worsened pressure ulcers at the facility level, which may improve the ability of the proposed quality measure to discriminate between poor- and high-performing facilities.

We solicited stakeholder feedback on this proposed measure by means of a public comment period held from October 17 through November 17, 2016. In general, we received considerable support for the proposed measure. A few commenters supported all of the changes to the current pressure ulcer measure that resulted in the proposed measure, with one commenter noting the significance of the work to align the pressure ulcer quality measure specifications across the PAC settings.

Many commenters supported the inclusion of unstageable pressure ulcers due to slough/eschar, due to non-removable dressing/device, and DTIs in the quality measure. Other commenters did not support the inclusion of DTIs in the quality measure because they stated that there is no universally accepted definition for this type of skin injury.

Some commenters provided feedback on the data elements used to calculate the proposed quality measure. We believe that these data elements will promote facilitation of cross-setting quality comparison as mandated by the IMPACT Act, alignment between quality measures and payment, reduction in redundancies in assessment items, and prevention of inappropriate underestimation of pressure ulcers. The currently implemented pressure ulcer measure is calculated using retrospective data elements that assess the number of new or worsened pressure ulcers at each stage, while the proposed measure is calculated using the number of unhealed pressure ulcers at each stage after subtracting the number that were present upon admission. Some commenters did not support the data elements that would be used to calculate the proposed measure,

[360] Black, Joyce M., et al. ''Pressure ulcers: Avoidable or unavoidable? Results of the national pressure ulcer advisory panel consensus conference.'' *Ostomy-Wound Management* 57.2 (2011): 24.

[361] Sullivan, R. (2013). A Two-year Retrospective Review of Suspected Deep Tissue Injury Evolution in Adult Acute Care Patients. Ostomy Wound Management 59(9). *http://www.o-wm.com/article/two-year-retrospective-review-suspected-deep-tissue-injury-evolution-adult-acute-care-patien.*

[362] Posthauer, M.E., Zulkowski, K. (2005). Special to OWM: The NPUAP Dual Mission Conference: Reaching Consensus on Staging and Deep Tissue Injury. Ostomy Wound Management 51(4) *http://www.o-wm.com/content/the-npuap-dual-mission-conference-reaching-consensus-staging-and-deep-tissue-injury.*

[363] Final Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements, available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html.*

[364] VanGilder, C., MacFarlane, G.D., Harrison, P., Lachenbruch, C., Meyer, S. (2010). The Demographics of Suspected Deep Tissue Injury in the United States: An Analysis of the International Pressure Ulcer Prevalence Survey 2006–2009. Advances in Skin & Wound Care. 23(6): 254–261.

[365] Schwartz, M., Nguyen, K.H., Swinson Evans, T.M., Ignaczak, M.K., Thaker, S., and Bernard, S.L.: Development of a Cross-Setting Quality Measure for Pressure Ulcers: OY2 Information Gathering, Final Report. Centers for Medicare & Medicaid Services, November 2013. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Development-of-a-Cross-Setting-Quality-Measure-for-Pressure-Ulcers-Information-Gathering-Final-Report.pdf.*

[366] Schwartz, M., Ignaczak, M.K., Swinson Evans, T.M., Thaker, S., and Smith, L.: The Development of a Cross-Setting Pressure Ulcer Quality Measure: Summary Report on November 15, 2013, Technical Expert Panel Follow-Up Webinar. Centers for Medicare & Medicaid Services, January 2014. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Development-of-a-Cross-Setting-Pressure-Ulcer-Quality-Measure-Summary-Report-on-November-15-2013-Technical-Expert-Pa.pdf.*

and requested further testing of these data elements. Other commenters supported the use of these data elements stating that these data elements simplified the measure calculation process.

The public comment summary report for the proposed measure is available on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*. This summary includes further detail about our responses to various concerns and ideas stakeholders raised.

The NQF-convened Measures Application Partnership (MAP) Post-Acute Care/Long-Term Care (PAC/LTC) Workgroup met on December 14 and 15, 2016, and provided input to CMS about this measure. The Workgroup provided a recommendation of ''support for rulemaking'' for use of the proposed measure in the LTCH QRP. The MAP Coordinating Committee met on January 24 and 25, 2017, and provided a recommendation of ''conditional support for rulemaking'' for use of the proposed measure in the LTCH QRP. The MAP's conditions of support include that, as a part of measure implementation, CMS provide guidance on the correct collection and calculation of the measure result, as well as guidance on public reporting Web sites explaining the impact of the specification changes on the measure result. The MAP's conditions also specify that CMS continue analyzing the proposed measure in order to investigate unexpected results reported in public comment. We intend to fulfill these conditions by offering additional training opportunities and educational materials in advance of public reporting, and by continuing to monitor and analyze the proposed measure. More information about the MAP's recommendations for this measure is available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=84452*.

We reviewed the NQF's consensus endorsed measures and were unable to identify any NQF-endorsed pressure ulcer quality measures for PAC settings that are inclusive of unstageable pressure ulcers. There are related measures, but after careful review, we determined these measures are not applicable for use in LTCHs based on the populations addressed or other aspects of the specifications. We are unaware of any other such quality measures that have been endorsed or adopted by another consensus organization for the LTCH setting. Therefore, based on the evidence discussed above, we proposed to adopt the quality measure entitled, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, for the LTCH QRP beginning with the FY 2020 LTCH QRP. We plan to submit the proposed measure to the NQF for endorsement consideration as soon as feasible.

(4) Data Collection

The data for this quality measure would be collected using the LTCH CARE Data Set, which is currently submitted by LTCHs through the QIES ASAP System. The proposed standardized patient assessment data applicable to this measure that must be reported by LTCHs for admissions as well as discharges occurring on or after April 1, 2018 is described in section IX.C.11. of the preamble of this final rule. While the inclusion of unstageable wounds in the proposed measure results in a measure calculation methodology that is different from the methodology used to calculate the current pressure ulcer measure, the data elements needed to calculate the proposed measure are already included on the LTCH CARE Data Set. In addition, our proposal to eliminate duplicative data elements that were used in calculation of the current pressure ulcer measure will result in an overall reduced reporting burden for LTCHs with respect to the proposed measure. To view the updated LTCH CARE Data Set, with the proposed changes, we refer readers to: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-CARE-Data-Set-and-LTCH-QRP-Manual.html*. For more information on LTCH CARE Data Set submission using the QIES ASAP System, we refer readers to: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Technical-Information.html*.

For technical information about this measure, including information about the measure calculation and the standardized patient assessment data elements used to calculate this measure, we refer readers to the document titled, *Final Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,* available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*.

We proposed that LTCHs would begin reporting the proposed pressure ulcer measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, which will replace the current pressure ulcer measure, with data collection beginning April 1, 2018.

We invited public comment on our proposal to replace the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), with a modified version of that measure, entitled Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, for the LTCH QRP beginning with the FY 2020 LTCH QRP.

Comment: Many commenters supported the proposed replacement of the current pressure ulcer measure, the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), with a modified version of that measure, entitled Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury. Commenters appreciated that the implementation of this modified measure will reduce regulatory burden for providers while continuing to maintain a high standard for measuring the quality of care. Commenters also encouraged the expansion of this measure into other settings.

Response: We appreciate the commenters' support, and also agree that this measure may be suitable to adapt for other settings.

Comment: Several commenters requested that additional testing analyses be conducted prior to the implementation of this measure. These commenters indicated that the purpose of this additional testing should be to verify that the specifications of this measure reflect actual differences in the care practices and the quality of care provided by LTCHs, rather than differences in compliance. Specifically, some commenters expressed concerns that the variation in measure scores between facilities could reflect differences in the interpretation of definitions for unstageable pressure ulcers or DTIs, rather than actual differences in quality or care practices. These commenters noted that a measure should not be changed to create performance variation, but rather to be consistent with current science or to provide clarity and consistent data collection. Commenters requested that additional guidance be provided to promote consistency in the way the new measure is interpreted among providers.

Response: We have performed testing to compare the performance of the proposed measure with the existing pressure ulcer/injury measure. Current findings indicate that the measure is both valid and reliable in the SNF, LTCH, and IRF settings. One of the differences between the current and

proposed pressure ulcer measures is that the proposed measure is calculated using the M0300 data element. Reliability and validity of the data elements used to calculate this quality measure have been tested in several ways.

Rigorous testing on both reliability and validity of the data elements in the MDS 3.0 provides evidence for the data elements used in the SNF, LTCH, and IRF settings.[367] The MDS 3.0 pilot test showed good reliability, and the results are applicable to the IRF–PAI as well as the LTCH CARE Data Set because the data elements tested are the same as those used in the IRF–PAI and LTCH CARE Data Set. Across pressure ulcer data elements, average gold-standard to gold-standard kappa statistic was 0.905. The average gold-standard to facility-nurse kappa statistic was 0.937. These kappa scores indicate ''almost perfect'' agreement using the Landis and Koch standard for strength of agreement.[368] Analyses conducted by the measure development contractor indicate that there is a high level of alignment between the M0300 data element and the M0800 data element, suggesting that the data elements assess an equivalent concept. Using the M0300 data elements improves accuracy by establishing a standardized calculation method.

A second main difference between the current and proposed pressure ulcer measures is that the proposed measure includes unstageable pressure ulcers, including DTIs, in the numerator of the quality measure, resulting in increased scores in all settings compared with the previously implemented pressure ulcer measure. An analysis conducted by the measure development contractor, using data from October through December 2016, showed mean scores increasing by 2.03 percentage points in LTCH. This is due to the fact that the proposed measure includes unstageable pressure ulcers, including DTIs, while the current measure does not, as well as the fact some pressure ulcers captured as new or worsened in the M0300 data element were not reported in the M0800 data element.

To assess the construct validity of this measure, or the degree to which the measure construct measures what it claims or purports to be measuring, our measure contractor sought input from TEPs over the course of several years. Most recently, on July 18, 2016, a TEP supported the inclusion in the numerator of unstageable pressure ulcers due to slough and/or eschar that are new or worsened, new unstageable pressure ulcers/injuries due to a non-removable dressing or device, and new DTIs. The measure testing activities were presented to TEP members for their input on the reliability, validity, and feasibility of this measure change. The TEP members supported the measure construct.

The proposed measure also increased the variability of measures scores between providers, as noted by some commenters. In the currently implemented pressure ulcer measure, analysis using 2015 data from Quarter 1 through Quarter 4 reveals that the LTCH mean score is 1.95 percent; the 25th and 75th percentiles are 0.53 percent and 2.49 percent, respectively; and 12.11 percent of facilities have perfect scores. In the proposed measure, during the same timeframe, the LTCH mean score is 3.73 percent; the 25th and 75th percentiles are 1.53 percent and 4.89 percent, respectively; and 5.46 percent of facilities have perfect scores. We would like to clarify that the goal of the proposed measure is not to create performance variation where none exists, but rather to better measure existing performance variation. This increased variability of scores between facilities will improve the ability of the measure to distinguish between high- and low-performing facilities. As described above, the proposed measure has been shown to be reliable and valid through testing of the measure and data elements, and input from stakeholders.

We will continue to perform reliability and validity testing in compliance with NQF guidelines and the Blueprint for the CMS Measures Management System to ensure that that the measure demonstrates scientific acceptability (including reliability and validity) and meets the goals of the QRP. Finally, as with all measure development and implementation, we will provide training and guidance prior to implementation of the measure to promote consistency in the interpretation of the measure.

Comment: A few commenters stated that the M0300 data element assesses the total number of unhealed pressure ulcers at the time of admission and of those, the total number of unhealed pressure ulcers at the time of discharge, for each stage. One commenter expressed concern that the proposed measure may disfavor LTCHs that admit patients with pressure ulcers because those pressure ulcers might not heal by the time the patients are discharged from the LTCH.

Response: We do not believe that this measure will disfavor LTCHs that admit patients who already have pressure ulcers. We wish to clarify that the proposed measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, is calculated using a subtraction method. The M0300 data element collects the number of unhealed pressure ulcers present at the time of the assessment (that is, discharge) for each stage, and the number of those pressure ulcers that were present upon admission. The pressure ulcers that were present upon admission are subtracted from the number of pressure ulcers at the same stage that are present at discharge and, as a result, are not included in the measure.

Comment: Commenters requested further training and guidance in completing the M0300 data element that will be used to calculate the proposed quality measure. Some commenters requested comprehensive guidance on completing the ''present on admission'' data element. Some commenters questioned how specific scenarios involving unstageable pressure ulcers should be coded. These commenters had questions about how to code a pressure ulcer that is unstageable at admission, and becomes numerically stageable during the patient's stay, remaining at that stage at discharge. One commenter supported the proposed measure calculation approach, which will not count pressure ulcers that were present at the time of admission at the same stage, but stated that this would add complexity in coding and would require further training. One commenter stated that the use of these data elements would require LTCHs to calculate the number of new or worsened pressure ulcers by subtracting those present on admission. Some commenters stated that the modified measure may be difficult for providers to capture because they are being asked to report on a different data element.

Response: The measure will be calculated using data reported on the M0300 data element collected at discharge, which only requires LTCHs to report the number of pressure ulcers for each stage (including stages 2, 3 and 4, unstageable due to slough and/or eschar, unstageable due to non-removable dressing/device, and DTIs) and of those, the number that were present on admission. The M0300 data element currently exists on the LTCH CARE Data Set, and the current LTCH QRP Manual, as well as prior versions

[367] Saliba, D., & Buchanan, J. (2008, April). Development and validation of a revised nursing home assessment tool: MDS 3.0. Contract No. 500–00–0027/Task Order #2. Santa Monica, CA: Rand Corporation. Retrieved from: *http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.*

[368] Landis, R., & Koch, G. (1977, March). The measurement of observer agreement for categorical data. Biometrics 33(1), 159– 174.

of the Manual, include guidance about how to complete the M0300 data element in the scenarios described by the commenters, including unstageable pressure ulcers that become numerically stageable. The LTCH QRP Manual can be found at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-CARE-Data-Set-and-LTCH-QRP-Manual.html*.

We will provide further training, education, and guidance prior to implementation of the proposed measure. The LTCH QRP Manual will be updated with additional examples to further address the coding of unstageable pressure ulcers, and to provide further clarification on the coding of pressure ulcers/injuries that are ''present on admission.''

Comment: Several comments expressed general support for the inclusion of all unstageable pressure ulcers in the proposed measure. One commenter stated that the measure will provide a more accurate picture of pressure ulcers and the quality of their prevention and treatment in PAC settings. This commenter stated that unstageable pressure ulcers may be prevented, accurately diagnosed, and effectively treated when they occur, that this measure will result in a more accurate picture of quality in post-acute care, and that the 2016 NPUAP staging definitions will help to improve diagnostic accuracy.

Some commenters did not support the inclusion of unstageable pressure ulcers in the quality measure as proposed. Some commenters stated that there is a lack of clear definitions for some types of unstageable pressure ulcers, and that those definitions may be too subjective to collect reliable data on unstageable pressure ulcers. One commenter requested that CMS clarify the criteria that would enable a LTCH to report that an unstageable pressure ulcer present on admission has improved by the time of discharge. One commenter stated that it was unclear whether mucosal pressure injuries are included in the measure, and what the definition of ''worsened'' is in the context of unstageable pressure ulcers. The commenter stated that it may not be possible to prevent unstageable pressure ulcers/injuries due to non-removable devices and dressings, or DTIs, and they questioned how this measure would inform improvement or inform the public. Commenters requested that CMS conduct additional testing to examine the inclusion of unstageable pressure ulcers.

Response: We appreciate the support we have received regarding the inclusion of unstageable pressure ulcers, including DTIs, in the proposed quality measure. We believe that the inclusion of unstageable pressure ulcers in the measure will result in a fuller picture of quality to patients and families, and lead to further quality improvement efforts that will advance patient safety by reducing the rate of facility acquired pressure ulcers at any stage.

To provide greater clarity about the definitions of different types of unstageable pressure ulcers and how to code them on the LTCH CARE Data Set, we are currently engaged in multiple educational efforts. These include training events, updates to the manuals and training materials, and responses to Help Desk questions to promote understanding and proper coding of these data elements. We will continue to engage in these training activities prior to implementation of the proposed measure.

With regard to provider concerns regarding the inclusion of mucosal pressure ulcers, we wish to clarify that mucosal pressure ulcers are not included in this measure. Further instruction about these types of pressure ulcers is provided in the LTCH QRP Manual, which can be found at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-CARE-Data-Set-and-LTCH-QRP-Manual.html*. We would like to clarify that the data elements used to collect information about unstageable pressure ulcers do not reflect whether a pressure ulcer is improved at discharge compared to admission. Rather, the data element collects the number of pressure ulcers present at each stage (at discharge), and the number of those there were present at the same stage at admission.

Comment: One commenter specifically supported the inclusion of DTIs. This commenter stated that the currently implemented pressure ulcer measure is biased because it does not include DTIs, and that the inclusion of DTIs in the measure has value and directly impacts the patient. The commenter stated that prompt assessment for a DTI at early onset is optimal to initial treatment protocols, and that a well-trained clinician is able to discern DTIs during an assessment. Another commenter stated that these types of injuries may be prevented, accurately diagnosed and effectively treated when they occur, and that the 2016 NPUAP staging definitions may help to improve diagnostic accuracy.

Other commenters did not support the inclusion of DTIs in the measure. Some commenters stated that there is not a universally accepted definition of DTIs, and one stated that DTIs are commonly misdiagnosed, which could lead to surveillance bias. One commenter stated that the category of DTI is not sufficiently mature enough to include in the measure, and that it may not be possible to prevent DTIs.

Response: We appreciate the comments regarding the specific inclusion of DTIs in the proposed quality measure. DTIs, often an avoidable outcome of medical care, are debilitating and painful, and can result in death and/or disability, similar to Stage 2, Stage 3 and Stage 4 pressure ulcers. While some DTIs may worsen, studies indicate that many DTIs, if managed using appropriate care, can be resolved without deteriorating into a worsened pressure ulcer. Therefore, we believe that the inclusion of DTIs in the proposed quality measure is essential to be able to accurately reflect the number of these types of pressure injuries and to provide the appropriate patient care. Further, we believe that it is important to do a thorough assessment on every patient in each PAC setting, including a thorough skin assessment documenting the presence of any pressure ulcers or injuries of any kind, including DTIs. We agree that it is important to conduct thorough and consistent assessments to avoid the possibility of surveillance bias.

When considering the addition of DTIs to the measure numerator, we convened cross-setting TEPs in June and November 2013, and obtained input from clinicians, experts, and other stakeholders. An additional cross-setting TEP convened by our measure development contractor in July 2016 also supported the recommendation to include unstageable pressure ulcers, including DTIs, in the numerator of the quality measure. Given DTIs' potential impact on mortality, morbidity, and quality of life, it may be detrimental to the quality of care to exclude DTIs from a pressure ulcer quality measure.

Comment: A few commenters recommended that CMS attain NQF endorsement of the Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury measure prior to implementation.

Response: While this measure is not currently NQF-endorsed, we recognize that the NQF endorsement process is an important part of measure development and plan to submit this measure for NQF endorsement consideration as soon as feasible.

Comment: Some commenters supported adopting the NPUAP terminology regarding the use of the term ''pressure injury.'' These commenters believed that use of NPUAP

language will help facilitate the use of consistent definitions across PAC settings. One commenter expressed support for the term ''injury'' to describe ''deep tissue injury,'' but not other types of pressure ulcers. This commenter requested further clarification on the term ''pressure ulcer/injury'' used in the proposed rule for this measure.

Other commenters opposed the use of the new NPUAP terminology. Commenters stated that the term ''injury'' is not universally supported by wound care organizations, does not differentiate closed versus open wounds, is clinically inaccurate, and does not align with ICD–10 codes in use for pressure ulcers. These commenters indicated that, while the term ''ulcer'' is related to underlying medical conditions, the term ''wound'' is related to the results of operations and accidents, which may imply intentionality.

Response: We are aware of the array of terms used to describe alterations in skin integrity due to pressure. Some of these terms include: Pressure ulcer, pressure injury, pressure sore, decubitus ulcer, and bed sore. However, for purposes of the proposed measure, a skin condition should be coded on the LTCH CARE Data Set as a pressure ulcer if the primary cause of the skin condition is related to pressure. For example, if the medical record reflects the presence of a Stage 2 pressure injury, it should be coded on the assessment as a Stage 2 pressure ulcer.

A TEP held by our measure development contractor on July 15, 2016 was very supportive of adopting the NPUAP terminology of ''pressure injury.'' Some members of the TEP stated that the term ''injury'' may be a more inclusive term than ''ulcer,'' and that the term ''pressure injury'' may be more easily and positively understood by patients, residents, and family members than ''pressure ulcer.'' The TEP recommended training for providers and consumers regarding any change in terminology. We concur with the TEP's recommendations. The purpose and intent of the measure is to provide increased surveillance of an important patient safety and quality of care issue, and language revisions are intended to ensure that patient wounds are captured in a comprehensive and systematic manner.

Regarding concerns about changes to ICD codes, we would like to clarify that the Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury measure is calculated using data elements from the LTCH CARE Data Set, and does not use ICD codes.

Comment: Several commenters expressed concern regarding the proposal to adopt a modified pressure ulcer measure. One commenter supported CMS' efforts to implement this measure as it may reduce the burden of collecting assessment data. Other commenters believed that the implementation of the modified pressure ulcer measure will create additional administrative and financial burdens for LTCHs. One commenter urged CMS to postpone the implementation of this measure, stating that this would allow LTCHs additional time to improve their performance on the existing pressure ulcer quality measure.

Response: We do not believe that the reporting of the proposed measure will impose a new burden on LTCHs because the measure is calculated using data elements that are currently included in the LTCH CARE Data Set. Further, our proposal to remove duplicative data elements that we are finalizing in this final rule will result in an overall reduced reporting burden for providers for the proposed measure.

Comment: Several commenters recommended using both the M0300 and M0800 data elements to calculate the pressure ulcer measure, and recommended that CMS maintain the M0800 data elements on the LTCH CARE Data Set. These commenters stated that M0800 data elements are used by PAC providers to verify the number of patients with pressure ulcers that are new or worsened since admission, and believed that the use of M0300 data elements might require PAC staff to review both admission and discharge assessments when verifying the accuracy of measure calculation. One commenter found the M0800 data elements to be clear and concise.

Response: We proposed to collect the proposed measure using the M0300 data element, and to remove the M0800 from the LTCH CARE Data Set, because we have found that use of the M0800 data element could result in the underreporting of pressure ulcers. Using the M0300 data element improves the reporting accuracy by establishing a standardized calculation. Further, the use of the M0300 data element facilitates standardization of the measure across settings.

During a TEP meeting held on July 18, 2016, to discuss this measure, multiple TEP members preferred the wording of the M0300 data element, compared with the M0800 data element. TEP members stated that this data element may be clearer and reduce opportunities for error. We agree with these views, and we plan to provide additional training opportunities to improve understanding of the data elements.

Comment: A few commenters noted that LTCH performance scores on the proposed measure are likely to differ from performance scores on the currently implemented pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678). They recommended development of educational materials for the public to explain the perceived shifts in performance.

Response: We appreciate commenters' concerns about differences in performance scores between the two measures and the possibility of misinterpretation. While the proposed measure will not be directly comparable to the existing measure, it is expected to provide an improved measure of quality moving forward since it will more accurately capture the number of new and worsened pressure ulcers and include unstageable pressure ulcers. Further information and training will be provided to providers as well as consumers regarding how to interpret scores on the proposed measure, to avoid any possible confusion between the proposed measure and the existing measure.

Comment: One commenter suggested that we include additional risk factors in the proposed measure, including age, mechanical ventilation status of the patient, and incontinence associated dermatitis. The commenter also recommended that we revise the terminology to be more specific (that is, ''diabetes mellitus'' instead of ''diabetes'' and ''impaired independent mobility'' instead of ''mobility'').

Response: We would like to note that this proposed quality measure will be risk adjusted for functional mobility admission performance, bowel continence, diabetes mellitus or peripheral vascular disease/peripheral arterial disease, and low body mass index in each of the four settings. In response to the commenters request for the use of more specific terminology of risk adjusters, we note that all terms are described in greater detail in the Specifications for LTCH QRP Quality Measures and Standardized Data Elements, available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html.* As with our measure modification and evaluation processes, we will continue to analyze this measure, specifically assessing the addition of variables to the risk adjustment model, and testing the

inclusion of other risk factors as additional risk adjustors. This continued refinement of the risk adjustment models will ensure that the measure remains valid and reliable to inform quality improvement within and across each PAC setting, and to fulfill the public reporting goals of quality reporting programs.

Comment: One commenter requested clarification on measure specification differences between LTCHs and other PAC settings. One commenter stated that there is an IMPACT Act mandate to implement ''interoperable measures'' across PAC settings.

Response: The Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury measure is harmonized across all PAC settings and uses standardized patient assessment data as required by the IMPACT Act. Further, we would like to clarify that the M0300 data element used to calculate this measure is standardized across all PAC settings, enabling interoperability. This standardization and interoperability of data elements allows for the exchange of information among PAC providers and other providers to whom this data is applicable. We refer readers to the measure specifications, which describe the specifications for the measure in PAC settings, *Final Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,* available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html.*

After consideration of the public comments we received, we are finalizing our proposal to remove the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), from the LTCH QRP measure set and replace it with a modified version of that measure, entitled Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, for the LTCH QRP with an implementation date of July 1, 2018.

b. Mechanical Ventilation Process Quality Measure: Compliance With Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay

Invasive mechanical ventilation care was identified through technical expert panels convened by our measure development contractor and public comment periods as a gap in the LTCH QRP measure set and aligns with the National Quality Strategy priority and the CMS Quality Strategy goal of ''promoting the most effective prevention and treatment practices'' by reducing the risk of complications from unnecessarily prolonged mechanical ventilation. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20092 through 20095), we proposed to adopt the quality measure, Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay, beginning with the FY 2020 LTCH QRP. The data applicable to this measure that must be reported by LTCHs for admissions as well as discharges occurring on or after April 1, 2018 is described in section IX.C.11. of the preamble of this final rule.

The Compliance with SBT by Day 2 of the LTCH Stay measure is a process quality measure. For patients on invasive mechanical ventilation support upon admission to the LTCH, except those who meet measure exclusion criteria, this measure assesses facility-level compliance with SBT, including Tracheostomy Collar Trial (TCT) or Continuous Positive Airway Pressure (CPAP) breathing trial, by Day 2 of the LTCH stay, where Day 1 is the day of admission to the LTCH and Day 2 is the subsequent calendar day. This measure is calculated and reported for the following two components: (1) The percentage of patients admitted on invasive mechanical ventilation who were assessed for readiness for SBT by Day 2 of the LTCH Stay, and (2) the percentage of patients deemed medically ready for SBT who received SBT by Day 2 of the LTCH stay. Higher percentages indicate better compliance. Patients are included in this quality measure if they are on invasive mechanical ventilation support upon admission to the LTCH, unless they meet measure exclusion criteria.

Patients on invasive mechanical ventilation support present a critical focus for assessment of high quality care because they comprise a substantial proportion of LTCH patient admissions. Mechanically ventilated patients are increasingly common in both acute care hospital intensive care units (ICUs), where up to 40 percent of patients require some duration of mechanical ventilation,[369] and LTCHs, where patients are frequently transferred for weaning following treatment in ICUs.[370 371 372] Patients who require invasive mechanical ventilation of longer than 14 or 21 days are undergoing prolonged mechanical ventilation (PMV). In 2012, about 22,000 or 15.8 percent of all LTCH discharges received PMV services during the LTCH stay.[373]

This ventilator weaning-related process quality measure is important for encouraging implementation of evidence-based weaning guidelines as early during the LTCH patient stay as is beneficial to the patient. Although often necessary for life support, invasive mechanical ventilation is not without risk of harm to patients, and these risks increase as duration of ventilation continues.[374 375 376] In both ICUs and LTCHs, unsuccessful weaning and delayed weaning increase patient exposure to a number of ventilator-associated negative health outcomes, including ventilator-associated pneumonia,[377 378 379 380] ventilator-associated lung injury,[381 382 383] ventilator induced diaphragm

[369] Dasta, J.F., et al. (2005). ''Daily cost of an intensive care unit day: the contribution of mechanical ventilation.'' *Crit Care Med* 33(6): 1266–1271.

[370] Dasta, J.F., et al. (2005). ''Daily cost of an intensive care unit day: the contribution of mechanical ventilation.'' *Crit Care Med* 33(6): 1266–1271.

[371] Kahn, J.M., et al. (2010). ''Long-term acute care hospital utilization after critical illness.'' *JAMA* 303(22): 2253–2259.

[372] Szubski, C.R., et al. (2014). ''Predicting discharge to a long-term acute care hospital after admission to an intensive care unit.'' *Am J Crit Care* 23(4): e46–53.

[373] MedPAC (2016). Chapter 10. Long-term Care Hospital Services. In: Report to the Congress: Medicare Payment Policy. Washington, DC, Medicare Payment Advisory Commission.

[374] Esteban, A., et al. (2002). ''Characteristics and outcomes in adult patients receiving mechanical ventilation: a 28-day international study.'' *JAMA* 287(3): 345–355.

[375] Cox, C.E., et al. (2007). ''Differences in one-year health outcomes and resource utilization by definition of prolonged mechanical ventilation: a prospective cohort study.'' *Crit Care* 11(1): R9.

[376] Penuelas, O., et al. (2011). ''Characteristics and outcomes of ventilated patients according to time to liberation from mechanical ventilation.'' *Am J Respir Crit Care Med* 184(4): 430–437.

[377] Cook, D.J., et al. (1998). ''Incidence of and risk factors for ventilator-associated pneumonia in critically ill patients.'' *Ann Intern Med* 129(6): 433–440.

[378] Papazian, L., et al. (1996). ''Effect of ventilator-associated pneumonia on mortality and morbidity.'' *Am J Respir Crit Care Med* 154(1): 91–97.

[379] Vincent, J.L., et al. (1995). ''The prevalence of nosocomial infection in intensive care units in Europe. Results of the European Prevalence of Infection in Intensive Care (EPIC) Study. EPIC International Advisory Committee.'' *JAMA* 274(8): 639–644.

[380] Safdar, N., et al. (2005). ''Clinical and economic consequences of ventilator-associated pneumonia: a systematic review.'' *Crit Care Med* 33(10): 2184–2193.

[381] Meade, M.O. and D.J. Cook (1995). ''The aetiology, consequences and prevention of barotrauma: a critical review of the literature.'' *Clin Intensive Care* 6(4): 166–173.

[382] Meade, M.O., et al. (1997). ''How to use articles about harm: the relationship between high tidal volumes, ventilating pressures, and ventilator-induced lung injury.'' *Crit Care Med* 25(11): 1915–1922.

[383] Slutsky, A.S. and L.N. Tremblay (1998). ''Multiple system organ failure. Is mechanical ventilation a contributing factor?'' *Am J Respir Crit Care Med* 157(6 Pt 1): 1721–1725.

dysfunction,[384] psychological distress [385 386 387] and post-traumatic stress disorder,[388] disability [389] and decreased functional status,[390 391] and chronic critical illness syndrome.[392] Furthermore, these ventilator-associated negative health outcomes particularly affect the LTCH population since a significant number of its patients are on PMV. The majority of mechanically ventilated patients who are transferred to an LTCH have received mechanical ventilation for at least 21 days.[393] PMV increases the risk of patient morbidity and short-term and long-term mortality. According to a recent systematic review, the pooled mortality of patients with PMV (defined here as invasive mechanical ventilation for ≥14 days) undergoing weaning attempts in LTCHs was 31 percent (18 studies); however, the pooled mortality at one year significantly increased to 73 percent (8 studies).[394]

In addition to increased morbidity and mortality, mechanical ventilation is also associated with higher costs. While the literature on costs of mechanical ventilation are limited for the LTCH setting, studies in the acute care hospital ICU setting indicate that patients who require mechanical ventilation can have up to 50 percent higher costs than patients who do not receive mechanical ventilation.[395] ICU patients who develop VAP incur at least $40,000 more in hospital costs than ventilated patients without VAP, and costs increase with increasing duration of mechanical ventilation.[396 397 398]

Although there is evidence regarding the benefit of daily assessments of patient readiness for weaning from invasive mechanical ventilation,[399] as well as for the importance of adherence to weaning protocols,[400] we are not aware of any studies in LTCHs that evaluate timing of assessment for readiness to wean with respect to the admission date. However, an international task force, convened in 2005, developed guideline recommendations to address the entire weaning process. Despite the limited evidence, this task force recommended that weaning be considered as soon as possible,[401] because failure to assess the patient for readiness to wean may lead to undue prolonged mechanical ventilation,[402] thus exposing patients unnecessarily to adverse ventilator-associated morbidity and mortality.[403] Based on studies and observations of implementation of regular assessment for SBTs and weaning protocols in ICUs, adherence to the recommended weaning processes, including prompt assessment of weaning readiness and initiation of SBTs, appears quite variable, likely due to differences in clinicians' intuitive thresholds for determination of patients' readiness to wean.[404 405] Clinician delays in recognizing that weaning may be possible and beginning assessment of weaning readiness are two common causes of weaning delays.[406] In one study, 50 percent of the patients considered to be incapable of sustaining spontaneous ventilation by clinicians later were able to tolerate a weaning trial. The authors concluded that tests used to validate clinician intuition on a patient's readiness for weaning are often inaccurate and that clinicians should follow explicit protocols to consistently test patients on their readiness to wean.[407] Because prompt identification of patients' readiness for SBTs has been shown to reduce weaning duration without harm to patients,[408] such delays indicate less than optimal performance [409] and opportunities for improvement.

Indirect evidence for the need for prompt recognition of patients' readiness to wean in LTCHs comes from a recent study of patients newly admitted to LTCHs on invasive mechanical ventilation, which reported that 32 percent of invasively mechanically ventilated patients admitted to an LTCH passed a 5-day TCT following admission.[410] That nearly one third of newly admitted LTCH patients were able to be completely weaned within five days underscores the need to assess patients' ability to breathe without assistance soon after admission to an LTCH, and also indicates that this quality measure

[384] Levine, S., et al. (2008). ''Rapid disuse atrophy of diaphragm fibers in mechanically ventilated humans.'' *N Engl J Med* 358(13): 1327–1335.

[385] Rose, L., et al. (2014). ''Psychological wellbeing, health related quality of life and memories of intensive care and a specialised weaning centre reported by survivors of prolonged mechanical ventilation.'' *Intensive Crit Care Nurs* 30(3): 145–151.

[386] Schou, L. and I. Egerod (2008). ''A qualitative study into the lived experience of post-CABG patients during mechanical ventilator weaning.'' *Intensive Crit Care Nurs* 24(3): 171–179.

[387] Rotondi, A.J., et al. (2002). ''Patients' recollections of stressful experiences while receiving prolonged mechanical ventilation in an intensive care unit.'' *Crit Care Med* 30(4): 746–752.

[388] Jubran, A., et al. (2010). ''Post-traumatic stress disorder after weaning from prolonged mechanical ventilation.'' *Intensive Care Med* 36(12): 2030–2037.

[389] Barnato, A.E., et al. (2011). ''Disability among elderly survivors of mechanical ventilation.'' *Am J Respir Crit Care Med* 183(8): 1037–1042.

[390] Scheinhorn, D.J., et al. (2007). ''Post-ICU mechanical ventilation at 23 long-term care hospitals: a multicenter outcomes study.'' *Chest* 131(1): 85–93.

[391] Cox, C.E., et al. (2007). ''Differences in one-year health outcomes and resource utilization by definition of prolonged mechanical ventilation: a prospective cohort study.'' *Crit Care* 11(1): R9.

[392] Cox, C.E., et al. (2007). ''Differences in one-year health outcomes and resource utilization by definition of prolonged mechanical ventilation: a prospective cohort study.'' *Crit Care* 11(1): R9.

[393] MacIntyre, N.R., Epstein, S.K., Carson, S., Scheinhorn, D., Christopher, K., Muldoon, S., & National Association for Medical Direction of Respiratory, C. (2005). Management of patients requiring prolonged mechanical ventilation: report of a NAMDRC consensus conference. Chest, 128(6), 3937–3954.

[394] Damuth, E., et al. (2015). ''Long-term survival of critically ill patients treated with prolonged mechanical ventilation: a systematic review and meta-analysis.'' *Lancet Respir Med.* 2015 May 20.

[395] Dasta, J.F., et al. (2005). ''Daily cost of an intensive care unit day: the contribution of mechanical ventilation.'' *Crit Care Med* 33(6): 1266–1271.

[396] Kollef, M.H., et al. (2012). ''Economic impact of ventilator-associated pneumonia in a large matched cohort.'' *Infect Control Hosp Epidemiol* 33(3): 250–256.

[397] Restrepo, M.I., et al. (2010). ''Economic burden of ventilator-associated pneumonia based on total resource utilization.'' *Infect Control Hosp Epidemiol* 31(5): 509–515.

[398] Sedwick, M.B., et al. (2012). ''Using evidence-based practice to prevent ventilator-associated pneumonia.'' *Crit Care Nurse* 32(4): 41–51.

[399] Robertson, T.E., et al. (2008). ''Improved extubation rates and earlier liberation from mechanical ventilation with implementation of a daily spontaneous-breathing trial protocol.'' *J Am Coll Surg* 206(3): 489–495.

[400] Blackwood, B., et al. (2014). ''Protocolized versus non-protocolized weaning for reducing the duration of mechanical ventilation in critically ill adult patients.'' *Cochrane Database Syst Rev* 11: Cd006904.

[401] Boles, J.M., et al. (2007). ''Weaning from mechanical ventilation.'' *Eur Respir J* 29(5): 1033–1056.

[402] MacIntyre, N.R., Epstein, S.K., Carson, S., Scheinhorn, D., Christopher, K., Muldoon, S., & National Association for Medical Direction of Respiratory, C. (2005). Management of patients requiring prolonged mechanical ventilation: report of a NAMDRC consensus conference. Chest, 128(6), 3937–3954.

[403] Hess, D.R., & MacIntyre, N.R. (2011). Ventilator discontinuation: why are we still weaning? Am J Respir Crit Care Med, 184(4), 392–394.

[404] MacIntyre, N.R. (2013). ''The ventilator discontinuation process: an expanding evidence base.'' *Respir Care* 58(6): 1074–1086.

[405] Kollef, M.H., et al. (1997). ''A randomized, controlled trial of protocol-directed versus physician-directed weaning from mechanical ventilation.'' *Crit Care Med* 25(4): 567–574.

[406] Boles, J.M., et al. (2007). ''Weaning from mechanical ventilation.'' *Eur Respir J* 29(5): 1033–1056.

[407] Cook, D., et al. (2000). Criteria for Weaning from Mechanical Ventilation. *Evidence Reports/Technology Assessments,* Agency for Healthcare Research and Quality.

[408] Ely, E.W., et al. (1996). ''Effect on the duration of mechanical ventilation of identifying patients capable of breathing spontaneously.'' *N Engl J Med* 335(25): 1864–1869.

[409] Blackwood, B., et al. (2014). ''Protocolized versus non-protocolized weaning for reducing the duration of mechanical ventilation in critically ill adult patients.'' *Cochrane Database Syst Rev* 11: Cd006904.

[410] Jubran, A., et al. (2013). ''Effect of pressure support vs unassisted breathing through a tracheostomy collar on weaning duration in patients requiring prolonged mechanical ventilation: a randomized trial.'' *JAMA* 309(7): 671–677.

has potential to positively impact the health and quality of care received by a considerable proportion of the LTCH patient population.

Because invasive mechanical ventilation should be discontinued as soon as patients are capable of breathing independently,[411] [412] unnecessarily prolonged mechanical ventilation can be an indicator of poor care quality or of persistent illness.[413] This quality measure is designed to encourage adherence to evidence-based and consensus-based guidelines through implementation of timely assessment of patient readiness to wean and trials of unassisted breathing. To increase timeliness of weaning and reduce patient risk of complications, it is important to assess a patient's need for continued mechanical ventilation at the time of admission. Measuring and comparing assessment of readiness to wean and compliance with SBT by Day 2 is expected to help differentiate among facilities with varying performance in this important domain. The anticipated improvement in quality is an improvement in timeliness of weaning and ventilator liberation for patients admitted to LTCHs on invasive mechanical ventilation. In addition, facilities can use results of this measure to improve timely compliance with evidence-based weaning guidelines and develop ventilator weaning quality improvement programs.

A TEP assembled by our measure development contractor convened nine meetings (two in-person meetings and seven webinars) between April 2014 and August 2016 in order to refine the quality measure's technical specifications, including the measure target population, inclusion and exclusion criteria, and key definitions (for example, ''non-weaning''). The TEP also offered feedback on the individual LTCH CARE Data Set ventilator weaning items and supported the feasibility of implementing this measure in the LTCH setting. The measure developer recruited two former patients successfully weaned from mechanical ventilation as well as the primary caregiver of one of the patients to solicit their views on the measures. The *2014–2016 Development of Long-Term Care Hospital (LTCH) Ventilator Weaning Quality Measures Technical Expert Panel Summary Report* is available on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*.

We also solicited stakeholder feedback on the development of this measure through a public comment period held from May 19, 2016, through June 9, 2016. Several stakeholders and organizations supported this measure for implementation, including hospitals and professional organizations. The public comment summary report for the proposed measure is available on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*.

Our measure development contractor conducted a pilot test on the data elements used to calculate this quality measure. The pilot test was conducted in 10 LTCHs among approximately 150 LTCH patients and used a mixed methods research design to collect data. Quantitative data on the ventilator weaning items was collected from May 27, 2016 through September 10, 2016, and qualitative data on these items was collected from June 6, 2016 through October 4, 2016. The LTCHs who participated in the pilot test were selected to represent variation across several key facility-level characteristics: geographic location, size, and profit status.

The qualitative data from the pilot test of the ventilator weaning process measure supported the importance of the measure. Results from qualitative and quantitative analysis further support the feasibility of data collection for this quality measure. Data collection for this quality measure was not seen as burdensome by pilot sites. The pilot test summary report for this measure is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*.

The NQF-convened MAP PAC/LTC Workgroup met on December 12, 2014 and again on December 14 and 15, 2015. During these meetings, the MAP encouraged continued development of this proposed measure, acknowledging that there is evidence for interventions that improve ventilator care,[414] that variation in quality of care exists among LTCHs,[415] and that ventilator care is an important safety priority for LTCHs.[416]

Since the MAP's review and recommendation of continued development in 2015, we have continued to refine this proposed measure in accordance with the MAP's recommendations. Results of continued development activities, including stakeholder feedback from the 2016 public comment period and 2016 pilot test findings, were presented to the MAP during the MAP feedback loop meeting in October 2016. The proposed measure is consistent with the information submitted to the MAP, and the original MAP submission and our continued refinements support its scientific acceptability for use in quality reporting programs. As discussed with the MAP, we fully anticipate that additional analyses will continue once data collection for the measure begins. More information about the MAP's recommendations for this proposed measure is available at: *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx*.

We reviewed the NQF's consensus endorsed measures and were unable to identify any NQF-endorsed ventilator weaning quality measures focused on assessment of readiness to wean for patients admitted on invasive mechanical ventilation in the LTCH setting. We are unaware of any other quality measures for weaning from invasive mechanical ventilation that have been endorsed or adopted by another consensus organization for the LTCH setting. Therefore, based on the evidence discussed above, we proposed to adopt the quality measure entitled, Compliance with SBT by Day 2 of the LTCH Stay, for the LTCH QRP beginning with the FY 2020 LTCH QRP. We plan to submit the quality measure to the NQF for consideration for endorsement.

We proposed that data for this ventilator weaning quality measure be collected through the LTCH CARE Data

[411] Blackwood, B., et al. (2011). ''Use of weaning protocols for reducing duration of mechanical ventilation in critically ill adult patients: Cochrane systematic review and meta-analysis.'' *BMJ* 342: c7237.

[412] Epstein, S.K. (2009). ''Weaning from ventilatory support.'' *Current opinion in critical care, 15*(1), 36–43. doi: 10.1097/MCC.0b013e3283220e07.

[413] MacIntyre, N.R. (2013). ''The ventilator discontinuation process: an expanding evidence base.'' *Respir Care* 58(6): 1074–1086.

[414] ''Spreadsheet of MAP 2015 Final Recommendations (XLSX).'' Measure Applications Partnership Post Acute Care/Long-Term Care Workgroup. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711*.

[415] ''Spreadsheet of MAP 2016 Final Recommendations (XLSX).'' Measure Applications Partnership Post Acute Care/Long-Term Care Workgroup. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593*.

[416] MAP 2015 Considerations for Implementing Measures in Federal Programs: Draft for Public Comment. Measure Applications Partnership Post Acute Care/Long-Term Care Workgroup. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75370*.

Set, with submission through the QIES ASAP System. For more information on LTCH QRP reporting using the QIES ASAP System, we refer readers to our Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Technical-Information.html*. We stated that we intended to revise the LTCH CARE Data Set to include new items that assess processes for weaning from invasive mechanical ventilation, should this proposed measure be adopted.

This measure is calculated and reported for two components. The proposed measure denominator for Component 1, Percentage of Patients Assessed for Readiness for SBT by Day 2 of LTCH Stay, is the total number of patients admitted during the reporting period who were on invasive mechanical ventilation upon admission to an LTCH and expected or anticipated by the provider to undergo weaning attempts at admission. The proposed measure numerator for Component 1 is the number of patients admitted on invasive mechanical ventilation during the reporting period who were assessed for readiness for SBT (including TCT or CPAP breathing trial) by Day 2 of the LTCH stay.

The proposed measure denominator for Component 2, Percentage of Patients Ready for SBT Who Received SBT by Day 2 of LTCH Stay, is the subset of patients in the denominator of the Component 1, who were assessed and deemed medically ready for SBT by Day 2 of the LTCH stay. The proposed measure numerator for Component 2, Percentage of Patients Ready for SBT Who Received SBT by Day 2 of LTCH Stay, is the number of patients admitted on invasive mechanical ventilation during the reporting period who were ready for SBT and who received an SBT (including TCT or CPAP breathing trial) by Day 2 of the LTCH stay.

For technical information about this proposed measure, including information about the measure calculation and proposed measure denominator exclusions, we refer readers to the document titled, *Final Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,* available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*.

We invited public comments on our proposal to adopt the quality measure, Compliance with SBT by Day 2 of the LTCH Stay, beginning with the FY 2020 LTCH QRP.

Comment: Some commenters expressed support for the adoption of Compliance with SBT by Day 2 of the LTCH Stay for the LTCH QRP. Commenters noted that reducing risks of complications associated with prolonged mechanical ventilation, such as VAEs, and improving ventilator weaning rates are important areas for quality measurement in LTCHs. Another commenter expressed support that this measure will provide data necessary to reduce the risk of complications from unnecessarily prolonged mechanical ventilation and reduce variations in practice that do not benefit patients.

Response: We appreciate the commenters' support of the Compliance with SBT by Day 2 of the LTCH Stay measure and support for this topic for the LTCH QRP. We agree that the objective of this measure aligns with guidelines on reducing time spent on mechanical ventilation to decrease risk of complications and to improve ventilator weaning rates.

Comment: Some commenters recommended that CMS further test the Compliance with SBT by Day 2 of the LTCH Stay measure prior to finalization and implementation for the LTCH QRP.

Response: Determination of measure readiness for implementation and data collection was informed by feedback and results from the pilot test and TEP discussions. Pilot sites were able to test the items related to the measure and provided feedback via a series of check-ins that further informed measure development. The TEPs further supported measure development by providing critical insight and feedback from clinicians, researchers, and experienced LTCH administrators. In addition, patient advocates provided insight into ventilated patient experiences in the LTCH and the utility of the ventilator weaning measures. Additional testing will be conducted as data collection ensues, and we will continue to test these measures on a quarterly basis if feasible and conduct maintenance and evaluation of the measure for reliability and validity.

Comment: One commenter appreciated that the measure has significantly evolved from conception and recommended that we submit the measure to NQF for consideration of endorsement.

Response: We appreciate the commenter for their comment about the extensive work that went into the measure development process. With regard to NQF endorsement, as noted in the proposed rule, we intend to submit the measure to NQF for consideration of endorsement. We further note that we consider and propose appropriate measures that have been endorsed by the NQF whenever possible. However, section 1886(m)(5)(D)(ii) of the Act allows the Secretary to specify a measure for the LTCH QRP that that is not NQF endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization. In the case of the proposed measure, we have not been able to identify other measures that are endorsed or adopted by a consensus organization. While we appreciate the importance of consensus endorsement and intend to seek such endorsement, we believe the need to address the measure gap in invasive mechanical ventilation care in the LTCH QRP outweighs the general rule of adopting an NQF endorsed measure at this time.

Comment: With respect to the addition of the two ventilator weaning measures for FY 2020, one commenter expressed concern that the expanded patient assessment data reporting requirements would impose a significant burden on providers.

Response: We appreciate the commenter's concern about the burden associated with the measure proposals; however, we believe that these measures are important to assess measure gaps for LTCH patients. We intend to provide guidance and training for providers to address their concerns regarding the expanded patient assessment data reporting requirements.

Comment: A commenter expressed concern that the small size of the pilot test used to inform the development of this measure may not be adequate to conclude that the measure is reliable and accurate.

Response: The focus of the pilot test was to inform measure development as well as to evaluate the feasibility of patient-level data collection and submission. To obtain a balanced sample of participants, pilot sites were chosen based on criteria including LTCH size, geographic region, and ownership type. Based on the size and projected number of ventilated patients, the number of sites recruited was deemed to provide a sufficient number of patients for analysis of the feasibility of data collection and validity of the mechanical ventilation quality measures. Pilot sites received in-depth trainings and provided feedback via a series of check-ins that further informed measure development during the course of the pilot study. We concluded that the pilot test was adequate to proceed with proposal of the measure for adoption under the LTCH QRP. We will continue to test these measures on a quarterly basis and conduct

maintenance and evaluation of the measure for reliability and validity.

Comment: Some commenters were concerned with the 2-day time frame to assess an admitted patient for readiness to perform SBT because it would be burdensome to providers especially for patients admitted during evenings or weekends. Some commenters recommended extending the time frame to complete the assessment to 5 days as used in a recent study led by Jubran et al., 2013.[417]

Response: We wish to clarify that the 5-day time frame used by a recent study led by Jubran et al., 2013 to assess LTCH patients on invasive mechanical ventilation is not an established protocol. A task force in 2005 on the subject of weaning from mechanical ventilation, which included international scientific experts and advisors, recommended that liberation be considered as soon as possible for patients to reduce risk of complications and mortality.[418] Accordingly, TEP members agreed that the 5-day time frame was too long compared to best practices and that assessment for ventilator liberation should be prior to 5 days. After extensive discussion, TEP members recommended the 2-day time frame to set a high standard to encourage high quality of care and increase the chance that patients are determined to be capable of liberation from mechanical ventilation earlier.

Comment: One commenter was concerned that the proposed measure conflicts with the site neutral payment policy.

Response: We appreciate the opportunity to clarify that the proposed measure is intended to ensure that patients on invasive mechanical ventilation support upon LTCH admission are assessed for readiness for SBT as recommended. In addition, if a patient on invasive mechanical ventilation is found ready for SBT, then a provider should perform an SBT. This measure does not conflict with the site neutral payment policy because providers are not assessed on the time to liberation (completion of an SBT and liberation from mechanical ventilation), but assessed on initiating the process (completing an assessment of the patient) to determine whether the patient is medically ready to be liberated from mechanical ventilation.

Comment: One commenter expressed concern about whether the proposed measure is a safe and feasible practice for patients. Another commenter noted that the short time frame may have unintended negative consequences for patient care and forces clinical judgment on weaning status.

Response: We appreciate the commenters' concerns pertaining to patient safety, and would like to emphasize that patient safety is a top priority in all measurement development efforts. We encourage providers to use best patient care practices when assessing patients for readiness for liberation. In addition, we note that while the measure assesses providers on completing an assessment of the patient to determine whether the patient is medically ready to be liberated from mechanical ventilation, it does not ''force'' providers to make any particular assessment, and we encourage providers to classify patients as ''weaning'' or ''non-weaning'' as clinically appropriate. Of note, evidence-based guidelines recommend that liberation be considered as soon as possible for patients to reduce risk of complications and mortality. If a clinician deemed a patient medically unready to perform SBT, then the decision should be documented and providers should code this item appropriately.

Comment: One commenter was concerned that the multi-component structure of the measure may be confusing to providers and that definitions embedded in the calculation of the two components (specifically, ''documentation,'' ''weaning,'' and ''non-weaning'') are too subjective.

Response: We would like to clarify that ''documentation'' that the patient was not deemed medically ready for SBT can be any medical record that a provider uses to document patient information. In regard to weaning status, we encourage providers to classify patients as ''weaning'' or ''non-weaning'' as clinically appropriate. We wish to further clarify that patients with specific conditions such as amyotrophic lateral sclerosis that may negate any expectation or anticipation of weaning attempts on admission may be considered ''non-weaning'' by the provider. We intend to provide training and guidance prior to the implementation of the quality measure to ensure that providers are prepared to properly collect the data and fully understand the measure specifications.

After consideration of the public comments we received, we are finalizing our proposal to adopt the measure, Compliance with SBT by Day 2 of the LTCH Stay, beginning with the FY 2020 LTCH QRP with an implementation date of July 1, 2018, as discussed in section IX.C.11. of the preamble of this final rule.

c. Mechanical Ventilation Outcome Quality Measure: Ventilator Liberation Rate

Invasive mechanical ventilation care was identified as an important gap in the LTCH QRP measure set,[419] and aligns with the National Quality Strategy priority and the CMS Quality Strategy goal of ''promoting the most effective prevention and treatment practices'' by reducing the risk of complications from unnecessarily prolonged mechanical ventilation. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20095 through 20097), we proposed to adopt the quality measure, Ventilator Liberation Rate, for the LTCH QRP beginning with the FY 2020 LTCH QRP. The data applicable to this measure that must be reported by LTCHs for admissions as well as discharges occurring on or after April 1, 2018 is described in section IX.C.11. of the preamble of this final rule.

The Ventilator Liberation Rate measure is an outcome quality measure. This quality measure is a facility-level measure that reports the percentage of LTCH patients admitted on invasive mechanical ventilation, for whom weaning attempts were expected or anticipated, and are fully weaned by the end of their LTCH stay. Patients who are considered fully weaned at discharge are those who did not require any invasive mechanical ventilation support for at least 2 consecutive calendar days immediately prior to discharge. While the first ventilator weaning measure we proposed captures the weaning process, this measure captures the key outcome of successful liberation from invasive mechanical ventilation.

We refer readers to section IX.C.7.b. of the preamble of this final rule for information regarding the literature review in support of proposing the mechanical ventilation process quality measure, Compliance with SBT by Day 2 of the LTCH Stay.

Discontinuation of invasive mechanical ventilation, known as weaning or liberation, is feasible for many ventilated patients, and is associated with improved health outcomes. In LTCHs, higher weaning rates have been associated with lower

[417] Jubran, A., et al. (2013). ''Effect of pressure support vs unassisted breathing through a tracheostomy collar on weaning duration in patients requiring prolonged mechanical ventilation: a randomized trial.'' *JAMA* 309(7): 671–677.

[418] Boles, J.M., et al. (2007). ''Weaning from mechanical ventilation.'' *Eur Respir J* 29(5): 1033–1056.

[419] Technical Expert Panel Report: Quality Measures for Long-Term Care Hospitals. Thaker, S., Gage, B., Bernard, S., and Nguyen, K. March 2011.

post-discharge mortality, even among the elderly,[420 421 422 423 424] and fewer days of mechanical ventilation may lead to decreased risk of ventilator-associated complications/events, enhanced rehabilitation opportunities, and a shorter length of stay.[425] Based on the evidence, increasing weaning rates is expected to reduce the risk of harm associated with invasive mechanical ventilation, thus contributing to more favorable clinical outcomes for patients[426 427] and decreased costs.

Numerous studies from 1991 through 2015 have reported a range of ventilator liberation rates among LTCHs. A review of nine single-center studies conducted between 1991 and 2001 reported that, among more than 3,000 patients with PMV >21 days, facility-level liberation rates ranged from 34 percent to 60 percent, with an overall weaning rate of 52 percent.[428] A recent systematic review identified nine studies (4,769 patients) reporting the proportion of patients successfully liberated from ventilation in LTCHs, and found a pooled weaning rate of 47 percent (95 percent CI 42–51); rates reported by individual studies conducted in the United States varied from 13 percent to 56 percent.[429] Lower liberation rates may indicate less-than-optimal performance.

Ventilator liberation rate is an actionable health care outcome. Multiple interventions have been shown to increase ventilator liberation rates, including selection and implementation of weaning protocols, ventilator modes, and type of pressure support strategies. Multiple studies in LTCHs[430 431 432] and ICUs[433 434] provide evidence to support the relationship between weaning processes and the successful weaning of mechanically ventilated LTCH patients. The effectiveness of these interventions suggests that improvement in liberation rates among LTCH patients is possible through modifying provider-led processes and interventions.

Expectations of successful ventilator liberation are high for many LTCH patients.[435 436 437] Unnecessarily prolonged mechanical ventilation increases the risk of negative patient outcomes and can be an indicator of poor quality care or of persistent illness.[438] Based on the evidence, improving weaning processes and increasing weaning rates are expected to mitigate the risk of harm associated with invasive mechanical ventilation, thus contributing to more favorable clinical outcomes for patients[439 440] and decreased costs.[441] This quality measure, Ventilator Liberation Rate, will assess the proportion of patients discharged alive from an LTCH who are fully weaned, thereby promoting weaning efforts and encouraging quality management of LTCH patients on invasive mechanical ventilation. Kahn et al. (2013) noted that inclusion of a liberation outcome measure is key to providing a truly patient-centered measure related to invasive mechanical ventilation weaning among LTCH patients.[442]

A TEP assembled by our measure development contractor convened nine meetings (two in-person meetings and seven webinars) between April 2014 and August 2016. TEP members provided input to guide the development of the quality measures, including feedback on the individual LTCH CARE Data Set ventilator weaning items, the target population, inclusion and exclusion criteria, and patient demographic and clinical factors that could affect ventilator weaning outcomes (risk adjustors). TEP members also supported the feasibility of implementing this measure in the LTCH setting. The measure developer recruited two former patients successfully weaned from mechanical ventilation as well as the primary caregiver of one of the patients to solicit their views on the measures. The *2014–2016 Development of Long-Term Care Hospital (LTCH) Ventilator Weaning Quality Measures Technical Expert Panel Summary Report* is available on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*.

[420] Blackwood, B., et al. (2014). ''Protocolized versus non-protocolized weaning for reducing the duration of mechanical ventilation in critically ill adult patients.'' *Cochrane Database Syst Rev* 11: Cd006904.

[421] Frengley, J., et al. (2014). ''Prolonged mechanical ventilation in 540 seriously ill older adults: effects of increasing age on clinical outcomes and survival.'' *J Am Geriatr Soc* 62(1): 1–9.

[422] Rose, L. and I.M. Fraser (2012). ''Patient characteristics and outcomes of a provincial prolonged-ventilation weaning centre: a retrospective cohort study.'' *Can Respir J* 19(3): 216–220.

[423] Scheinhorn, D.J., et al. (2007). ''Post-ICU mechanical ventilation at 23 long-term care hospitals: a multicenter outcomes study.'' *Chest* 131(1): 85–93.

[424] Stearn-Hassenpflug, M., et al. (2013). ''Post-ICU Mechanical Ventilation: Trends in Mortality and 12-month Post-discharge Survival.'' *Critical Care Medicine* 41(12): A166.

[425] Hassenpflug, M.S., et al. (2015). Post-ICU Mechanical Ventilation: Outcomes of the Revised Therapist-Implemented Patient-Specific Weaning Protocol. [abstract] *B44. Invasive And Non-Invasive Mechanical Ventilation,* American Thoracic Society: A3166–A3166.

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[430] Jubran, A., et al. (2013). ''Effect of pressure support vs unassisted breathing through a tracheostomy collar on weaning duration in patients requiring prolonged mechanical ventilation: a randomized trial.'' *JAMA* 309(7): 671–677.

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[432] Hassenpflug, M.S., et al. (2015). Post-ICU Mechanical Ventilation: Outcomes of the Revised Therapist-Implemented Patient-Specific (TIPS?) Weaning Protocol. *B44. Invasive And Non-Invasive Mechanical Ventilation,* American Thoracic Society: A3166–A3166.

[433] Ely, E.W., et al. (1996). ''Effect on the duration of mechanical ventilation of identifying patients capable of breathing spontaneously.'' *N Engl J Med* 335(25): 1864–1869.

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[436] Hassenpflug, M.S., et al. (2011). Post-ICU Mechanical Ventilation: Extended Care Facility Residents Transferred From Intensive Care To Long-Term Acute Care. *American Thoracic Society 2011 International Conference.* Denver, Colorado.

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[442] Kahn, J.M., & Carson, S.S. (2013). Generating evidence on best practice in long-term acute care hospitals. *JAMA, 309*(7), 719–720.

We also solicited stakeholder feedback on the development of this measure through a public comment period held from May 19, 2016, through June 9, 2016. Several stakeholders and organizations supported this measure for implementation, including hospitals and professional organizations. The public comment summary report for the proposed measure is available on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*.

Our measure development contractor conducted a pilot test on the proposed data elements used to calculate this quality measure. The pilot test was conducted in ten LTCHs which included approximately 150 LTCH patients and used a mixed methods research design to collect data. Quantitative data on the ventilator weaning items was collected from May 27, 2016 through September 10, 2016, and qualitative data on these items was collected from June 6, 2016 through October 4, 2016. The LTCHs who participated in the pilot test were selected to represent variation across several key facility-level characteristics: Geographic location, size, and profit status.

The qualitative data from the pilot test of the ventilator liberation quality measure supported the importance of the measure; results from qualitative and quantitative analysis also supported the feasibility of data collection. Data collection for this quality measure was not seen as burdensome by pilot sites. The pilot test summary report for this measure is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*.

The NQF-convened MAP PAC/LTC Workgroup met on December 12, 2014, and on December 14 and 15, 2015. During these meetings, the MAP provided input on the importance and specifications of this measure. The MAP encouraged continued development of the measure, stating that this measure has high value potential for the LTCH QRP[443] because successful weaning is important for improving quality of life and decreasing morbidity, mortality, and resource use among patients.[444] [445]

Since the MAP's review and recommendation of continued development in 2015, we have continued to refine this proposed measure in accordance with the MAP's recommendations. Results of continued development activities, including stakeholder feedback from the 2016 public comment period and 2016 pilot test findings, were presented to the MAP during the MAP feedback loop meeting in October 2016. The proposed measure is consistent with the information submitted to the MAP, and the original MAP submission and our continued refinements support its scientific acceptability for use in quality reporting programs. As discussed with the MAP, we fully anticipate that additional analyses will continue once data collection for the measure begins. More information about the MAP's recommendations for this measure is available at: *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx*.

We reviewed the NQF's consensus endorsed measures and were unable to identify any NQF-endorsed ventilator weaning quality measures focused on the liberation status at discharge for patients admitted on invasive mechanical ventilation in the LTCH setting. We are unaware of any other quality measures for liberation from invasive mechanical ventilation that have been endorsed or adopted by another consensus organization for the LTCH setting. Therefore, based on the evidence discussed above, we proposed to adopt the quality measure entitled, Ventilator Liberation Rate, for the LTCH QRP beginning with the FY 2020 LTCH QRP. We plan to submit the quality measure to the NQF for consideration for endorsement.

We proposed that data for this quality measure be collected through the LTCH CARE Data Set, with the submission through the QIES ASAP System. For more information on LTCH QRP reporting using the QIES ASAP system, we refer readers to our Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Technical-Information.html*. We stated that we intended to revise the LTCH CARE Data Set to include new items that assess invasive mechanical ventilation liberation at discharge, should this proposed measure be adopted.

This measure reports facility-level Ventilator Liberation Rate for patients admitted to an LTCH on invasive mechanical ventilation, *and* for whom weaning attempts were expected or anticipated as reported on the Admission Assessment. The Ventilator Liberation Rate is defined as the percentage of patients on invasive mechanical ventilation upon admission who are alive and fully liberated at discharge. The proposed measure denominator is the number of patients requiring invasive mechanical ventilation support upon admission to an LTCH, except those who meet exclusion criteria. The proposed measure numerator is the number of patients who are discharged alive and fully liberated. This measure is risk-adjusted for variables such as age, neurological injury or disease, dialysis, and other comorbidities and treatments. If a patient has more than one LTCH stay during the reporting period, then each LTCH stay will be included in the measure calculation and reporting. For technical information about this measure, including information about the measure calculation, risk adjustment, and proposed measure denominator exclusions, we refer readers to the document titled, *Final Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,* available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*.

We invited public comments on our proposal to adopt the quality measure, Ventilation Liberation Rate, beginning with the FY 2020 LTCH QRP.

Comment: Some commenters expressed support for the adoption of Ventilator Liberation Rate into the LTCH QRP.

Response: We appreciate commenters' support for the adoption of Ventilator Liberation Rate.

Comment: Some commenters recommended that CMS further test the Ventilator Liberation Rate measure prior to finalization and implementation for the LTCH QRP.

Response: Determination of measure readiness for implementation and data collection was informed by feedback

[443] ''Spreadsheet of MAP 2016 Final Recommendations (XLSX).'' Measure Applications Partnership Post Acute Care/Long-Term Care Workgroup. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593*.

[444] MAP 2015 Considerations for Implementing Measures in Federal Programs: Draft for Public Comment. Measure Applications Partnership Post Acute Care/Long-Term Care Workgroup. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75370*.

[445] ''Spreadsheet of MAP 2016 Final Recommendations (XLSX).'' Measure Applications Partnership Post Acute Care/Long-Term Care Workgroup. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593*.

and results from the pilot test and TEP discussions. Pilot sites were able to test the items related to the measure and provided feedback via a series of check-ins that further informed measure development. The TEPs further supported measure development by providing critical insight and feedback from clinicians, researchers, and experienced LTCH administrators. In addition, patient advocates provided insight into ventilated patient experiences in the LTCH and the utility of the ventilator weaning measures. Additional testing will be conducted as data collection ensues and we will continue to test these measures on a quarterly basis if feasible and conduct maintenance and evaluation of the measure for reliability and validity.

Comment: One commenter appreciated that the measure has significantly evolved from conception. This commenter recommended that we submit the measure to NQF for consideration of endorsement.

Response: We appreciate the commenter for their comment about the extensive work that went into the measure development process. With regard to NQF endorsement, as noted in the proposed rule, we intend to submit the measure to NQF for consideration of endorsement. We further note that we consider and propose appropriate measures that have been endorsed by the NQF whenever possible. However, section 1886(m)(5)(D)(ii) of the Act allows the Secretary to specify a measure for the LTCH QRP that that is not NQF endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization. In the case of the proposed measure, we have not been able to identify other measures that are endorsed or adopted by a consensus organization. While we appreciate the importance of consensus endorsement and intend to seek such endorsement, we believe the need to address the measure gap in invasive mechanical ventilation care in the LTCH QRP outweighs the general rule of adopting an NQF endorsed measure at this time.

Comment: With respect to the addition of the two ventilator weaning measures beginning with the FY 2020 LTCH QRP, one commenter expressed concern that the expanded patient assessment data reporting requirements would impose a significant burden on providers.

Response: We appreciate the commenter's concern about the burden associated with the measure proposals; however, we believe that these measures are important to assess measure gaps for LTCH patients. We intend to provide guidance and training for providers to address their concerns regarding the expanded patient assessment data reporting requirements.

Comment: A commenter expressed concern that the small size of the pilot test used to inform the development of this measure may not be adequate to conclude that the measure is reliable and accurate.

Response: The focus of the pilot test was to inform measure development as well as to evaluate the feasibility of patient-level data collection and submission. To obtain a balanced sample of participants, pilot sites were chosen based on criteria including LTCH size, geographic region, and ownership type. Based on the size and projected number of ventilated patients, the number of sites recruited was deemed to provide a sufficient number of patients for analysis of the feasibility of data collection and validity of the mechanical ventilation quality measures. Pilot sites received in-depth trainings and provided feedback via a series of check-ins that further informed measure development during the course of the pilot study. We concluded that the pilot test was adequate to proceed with proposal of the measure for adoption under the LTCH QRP. We will continue to test these measures on a quarterly basis and conduct maintenance and evaluation of the measure for reliability and validity.

Comment: With respect to data coding restrictions for item O0200, Ventilator Liberation Rate, one commenter requested clarification on the appropriate coding for the item for patients admitted on mechanical ventilation who were not expected to wean but are liberated at discharge and for patients ventilated during the LTCH stay who were liberated at discharge.

Response: We would like to clarify that all patients who were liberated from mechanical ventilation should be coded as indicated regardless of admission status of the patient to ensure accurate data. The measure calculations for item O0200, Ventilator Liberation Rate, exclude the two sets of patients described by the commenter from the denominator. Therefore, data coding restrictions are not needed for item O0200, Ventilator Liberation Rate.

Comment: A few commenters supported that the measure was risk-adjusted and noted the importance of adequate risk adjustment to ensure that providers who care for more complex patients do not fare worse because of insufficient risk adjustment. Some commenters questioned whether the current risk-adjustment model for the measure was adequate. Specifically, one commenter suggested that cases with progressive neuromuscular disease and severe neuromuscular injury, disease or dysfunction be excluded from the measure numerator and denominator, and another commenter recommended to combine and risk-adjust these cases together, as the conditions are captured under one category in the LTCH CARE Data Set. Another commenter recommended that ventilated patients undergoing dialysis also be considered as a measure exclusion and that special adjustments be made for larger ventilator weaning programs where most ventilated patients are accepted, unlike LTCHs that only admit patients identified for weaning.

Response: We appreciate the importance of adequate risk adjustment for this measure and appreciate the commenters' recommendations. The TEP identified several risk factors that affect ventilator liberation outcome, and these factors were included in the risk-adjustment model for initial measure testing. In addition, pilot sites have provided CMS feedback on these risk-adjustment variables. We will continue to test and refine the risk-adjustment model by further evaluating conditions such as progressive neuromuscular disease, severe neuromuscular injury, disease or dysfunction, and dialysis to ensure sufficient risk adjustment. We note that the LTCH CARE Data Set V4.00 contains two separate items that indicate either ''Other Progressive Neuromuscular Disease'' and ''Other Severe Neurological Injury, Disease, or Dysfunction.'' We would like to clarify that patients who were deemed non-weaning on admission are excluded from the denominator for Ventilator Liberation Rate. As a result of this exclusion, performance on the measure would not be impacted by the proportion of patients admitted that are undergoing mechanical ventilation and identified as weaning.

After consideration of the public comments we received, we are finalizing our proposal to adopt the measure, Ventilator Liberation Rate, beginning with the FY 2020 LTCH QRP with an implementation date of July 1, 2018, as discussed in section IX.C.11. of the preamble of this final rule.

8. Removal of the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge From LTCHs From the LTCH QRP

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20097 through 20098), we proposed to remove the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs

(NQF #2512) beginning with the FY 2019 LTCH QRP.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49730 through 49731), we adopted the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512) for the LTCH QRP. This measure assesses all-cause unplanned hospital readmissions from LTCHs. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57215 through 57219), we adopted the Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP to fulfill IMPACT Act requirements. In response to the FY 2017 IPPS/LTCH PPS proposed rule, we received public comments expressing concern over the multiplicity of readmission measures and the overlap between the All-Cause Readmission and Potentially Preventable Readmission (PPR) 30-Day Post-Discharge measures (see 81 FR 57217 through 57218). Commenters also stated that more than one readmission measure would create confusion and require additional effort by providers to track and improve performance.

We retained the All-Cause Readmission measure because it would allow us to monitor trends in both all-cause and PPR rates. In particular, we could compare facility performance on the All-Cause Readmission and PPR 30-Day Post-Discharge measures. However, upon further consideration of the public comments, we believe that removing the All-Cause Readmission measure and retaining the PPR 30-Day Post-Discharge measure in the LTCH QRP would prevent duplication, because potentially preventable readmissions are a subset of all-cause readmissions. Although there is no data collection burden associated with these claims-based measures, we recognize that having two hospital readmission measures in the LTCH QRP may create confusion. We agree with commenters that there is overlap between the All-Cause Readmission measure and the PPR 30-Day Post-Discharge measure, which identifies a subset of all-cause readmissions, and believe the PPR measure will be more actionable for quality improvement.

Accordingly, we proposed to remove the All-Cause Unplanned Readmission measure beginning with the FY 2019 LTCH QRP. We proposed that public reporting of this measure would end by October 2018 when public reporting of the PPR 30-Day Post-Discharge measure begins by October 2018. We refer readers to section IX.C.17. of the preamble of this final rule for more information regarding our proposal to publicly report the PPR 30-Day Post-Discharge measure. We refer readers to the PPR 30-Day Post-Discharge measure specifications available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/Downloads/Measure-Specifications-for-FY17–LTCH–QRP-Final-Rule.pdf.*

We invited public comment on our proposal to remove the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512) from the LTCH QRP, beginning with the FY 2019 LTCH QRP.

Comment: Commenters supported the proposed removal of the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs from the LTCH QRP. The commenters stated that the lack of patient level data makes it difficult to track and improve performance on this measure. Several commenters supported the removal of this measure because they consider it confusing and duplicative of the PPR 30-Day Post-Discharge Measure for LTCH QRP. Some commenters urged CMS to evaluate PAC readmission measures adopted for quality reporting to ensure that they create consistent incentives across the system. One commenter requested additional detail on the components of the all-cause readmission measure that are not represented in the PPR measure, as well as details on the components of the PPR measure.

Response: We appreciate the support for the proposed removal of the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs from the LTCH QRP. We note the commenters' concerns regarding the availability of patient level data for tracking and improving performance, and we are exploring the feasibility of making additional data available to LTCHs. We thank the commenters for their concern over consistent incentives and will continue to monitor PAC readmission measures to ensure they align incentives across the system.

We appreciate the request for additional detail on the components of the all-cause and PPR measures. We wish to clarify that the PPR measure captures readmissions for conditions considered potentially preventable and unplanned, whereas the all-cause measure captured the broader set of all unplanned readmissions. For additional details on the components of the PPR measure, we refer readers to the measure specifications and Appendix 2 for the list of conditions used to define PPRs, available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/Downloads/Measure-Specifications-for-FY17–LTCH–QRP-Final-Rule.pdf.*

After consideration of the public comments we received, we are finalizing our proposal to remove the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512) from the LTCH QRP, beginning with the FY 2019 LTCH QRP.

9. LTCH QRP Quality Measures Under Consideration for Future Years

a. LTCH QRP Quality Measures Under Consideration for Future Years

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20098), we invited public comment on the importance, relevance, appropriateness, and applicability of each of the quality measures listed in the table below for future years in the LTCH QRP.

LTCH QRP Quality Measures Under Consideration for Future Years

NQS Priority: Patient- and Caregiver-Centered Care	
Measures	• Experience of Care. • Application of Percent of Residents Who Self-Report Moderate to Severe Pain (Short Stay) (NQF #0676). • Advance Care Plan.
NQS Priority: Patient Safety	
Measure	• Patients Who Received an Antipsychotic Medication.

LTCH QRP QUALITY MEASURES UNDER CONSIDERATION FOR FUTURE YEARS—Continued

NQS Priority: Communication and Care Coordination	
Measure	• Modification of the Discharge to Community-PAC LTCH QRP measure.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20098), we also solicited public comments on the use of survey-based experience of care measures for the LTCH QRP. We are currently developing an experience of care survey for LTCHs and survey-based measures will be developed from this survey. These survey-based measures may be considered for inclusion in the LTCH QRP through future notice-and-comment rulemaking. This survey was developed using a rigorous survey development methodology that included a public request for measures titled Request for Information To Aid in the Design and Development of a Survey Regarding Patient and Family Member Experiences With Care Received in Long-Term Care Hospitals (80 FR 72722 through 72725); focus groups and interviews with patients, family members, and caregivers; input from a TEP of LTCHs, researchers, and patient advocates; and cognitive interviewing. The survey has also been field tested. The survey explores experience of care across five main areas: (1) Beginning stay at the hospital; (2) interactions with staff; (3) experience during the hospital stay; (4) preparing for leaving hospital; and (5) overall hospital rating. We are specifically interested in comments regarding survey implementation and logistics, use of the survey-based measures in the LTCH QRP, and general feedback.

Also, we are considering a measure focused on pain that relies on the collection of patient-reported pain data, and another measure that documents whether a patient has an Advance Care Plan. Finally, we are considering a measure related to patient safety, specifically, Patients Who Received an Antipsychotic Medication.

We invited public comment on the possible inclusion of such measures in future years of the LTCH QRP.

Comment: Several commenters provided feedback on the use of an experience of care survey in the LTCH setting.

Response: We thank the commenters who submitted comments about the experience of care survey. We will take those comments into consideration as we finish developing the measure and related survey-based measures.

Comment: A number of commenters supported the inclusion of an Advance Care Plan measure in the LTCH QRP. Several commenters expressed concern regarding the ability of the LTCH population to engage in advance care planning given their severity of illness. One commenter emphasized the importance of ensuring access to advance care plans from the short-term acute care hospital. One commenter recommended inclusion of a more detailed measure that specifies the contents of an advanced care plan. Several commenters supported adoption of the NQF-endorsed measure, Advance Care Plan (NQF #0326). One commenter supported a revision of the current NQF-endorsed measure into two separate measures to capture the distinction between advance care plans and surrogate decision makers. One commenter also discussed the need to define what is considered an advance care plan, and the ability of the measure to account for the patient's willingness to engage in such planning. The commenter also emphasized the important role a patient's goals, values, and preferences play in the care planning process.

Response: We appreciate the commenters' thoughtful comments and agree with the importance of advanced care plans as they relate to the critically, chronically ill and vulnerable patient population in LTCHs. As with all measures, we work to fulfill the aims of the NQS. Improving care through the provision of patient-centered care is one of the NQS's aims that we seek to fulfill. We acknowledge the importance of including patient preferences in advance care planning. We will take these comments into consideration as we develop future measures pertaining to advance care plans for the LTCH QRP.

Comment: A commenter stated that, regarding the Application of Percent of Residents Who Self-Report Moderate to Severe Pain (Short Stay) (NQF #0676) measure for future consideration in the LTCH QRP, the pain experience alone should not be a quality measure and suggested that CMS revisit how pain is captured and monitored, as the presence of pain, its frequency, and severity do not provide enough information to help an individual's overall quality of life. The commenter expressed support for use of a pain measure that does not encourage unnecessary opioid prescribing, and recommended modification of the existing measure to one that relates pain to important daily functional tasks. The commenter suggested that such a measure would better capture the functional abilities of patients, as pain levels do not frequently change. Another commenter expressed caution in expanding the existing measure to the LTCH setting due to concerns with reliability, based on their experience, noting variable and inconsistent findings related to how the MDS is used to capture the data for this measure.

Response: We appreciate the comments pertaining to the Application of Percent of Residents Who Self-Report Moderate to Severe Pain (Short Stay) (NQF #0676) measure under consideration for future implementation in the LTCH QRP. We note that appropriately assessing pain as an outcome is important, acknowledge the importance of avoiding unintended consequences that may arise from such assessments, and will take into consideration the commenters' recommendations.

Comment: A commenter supported appropriate use of antipsychotic medications. Specifically, the commenter noted that measures implemented for this purpose should account for informed consent, preference, and potential improvements in the quality of life in order to accurately measure appropriate use of such medications. Another commenter suggested further development of the measure, as there is no existing baseline measurement to provide it with meaning as a measure of quality of care. A commenter noted the distinction between appropriate and inappropriate use of antipsychotic medications, and the lack of sensitivity of the proposed measure. Another commenter expressed opposition against adoption of the measure until CMS provides additional information regarding measure utilization, rationale, and specification.

Response: We appreciate the comments received pertaining to the development of this potential quality measure construct. We note the support for the inclusion of an antipsychotic measure in the LTCH QRP, but recognize the potential limitations to the inclusion of this type of measure, as stated by the commenters. As we continue to explore the development of this future measure construct, we will take the commenters' recommendations

into consideration in our measure development and testing efforts, as well as in our ongoing efforts to identify and propose appropriate measures for the LTCH QRP in the future.

Comment: A commenter supported the use of a cross-setting malnutrition measure. Another commenter also encouraged the use of malnutrition measures in post-acute care settings, and recommended the use of a nationally recognized ''blueprint'' that was developed to prevent and reduce malnutrition among older adults.

Response: We agree with the commenters' rationale for consideration of adopting malnutrition quality measures, including a malnutrition care composite measure, to prevent and reduce malnutrition among older adults across the care continuum as they are important components of care for LTCH patients. We will take the suggestions into consideration as we develop future measures for the LTCH QRP.

Comment: A commenter suggested the use of pain related questions in an HCAHPS survey in the LTCH setting instead of implementing the Application of Percent of Residents Who Self-Report Moderate to Severe Pain (Short Stay) (NQF #0676) measure.

Response: We thank the commenter for the suggestion. We will continue to take these and future stakeholder inputs under advisement to inform our ongoing quality measure development.

Comment: One commenter emphasized the importance of establishing quality measures for individuals with advanced illness which address symptom management, social and spiritual support, care coordination, and identification of goals and preferences and whether those goals are met, given unique care needs and the aging of the population as CMS considers future measure topics for consideration in the LTCH QRP.

Response: We appreciate the commenter's suggestions regarding future measures, and will take them into consideration.

b. IMPACT Act Measure—Possible Future Update To Measure Specifications

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57207 through 57215), we finalized the Discharge to Community-PAC LTCH QRP measure, which assesses successful discharge to the community from an LTCH setting, with successful discharge to the community including no unplanned rehospitalizations and no death in the 31 days following discharge from the LTCH. We received public comments (see 81 FR 57211) recommending exclusion of baseline nursing facility residents from the measure, as these residents did not live in the community prior to their LTCH stay. At that time, we highlighted that, using Medicare FFS claims alone, we were unable to accurately identify baseline nursing facility residents. We stated that potential future modifications of the measure could include assessment of the feasibility and impact of excluding baseline nursing facility residents from the measure through the addition of patient assessment-based data. In response to these public comments, we are considering a future modification of the Discharge to Community-PAC LTCH QRP measure, which would exclude baseline nursing facility residents from the measure.

We invited public comment on the possibility of excluding baseline nursing facility residents from the Discharge to Community-PAC LTCH QRP measure in future years of the LTCH QRP.

Comment: Several commenters expressed support for excluding baseline nursing facility residents from the discharge to community measure as a potential future measure modification. Commenters stated that this exclusion would result in the measure more accurately portraying quality of care provided by LTCHs, while controlling for factors outside of LTCH control.

Response: We thank commenters for their support for exclusion of baseline nursing facility residents as a potential future measure modification. We will consider their views and determine whether to propose to exclude baseline nursing facility residents from the Discharge to Community-PAC LTCH QRP measure in future years of the LTCH QRP.

c. IMPACT Act Implementation Update

As a result of the input and suggestions provided by technical experts at the TEPs held by our measure developer, and through public comment, we are engaging in additional development work, including performing additional testing, with respect to two measures that would satisfy the domain of accurately communicating the existence of and providing for the transfer of health information and care preferences when the individual transitions, in section 1899B(c)(1)(E) of the Act. The measures under development are: *Transfer of Information at Post-Acute Care Admission, Start or Resumption of Care from other Providers/Settings;* and *Transfer of Information at Post-Acute Care Discharge, and End of Care to other Providers/Settings.* We intend to specify these measures under section 1899B(c)(1)(E) of the Act no later than October 1, 2018, and we intend to propose to adopt them for the FY 2021 LTCH QRP, with data collection beginning on or about April 1, 2019.

Comment: Commenters suggested that CMS be cautious in its development of the Transfer of Health Information measure set and only proceed to propose and adopt measures that receive NQF endorsement. One commenter cited concerns about the measure development, citing the 2016 MAP PAC/LTC meeting. One commenter noted that the unique goals, preferences, and needs of the patient should be considered in transferring patient information, and that care transitions can be a confusing time for the patient and family/caregiver. The commenter recommended that the measures require PAC facilities to communicate their capabilities and limitations to ensure that they can provide the level of care that meets a patient's clinically assessed needs, as determined by the relevant decision-makers.

Response: We appreciate the comments and feedback on the Transfer of Health Information measures that are currently under development. As we continue to develop these measures, we will take into account the feedback pertaining to modes of information transfer, prescreening requirements for LTCHs, and patient goals and preferences. We intend to re-submit these measures for review to the MAP PAC/LTC Workgroup. Further, we plan to submit the measures to the NQF for consideration for endorsement when we believe that they are ready for NQF review.

10. Standardized Patient Assessment Data Reporting for the LTCH QRP

a. Standardized Patient Assessment Data Reporting for the FY 2019 LTCH QRP

Section 1886(m)(5)(F)(ii) of the Act requires that for fiscal year 2019 and each subsequent year, LTCHs report standardized patient assessment data required under section 1899B(b)(1) of the Act. As we describe in more detail above, we are finalizing that the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), will be removed and replaced with the proposed pressure ulcer measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, beginning with the FY 2020 LTCH QRP. The current pressure ulcer measure will remain in the LTCH QRP until that time. Accordingly, in the FY 2018 IPPS/LTCH

PPS proposed rule (82 FR 20099), with respect to the requirement that LTCHs report standardized patient assessment data for the FY 2019 LTCH QRP, we proposed that the data elements used to calculate the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), meet the definition of standardized patient assessment data with respect to medical conditions and co-morbidities under section 1899B(b)(1)(B)(iv) of the Act, and that the successful reporting of that data under section 1886(m)(5)(F)(i) of the Act with respect to admissions as well as discharges occurring during last three quarters of CY 2017 would also satisfy the requirement to report standardized patient assessment data for the FY 2019 LTCH QRP.

The collection of assessment data pertaining to skin integrity, specifically pressure related wounds, is important for multiple reasons. Clinical decision support, care planning, and quality improvement all depend on reliable assessment data collection. Pressure related wounds represent poor outcomes, are a serious medical condition that can result in death and disability, are debilitating, painful and are often an avoidable outcome of medical care.[446] [447] [448] [449] [450] [451] Pressure related wounds are considered healthcare acquired conditions.

As we note above, the data elements needed to calculate the current pressure ulcer measure are already included on the LTCH CARE Data Set and reported by LTCHs, and exhibit validity and reliability for use across PAC providers. Item reliability for these data elements was also tested for the nursing home setting during implementation of MDS 3.0. Testing results are from the RAND Development and Validation of MDS 3.0 project.[452] The RAND pilot test of the MDS 3.0 data elements showed good reliability and is also applicable to both the IRF–PAI and the LTCH CARE Data Set because the data elements tested are the same. Across the pressure ulcer data elements, the average gold-standard nurse to gold-standard nurse kappa statistic was 0.905. The average gold-standard nurse to facility-nurse kappa statistic was 0.937. Data elements used to risk adjust this quality measure were also tested under this same pilot test, and the gold-standard to gold-standard kappa statistic, or percent agreement (where kappa statistic not available), ranged from 0.91 to 0.99 for these data elements. These kappa scores indicate ''almost perfect'' agreement using the Landis and Koch standard for strength of agreement.[453]

The data elements used to calculate the current pressure ulcer measure received public comment on several occasions, including when that measure was proposed in the FY 2012 IRF PPS (76 FR 47876) and IPPS/LTCH PPS proposed rules (76 FR 51754). Further, they were discussed in the past by TEPs held by our measure development contractor on June 13 and November 15, 2013, and recently by a TEP on July 18, 2016. TEP members supported the measure and its cross-setting use in PAC. The report, *Technical Expert Panel Summary Report: Refinement of the Percent of Patients or Residents with Pressure Ulcers that are New or Worsened (Short Stay) (NQF #0678) Quality Measure for Skilled Nursing Facilities (SNFs), Inpatient Rehabilitation Facilities (IRFs), Long-Term Care Hospitals (LTCHs), and Home Health Agencies (HHAs),* is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/July-2016-Pressure-Ulcer-TEP-Report_revised.pdf.*

We invited public comment on this proposal.

Comment: Several comments supported reporting the data elements already implemented in the LTCH QRP to fulfill the requirement to report standardized patient assessment data for the FY 2019 LTCH QRP.

Response: We appreciate the commenters' support of the proposal and agree that these data elements currently reported by LTCHs meet the definition of standardized patient assessment data and satisfy the requirement to report standardized patient assessment data.

Comment: One commenter expressed concern regarding the proposed reporting schedule for new standardized patient assessment data elements given the volume of data that will need to be reported by LTCHs. The commenter emphasized the reporting requirements for the current pressure ulcer measure, which fulfills the standardized patient assessment data element requirements beginning with the FY 2019 LTCH QRP.

Response: We acknowledge the concerns raised by the commenter. Upon further consideration of the appropriate timeline for LTCHs to report this data for the FY 2019 LTCH QRP, we are finalizing that LTCHs would be required to report the current pressure ulcer measure for the last quarter of CY 2017 to meet the requirements for reporting standardized patient assessment data. We do not believe that the continued reporting of the current pressure ulcer measure is too burdensome on the LTCH industry since LTCHs will not need to change their reporting practices with respect to reporting the standardized pressure ulcer data, nor will they be reporting additional data as of October 1, 2017. The submission of the current pressure ulcer measure data will act to meet the requirement of submitting standardized patient assessment data beginning October 1, 2017. Further, in response to similar comments expressing concern with increased burden, CMS has decided to move the release date of the LTCH CARE Data Set Version 4.00 from April 1, 2018 to July 1, 2018 which gives LTCHs an additional 3 months to prepare. We refer readers to section IX.C.11.d which describes the effect of the delayed release date of the LTCH CARE Data Set Version 4.00 on the currently adopted LTCH QRP measures.

After consideration of the public comments received, we are finalizing our proposal, as proposed, that the data elements currently reported by LTCHs to calculate the current measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), meet the definition of standardized patient assessment data with respect to medical conditions and co-morbidities under section 1899B(b)(1)(B)(iv) of the Act, and that the successful reporting of that data under section 1886(m)(5)(F)(i) of the Act would also satisfy the requirement to report standardized patient assessment data under section 1886(m)(5)(F)(ii) of the Act beginning October 1, 2017 for the FY 2019 LTCH QRP. We are also finalizing the change

[446] Casey, G. (2013). ''Pressure ulcers reflect quality of nursing care.'' Nurs N Z 19(10): 20–24.

[447] Gorzoni, M.L. and S.L. Pires (2011). ''Deaths in nursing homes.'' Rev Assoc Med Bras 57(3): 327–331.

[448] Thomas, J.M., et al. (2013). ''Systematic review: health-related characteristics of elderly hospitalized adults and nursing home residents associated with short-term mortality.'' J Am Geriatr Soc 61(6): 902–911.

[449] White-Chu, E.F., et al. (2011). ''Pressure ulcers in long-term care.'' Clin Geriatr Med 27(2): 241–258.

[450] Bates-Jensen B.M. Quality indicators for prevention and management of pressure ulcers in vulnerable elders. Ann Int Med. 2001;135 (8 Part 2), 744–51.

[451] Bennet, G., Dealy, C., Posnett, J. (2004). The cost of pressure ulcers in the UK, *Age and Aging,* 33(3):230–235.

[452] Saliba, D., & Buchanan, J. (2008, April). *Development and validation of a revised nursing home assessment tool: MDS 3.0.* Contract No. 500–00–0027/Task Order #2. Santa Monica, CA: Rand Corporation. Retrieved from: *http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.*

[453] Landis, R., & Koch, G. (1977, March). The measurement of observer agreement for categorical data. Biometrics 33(1), 159–174.

in the release date of the LTCH CARE Data Set Version 4.00 from April 1, 2018 to July 1, 2018. We refer readers to section IX.C.11.c. of the preamble of this final rule for discussion on this issue.

b. Standardized Patient Assessment Data Reporting Beginning With the FY 2020 LTCH QRP

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20099 through 20116) we described our proposals for the reporting of standardized patient assessment data by LTCHs beginning with the FY 2020 LTCH QRP. LTCHs would be required to report these data with respect to LTCH admissions and discharges that occur between April 1, 2018 and December 31, 2018, with the exception of three data elements (Brief Interview of Mental Status (BIMS), Hearing, and Vision), which would be required with respect to LTCH admissions only that occur between April 1, 2018 and December 31, 2018. Following the initial reporting year for the FY 2020 LTCH QRP, subsequent years for the LTCH QRP would be based on a full calendar year of such data reporting.

In selecting the data elements proposed in the FY 2018 IPPS/LTCH PPS proposed rule, we carefully weighed the balance of burden in assessment-based data collection and aimed to minimize additional burden through the utilization of existing data in the assessment instruments. We also took into consideration the following factors with respect to each data element: Overall clinical relevance; ability to support clinical decisions, care planning and interoperable exchange to facilitate care coordination during transitions in care; and the ability to capture medical complexity and risk factors that can inform both payment and quality. In addition, the data elements had to have strong scientific reliability and validity; be meaningful enough to inform longitudinal analysis by providers; had to have received general consensus agreement for its usability; and had to have the ability to collect such data once but support multiple uses. Further, to inform the final set of data elements for proposal, we took into account technical and clinical subject matter expert review, public comment, and consensus input in which such principles were applied. We also took into account the consensus work and empirical findings from the PAC PRD.

Comment: Many commenters expressed significant concerns with respect to our standardized patient assessment data proposals. Several commenters stated that the new standardized patient assessment data reporting requirements will impose significant burden on providers, given the volume of new standardized patient assessment data elements that were proposed to be added to the LCDS. A few commenters noted that the addition of the proposed standardized patient assessment data elements would require hiring more staff, retraining staff on revised questions or coding guidance, and reconfiguring internal databases and EHRs. Other commenters expressed concerns about the gradual but significant past and future expansion of the LCDS through the addition of standardized patient assessment data elements and quality measures, noting the challenge of coping with ongoing additions and changes.

Several commenters expressed concern related to the implementation timeline in the proposed rule, which would require LTCHs to begin collecting the proposed standardized patient assessment data elements in the timeframe stated in the proposed rule. One commenter stated that there would not be sufficient time to be ready by April 1, 2018. Another commenter noted that CMS had not yet provided sufficient specifications or educational materials to support implementation of the new patient assessments in the proposed timeline.

Several commenters urged CMS to delay the reporting of new standardized patient assessment data elements by at least one year, and to carefully assess whether all of the proposed standardized patient assessment data elements are necessary under the IMPACT Act. Commenters suggested ways to delay the proposals for standardized patient assessment data elements in the categories of Cognitive Function and Mental Status; Special Services, Treatments, and Interventions; and Impairments, including allowing voluntary or limited reporting for a period of time before making comprehensive reporting mandatory, and delaying the beginning of mandatory data collection for a period of time. Some commenters recommended that during the delay, CMS re-evaluate whether it can require the reporting of standardized patient assessment data in a less burdensome manner.

Response: We understand the concerns raised by commenters that the finalization of our standardized patient assessment data proposals would require LTCHs to spend a significant amount of resources preparing to report the data, including updating relevant protocols and systems and training appropriate staff. We also recognize that we can meet our obligation to require the reporting of standardized patient assessment data with respect to the categories described in section 1899B(b)(1)(B) of the Act while simultaneously being responsive to these concerns. Therefore, after consideration of the public comments we received on these issues, we have decided that at this time, we will not finalize the standardized patient assessment data elements we proposed for three of the five categories under section 1899B(b)(1)(B) of the Act: Cognitive Function and Mental Status; Special Services, Treatments, and Interventions; and Impairments. Although we believe that the proposed standardized patient assessment data elements would promote transparency around quality of care and price as we continue to explore reforms to the PAC payment system, the data elements that we proposed for each of these categories would have imposed a new reporting burden on LTCHs. We agree that it would be useful to evaluate further how to best identify the standardized patient assessment data that would satisfy each of these categories; would be most appropriate for our intended purposes including payment and measure standardization; and can be reported by LTCHs in the least burdensome manner. As part of this effort, we intend to conduct a national field test that allows for stakeholder feedback and to consider how to maximize the time LTCHs have to prepare for the reporting of standardized patient assessment data in these categories. We intend to make new proposals with respect to the categories described in sections 1899B(b)(1)(B)(ii), (iii) and (v) of the Act no later than in the FY 2020 IPPS/LTCH PPS proposed rule.

In this final rule, we are finalizing the standardized patient assessment data elements that we proposed to adopt for the IMPACT Act categories of Functional Status and Medical Conditions and Co-Morbidities. Unlike the standardized patient assessment data that we are not finalizing, the standardized patient assessment data that we proposed for these categories are already required to calculate the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (NQF #0678) quality measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury quality measure (which we are finalizing in this final rule), and the Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631)

quality measure (which we finalized in the FY 2016 IPPS/LTCH PPS final rule). As a result, we do not believe that finalizing these proposals creates a new reporting burden for LTCHs or otherwise necessitates a delay.

Comment: Several commenters expressed support for the adoption of standardized patient assessment data elements. One commenter expressed support for standardizing the definitions as well as the implementation of the data collection effort. The commenter also supported CMS' goal of standardizing the questions and responses across all PAC settings to help ''enable the data to be interoperable, allowing it to be shared electronically, or otherwise between PAC provider types.'' One commenter stated that streamlining requirements across Medicare's quality reporting programs will reduce the administrative burden of quality reporting for these facilities as well as the physicians and other clinicians who contribute to that reporting. Another commenter noted full support of the IMPACT Act's goals and objectives and appreciated CMS' efforts to regularly communicate with stakeholders through various national provider calls, convening of stakeholders, and meetings with individual organizations. Another commenter recognized the value of a unified patient assessment system for PAC as part of a potential unified payment system for PAC, but encouraged CMS to look carefully at opportunities to streamline the assessment and avoid duplication.

Response: We appreciate the support of these proposals, but note that for the reasons explained above, we have decided at this time to not finalize the proposals for three of the five categories under section 1899B(b)(1)(B) of the Act: Cognitive Function and Mental Status; Special Services, Treatments, and Interventions; and Impairments.

Comment: Several commenters addressed the variation in the look-back period associated with the standardized patient assessment data elements. In general, commenters were concerned about the variation in look-back periods across items and how differences in look-back periods would affect the validity of the item responses and assessor burden. One commenter stated that the many and varied look-back periods associated with the proposed standardized patient assessment data elements would cause confusion for the assessors and patients.

Response: We appreciate the commenters' review of the proposed standardized patient assessment data elements and concerns about implementation. We acknowledge that the look-back periods would vary for different standardized patient assessment data elements within a setting, but we wish to clarify that the look-back periods for each standardized patient assessment data element would be the same across PAC settings. In our ongoing work to identify candidate data elements for standardization, we will continue to carefully consider the impact of different look-back periods for different standardized patient assessment data elements on the validity of the data and assessor burden. We believe that it is important to collect the same information across settings, including over the same look-back period, and we will work to identify the best options for achieving this aspect of standardized assessment in the future.

Comment: Several commenters stated that there is insufficient evidence demonstrating the reliability and validity of the proposed standardized patient assessment data elements. Some commenters stated that the expanded standardized patient assessment data reporting requirements have not yet been adequately tested to ensure they collect accurate and useful data in this setting. A few commenters stated that only five of the proposed 23 standardized patient assessment data elements are currently reported in the CARE Data Set and the other 18 are currently used in other post-acute setting patient assessment instruments, mainly the Minimum Data Set (MDS) 3.0 used in skilled nursing facilities (SNFs). Other commenters stated that CMS' conclusion that the collection of these standardized patient assessment data elements in the LTCH setting would be feasible and the standardized patient assessment data elements would result in valid and reliable data was based on the current use of these data elements in the MDS and the testing of these data elements in the PAC PRD.

A few commenters stated that several of the proposed standardized patient assessment data elements that had not been adequately tested were deemed close enough to an item that had been tested in the PAC PRD or in other PAC settings and thus appropriate for implementation.

Response: Our standardized patient assessment data elements were selected based on a rigorous multi-stage process that was described in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20088 through 20089). In addition, we believe that the PAC PRD testing of many of these data elements provides good evidence from a large, national sample of patients and residents in PAC settings to support the use of these standardized patient assessment data elements in and across PAC settings. However, as noted above, we have decided at this time to not finalize the proposals for three of the five categories under section 1899B(b)(1)(B) of the Act: Cognitive Function and Mental Status; Special Services, Treatments, and Interventions; and Impairments. Prior to making new proposals for these categories, we intend to conduct extensive testing to ensure that the standardized patient assessment data elements we select are reliable, valid and appropriate for their intended use.

A full discussion of the standardized patient assessment data elements that we proposed to adopt for the categories described in sections 1899B(b)(1)(B)(ii), (iii) and (v) of the Act can be found in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20100 through 20116). In light of our decision to not finalize our proposals with respect to these categories, we are not going to address in this final rule the specific technical comments that we received on these proposed data elements. However, we appreciate the many technical comments we did receive specific to each of these data elements, and we will take them into consideration as we develop new proposals for these categories. Below we discuss the comments we received specific to the standardized patient assessment data we proposed to adopt, and are finalizing in this final rule, for the categories of Functional Status and Medical Conditions and Co-Morbidities.

(1) Functional Status Data

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20100), we proposed that the data elements currently reported by LTCHs to calculate the measure, Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631), would also meet the definition of standardized patient assessment data with respect to functional status under section 1899B(b)(1)(B)(i) of the Act, and that the successful reporting of that data under section 1886(m)(5)(F)(i) of the Act would also satisfy the requirement to report standardized patient assessment data under section 1886(m)(5)(F)(ii) of the Act.

These patient assessment data for functional status are from the CARE Item Set. The development of the CARE Item Set and a description and rationale for each item is described in a report entitled ''The Development and Testing of the Continuity Assessment Record

and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set: Volume 1 of 3.'' [454] Reliability and validity testing were conducted as part of CMS' Post-Acute Care Payment Reform Demonstration, and we concluded that the functional status items have acceptable reliability and validity. A description of the testing methodology and results are available in several reports, including the report entitled ''The Development and Testing of the Continuity Assessment Record And Evaluation (CARE) Item Set: Final Report On Reliability Testing: Volume 2 of 3'' [455] and the report entitled ''The Development and Testing of The Continuity Assessment Record And Evaluation (CARE) Item Set: Final Report on Care Item Set and Current Assessment Comparisons: Volume 3 of 3.'' [456] The reports are available on CMS' Post-Acute Care Quality Initiatives Web page at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html*.

For more information about this quality measure and the data elements used to calculate it, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49739 through 49747).

We invited public comment on this proposal.

Comment: One commenter requested that the following self-care and cognitive items to be added to the Percent of Long-Term Care Hospital (LTCH) Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631) measure in order to meet the definition of standardized patient assessment data with respect to functional status: upper body dressing, lower body dressing, and putting on/taking off footwear.

Response: We will take these suggestions into consideration. We believe we should seek additional stakeholder input before considering proposing adding these data elements to the LTCH CARE Data Set, because we are mindful of burden associated with adding any new data elements. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49739 through 49747) for a detailed discussion of the Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631) measure.

After consideration of the public comments we received, we are finalizing as proposed that the data elements currently reported by LTCHs to calculate the measure, Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631), also meet the definition of standardized patient assessment data with respect to functional status under section 1899B(b)(1)(B)(i) of the Act, and that the successful reporting of that data under section 1886(m)(5)(F)(i) of the Act will also satisfy the requirement to report standardized patient assessment data under section 1886(m)(5)(F)(ii) of the Act.

(2) Medical Condition and Comorbidity Data

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20113 through 20114), we proposed that the data elements needed to calculate the current measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), and the proposed measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, meet the definition of standardized patient assessment data with respect to medical conditions and co-morbidities under section 1899B(b)(1)(B)(iv) of the Act, and that the successful reporting of that data under section 1886(m)(5)(F)(i) of the Act would also satisfy the requirement to report standardized patient assessment data under section 1886(m)(5)(F)(ii) of the Act.

''Medical conditions and comorbidities'' and the conditions addressed in the standardized data elements used in the calculation and risk adjustment of these measures, that is, the presence of pressure ulcers, diabetes, incontinence, peripheral vascular disease or peripheral arterial disease, mobility, as well as low body mass index, are all health-related conditions that indicate medical complexity that can be indicative of underlying disease severity and other comorbidities.

Specifically, the data elements used in the measure are important for care planning and provide information pertaining to medical complexity. Pressure ulcers are serious wounds representing poor healthcare outcomes, and can result in sepsis and death. Assessing skin condition, care planning for pressure ulcer prevention and healing, and informing providers about their presence in patient transitions of care is a customary and best practice. Venous and arterial disease and diabetes are associated with low blood flow which may increase the risk of tissue damage. These diseases are indicators of factors that may place individuals at risk for pressure ulcer development and are therefore important for care planning. Low BMI, which may be an indicator of underlying disease severity, may be associated with loss of fat and muscle, resulting in potential risk for pressure ulcers. Bowel incontinence, and the possible maceration to the skin associated, can lead to higher risk for pressure ulcers. In addition, the bacteria associated with bowel incontinence can complicate current wounds and cause local infection. Mobility is an indicator of impairment or reduction in mobility and movement which is a major risk factor for the development of pressure ulcers. Taken separately and together, these data elements are important for care planning, transitions in services and identifying medical complexities.

In sections IX.C.7.a. and IX.C.10.a. of the preamble of this final rule, we discuss our rationale for proposing that the data elements used in the measures meet the definition of standardized patient assessment data. In summary, we believe that the collection of such assessment data is important for multiple reasons, including clinical decision support, care planning, and quality improvement, and that the data elements assessing pressure ulcers and the data elements used to risk adjust showed good reliability. We solicited stakeholder feedback on the quality measure, and the data elements from which it is derived, by means of a public comment period and TEPs, as described in section IX.C.7.a. of the preamble of this final rule.

We invited public comment on this proposal.

Comment: Some commenters supported the reporting of data elements already implemented in the LTCH QRP to satisfy the requirement to report standardized patient assessment data.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing as proposed that the data elements currently reported by LTCHs to calculate the current measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), and the proposed measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, meet the definition of standardized patient assessment data with respect to medical conditions and

[454] Barbara Gage et al., ''The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set'' (RTI International, 2012).

[455] *Ibid.*

[456] *Ibid.*

co-morbidities under section 1899B(b)(1)(B)(iv) of the Act, and that the successful reporting of that data under section 1886(m)(5)(F)(i) of the Act would also satisfy the requirement to report standardized patient assessment data under section 1886(m)(5)(F)(ii) of the Act.

For comments related to the pressure ulcer quality measure, we refer readers to section IX.C.7.a of the preamble of this final rule.

11. Form, Manner, and Timing of Data Submission Under the LTCH QRP

a. Start Date for Standardized Patient Assessment Data Reporting by New LTCHs

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49749 through 49752), we adopted timing for new LTCHs to begin reporting quality data under the LTCH QRP beginning with the FY 2017 LTCH QRP. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20116), we proposed that new LTCHs will be required to begin reporting standardized patient assessment data on the same schedule.

We invited public comment on this proposal. We did not receive any public comments on this proposal; therefore, we are finalizing as proposed the start date for standardized patient assessment data reporting by new LTCHs.

b. Mechanism for Reporting Standardized Patient Assessment Data Beginning With the FY 2019 LTCH QRP

Under our current policy, LTCHs report data by completing applicable sections of the LCDS, and submitting the LCDS to CMS through the QIES ASAP system. For more information on LTCH QRP reporting through the QIES ASAP system, refer to the ''Related Links'' section at the bottom of: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Technical-Information.html*.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20116), we stated that the proposed standardized patient assessment data elements are already included on, or would be added to, the LCDS. Details regarding the LCDS with respect to the proposed standardized patient assessment data are available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*.

We invited public comments on this proposal. We did not receive any comments on this proposal; therefore, we are finalizing as proposed the mechanism for reporting standardized patient assessment data beginning with the FY 2019 LTCH QRP.

c. Schedule for Reporting Standardized Patient Assessment Data Beginning With the FY 2019 LTCH QRP

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20116 through 20117), we proposed that the standardized patient assessment data necessary to calculate the quality measure ''Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678)'' would be used for the FY 2019 LTCH QRP. We also proposed that for purposes of the FY 2019 LTCH QRP program year such data would only include the last three quarters of calendar year 2017 (April 1, 2017 through December 31, 2017). In section IX.C.7.a of the preamble of the proposed rule, we discussed our proposal to adopt the measure, ''Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury'' to replace the current measure, ''Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678)'' with data collection beginning on April 1, 2018. We also stated that should the proposed measure be finalized, the FY 2020 LTCH QRP will be determined using the data from the first quarter of CY 2018 using the current measure, ''Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678)'' and last three quarters of CY 2018 using the data from the proposed measure, ''Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury.''

In section IX.C.10.b of the preamble of the proposed rule, we discussed the additional standardized patient assessment data proposed beginning with the FY 2020 LTCH QRP. Unless otherwise indicated, under our current policy, except for the first program year for which a measure is adopted, LTCHs must report data on measures with respect to LTCH admissions and discharges that occur during the 12 month calendar year period that applies to the program year. For the first program year for which a measure is adopted, LTCHs are usually required to report data for LTCH admissions and discharges that occur during the last three quarters of the calendar year that applies to that program year, as the version of the LTCH CARE Data Set that will contain the new items for LTCHs to report a new measure, is routinely released on April 1st of any given year.

For example, for the FY 2018 LTCH QRP, data on measures adopted for earlier program years must be reported with respect to all CY 2016 LTCH admissions and discharges. However, data on new measures adopted for the first time for the FY 2018 LTCH QRP must only be reported with respect to LTCH admissions and discharges that occur during the last three calendar quarters of 2016.

The tables below illustrate the data collection timeframes and data submission deadlines related to the April 1st standard release of the LTCH CARE Data Set:

SUMMARY ILLUSTRATION OF INITIAL REPORTING CYCLE FOR MEASURES AND STANDARDIZED PATIENT ASSESSMENT DATA REPORTING USING CY QUARTERS 2, 3, AND 4 DATA *

Data collection/submission quarterly reporting period *	Data submission quarterly deadlines for the FY [year] LTCH QRP * ^
Q2: April 1–June 30	Q2 Deadline: November 15.
Q3: July 1–September 30	Q3 Deadline: February 15.
Q4: October 1–December 30	Q4 Deadline: May 15.

* Applies to data reporting using the LTCH CARE Data Set and data reporting using the National Healthcare Safety Network.

^ The term ''FY [year] LTCH QRP'' means the fiscal year for which the LTCH QRP requirements applicable to that fiscal year must be met in order for an LTCH to receive the full annual update when calculating the payment rates applicable to it for that fiscal year.

SUMMARY ILLUSTRATION OF CALENDAR YEAR QUARTERLY REPORTING CYCLE FOR MEASURES AND STANDARDIZED PATIENT ASSESSMENT DATA REPORTING *

Data collection/submission quarterly reporting period *	Data submission quarterly deadlines for the FY [year] LTCH QRP * ^
Q1: January 1–March 31	Q1 Deadline: August 15.
Q2: April 1–June 30	Q2 Deadline: November 15.
Q3: July 1–September 30	Q3 Deadline: February 15.
Q4: October 1–December 31	Q4 Deadline: May 15.

*Applies to data reporting using the LTCH CARE Data Set and data reporting using the National Healthcare Safety Network.
^The term "FY [year] LTCH QRP" means the fiscal year for which the LTCH QRP requirements applicable to that fiscal year must be met in order for an LTCH to receive the full annual update when calculating the payment rates applicable to it for that fiscal year.

We invited public comment on our proposal for standardized patient assessment data reporting beginning with the FY 2019 LTCH QRP and to extend our current policy governing the schedule for reporting quality measure data to the reporting of standardized patient assessment data beginning with the FY 2020 LTCH QRP.

The FY 2019 LTCH QRP will be determined using standardized patient assessment data collected from October 1, 2017 through December 31, 2017 using the current measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), as described in section IX.C.10.a. of the preamble of this final rule.

As described in section IX.C.10.b of the preamble of this final rule, commenters expressed concern related to the implementation timeline in the proposed rule and stated that there would not be sufficient time to be ready by April 1, 2018. In response to those comments, we are moving the implementation of the LTCH CARE Data Set Version 4.00 from April 1, 2018 to July 1, 2018.

As a result of the delayed implementation of the LTCH CARE Data Set Version 4.00, the FY 2020 LTCH QRP will be determined using the standardized patient assessment data from the first two quarters of CY 2018 using the current measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), and last two quarters of CY 2018 using the standardized patient assessment data from the finalized measures, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury and Application of Percent of Long-Term Care Hospital (LTCH) Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631), as described in IX.C.10.b. of the preamble of this final rule.

For the FY 2020 LTCH QRP, and with this final rule, LTCHs will be required to report measures and standardized patient assessment data for LTCH admissions and discharges during the last two quarters of CY 2018 as the version of the LTCH CARE Data Set that will contain the new items for LTCHs to report new measures and standardized patient assessment data will be released July 1, 2018. This exception to our standard policy is relevant only to LTCH CARE Data Set data to be reported to CMS for new measures and standardized patient assessment data that is finalized in this FY 2018 IPPS/LTCH PPS final rule, and for which LTCHs will begin reporting data on July 1, 2018, with the release of the LTCH CARE Data Set Version 4.00, as all subsequent releases of LTCH CARE Data Set versions will revert back to their standard release date of April 1 of any given year.

The FY 2021 LTCH QRP will be determined using standardized patient assessment data from CY 2019 from the finalized measures, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury and Application of Percent of Long-Term Care Hospital (LTCH) Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).

The tables below illustrate the data collection timeframes and submission deadlines for measures and standardized patient assessment data finalized for the FY 2020 and FY 2021 LTCH QRP.

SUMMARY ILLUSTRATION OF INITIAL REPORTING CYCLE FOR NEWLY ADOPTED MEASURES AND STANDARDIZED PATIENT ASSESSMENT DATA REPORTING FOR CY 2018 QUARTERS 3 AND 4 DATA *

Finalized data collection/submission quarterly reporting period *	Finalized data submission quarterly deadlines beginning with the FY 2020 LTCH QRP * ^
Q3: CY 2018—7/1/2018–9/30/2018	CY 2018 Q3 Deadline: February 15, 2019.
Q4: CY 2018—10/1/2018–12/31/2018	CY 2018 Q4 Deadline: May 15, 2019.

*Applies to data reporting using the LTCH CARE Data Set and data reporting using the National Healthcare Safety Network.
^The term "FY 2020 LTCH QRP" means the fiscal year for which the LTCH QRP requirements applicable to that fiscal year must be met in order for an LTCH to receive the full annual update when calculating the payment rates applicable to it for that fiscal year.

SUMMARY ILLUSTRATION OF CALENDAR YEAR QUARTERLY REPORTING CYCLE FOR MEASURES AND STANDARDIZED PATIENT ASSESSMENT DATA REPORTING *

Finalized data collection/submission quarterly reporting period *	Finalized data submission quarterly deadlines beginning with the FY 2021 LTCH QRP * ^
Q1: CY 2019—1/1/2019–3/31/2019	CY 2019 Q1 Deadline: August 15, 2019.
Q2: CY 2019—4/1/2019–6/30/2019	CY 2019 Q2 Deadline: November 15, 2019.
Q3: CY 2019—7/1/2019–9/30/2019	CY 2019 Q3 Deadline: February 15, 2020.
Q4: CY 2019—10/1/2019–12/31/2019	CY 2019 Q4 Deadline: May 15, 2020.

*Applies to data reporting using the LTCH CARE Data Set and data reporting using the National Healthcare Safety Network.

^The term "FY 2021 LTCH QRP" means the fiscal year for which the LTCH QRP requirements applicable to that fiscal year must be met in order for an LTCH to receive the full annual update when calculating the payment rates applicable to it for that fiscal year.

We are finalizing our proposal for reporting standardized patient assessment data beginning with the FY 2019 LTCH QRP. We are also finalizing the exception to the standard policy related to the timing of reporting standardized patient assessment data for the FY 2020 LTCH QRP and subsequent releases of the LTCH CARE Data Set will revert back to their standard release date of April 1 of any given year.

d. Schedule for Reporting the Newly Finalized Quality Measures Beginning With the FY 2020 LTCH QRP

As discussed in section IX.C.7. of the preamble of this final rule, we adopted three quality measures beginning with the FY 2020 LTCH QRP: Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury; Compliance with SBT by Day 2 of the LTCH Stay; and Ventilator Liberation Rate. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20117), we proposed that LTCHs would report data on these measures using the LTCH CARE Data Set that is submitted through the QIES ASAP system and LTCHs would be required to report these data beginning with LTCH admissions and discharges that occur between April 1, 2018 and December 31, 2018. More information on LTCH reporting using the QIES ASAP system is located at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Technical-Information.html*.

Under our current policy, LTCHs would only be required to submit data on the proposed measures for the last three quarters of CY 2018 for purposes of the FY 2020 LTCH QRP. Starting in CY 2019, LTCHs would be required to submit data for the entire calendar year beginning with the FY 2021 LTCH QRP.

We invited public comment on this proposal.

Comment: A commenter requested that CMS reduce the unnecessary burden of the LTCH CARE Data Set, including revising the response timing requirements of the LTCH CARE Data Set, and suggested extending the response time beyond three days. The commenter also stated that CMS should provide clear assessment guidelines and guidance for reporting data.

Response: We appreciate the comment, and we are working on ways to minimize the overall burden associated with the LTCH CARE Data Set, while keeping in mind our goal to collect valid, reliable and appropriate data for the LTCH QRP.

The three-day assessment period is in place to standardize responses from all LTCHs in order to ensure that the data are comparable across LTCHs. In addition, when choosing the appropriate length of time in which to require that the assessment take place, we weighed the need for providers to have sufficient time to accurately assess the patient's clinical status at the time of admission. Due to the high acuity of LTCH patients, we believe extending the 3-day assessment period would not allow a true picture of the patient's clinical status at the time of admission. Moreover, LTCHs have approximately 135 days following the end of each calendar year quarter, during which to submit, review, and correct their quality data for that CY quarter, with exception of the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure, in which data is submitted annually and not quarterly. These timeframes are aligned with those of other quality reporting programs and allow an appropriate amount of time for LTCHs to review and correct quality data prior to the public display of that data.

We provide comprehensive training to assist LTCHs with completing the LCDS, including through training manuals, webinars, open door forums, help desk support, and a Web site that hosts training information (*http://www.youtube.com/user/CMSHHSgov*). We also provide guidance on completing and submitting the LTCH CARE Data Set in Chapter 2 of the LTCH QRP Manual, which is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-CARE-Data-Set-and-LTCH-QRP-Manual.html*.

Comment: Some commenters requested crosswalks from ICD–10 codes to LTCH CARE Data Set items. One commenter requested that these crosswalks be kept up-to-date contemporaneously with ICD–10 changes.

Response: A list of ICD–10 codes for the 2018 LTCH CARE Data Set items will be available no sooner than July 2018. We also intend to provide and update this information in LTCH manuals, training events, and on Web site postings.

As described in section IX.C.10.c. of the preamble of this final rule, we are finalizing the schedule for reporting the newly finalized measures beginning July 1, 2018 for the FY 2020 LTCH QRP in response to public comments.

As a result of the delayed implementation of the LTCH CARE Data Set Version 4.00, as described in section IX.C.10.c of the preamble of this final rule, in addition to the currently adopted measures in the LTCH QRP, LTCHs will be required to submit data on the finalized measures, Change in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, Compliance with SBT by Day 2 of the LTCH Stay, and Ventilator Liberation Rate, beginning with the last two quarters of CY 2018 for the FY 2020 LTCH QRP. LTCHs will also submit data on the previously finalized measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, beginning with the last two quarters of CY 2018 for the FY 2020 LTCH QRP. Starting in CY 2019, LTCHs will be required to submit data for the entire calendar year beginning with the FY 2021 LTCH QRP. The finalized LTCH CARE Data Set Version 4.00 is available for review at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-CARE-Data-Set-and-LTCH-QRP-Manual.html*.

In summary, we are finalizing our proposal for reporting the standardized patient assessment data necessary to calculate quality measures beginning with the FY 2019 LTCH QRP. We are also finalizing our proposal to extend our current policy governing the schedule for reporting quality measure data to the reporting of standardized patient assessment data, including the schedule for reporting newly finalized measures beginning July 1, 2018 for the FY 2020 LTCH QRP.

e. Removal of Interrupted Stay Items From the LTCH CARE Data Set

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20117), we proposed to remove the program interruption items from the LTCH CARE Data Set. Specifically, we proposed to remove the following items: (1) A2500, Program Interruption(s); (2) A2510, Number of Program Interruptions During This Stay in This Facility; and (3) A2525, Program Interruption Dates, because we do not currently utilize this information nor do we have plans to utilize this information for the LTCH QRP. For a detailed discussion of burden related to LTCH CARE Data Set, we refer readers to section XIV.B.9. of the preamble of this final rule.

We invited public comment on this proposal.

Comment: Several commenters supported the removal of the interrupted stay items from the LTCH CARE Data Set, and commended CMS' efforts to reduce burden with the removal of these items.

Response: We thank the commenters for their support of our efforts to reduce burden.

After consideration of the public comments we received, we are finalizing our proposal to remove the program interruption items (A2500, A2510, and A2525) from the LTCH CARE Data Set Version 4.00, effective July 1, 2018.

12. Application of the LTCH QRP Participation Requirements to the Submission of Standardized Patient Assessment Data

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20117), we proposed to revise the regulatory text at § 412.560(a) to state that an LTCH must begin submitting quality data, including standardized patient assessment data, under the LTCH QRP by no later than the first day of the calendar quarter subsequent to 30 days after the date on its CMS Certification Number (CCN) notification letter.

We invited public comments on this proposal. We did not receive any public comments on this proposal. Therefore, we are finalizing our proposal as proposed to revise the regulatory text at § 412.560(a) to state that an LTCH must begin submitting quality data, including standardized patient assessment data, under the LTCH QRP by no later than the first day of the calendar quarter subsequent to 30 days after the date on its CMS Certification Number (CCN) notification letter.

13. Application of the LTCH QRP Data Submission Requirements to the Submission of Standardized Patient Assessment Data

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20117), we proposed to revise the regulatory text at § 412.560(b)(1) to require LTCHs to report both data on measures and standardized patient assessment data under the LTCH QRP in a form and manner, and at a time, specified by CMS.

We invited public comments on this proposal. We did not receive any public comments on this proposal. Therefore, we are finalizing our proposal as proposed to revise the regulatory text at § 412.560(b)(1) to require LTCHs to report both data on measures and standardized patient assessment data under the LTCH QRP in a form and manner, and at a time, specified by CMS.

14. Application of the LTCH QRP Exception and Extension Requirements to the Submission of Standardized Patient Assessment Data

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20117 through 20118), we proposed to revise the regulatory text at § 412.560(c) to extend the Exception and Extension requirement policies to the submission of standardized patient assessment data beginning with the FY 2019 LTCH QRP.

We invited public comments on this proposal. We did not receive any public comments on this proposal. Therefore, we are finalizing our proposal as proposed to revise the regulatory text at § 412.560(c) to extend these policies to the submission of standardized patient assessment data beginning with the FY 2019 LTCH QRP.

15. Application of the LTCH QRP Reconsideration Policy to the Submission of Standardized Patient Assessment Data

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20118), we proposed to revise the regulatory text at § 412.560(d) to extend the reconsideration policies to the submission of standardized patient assessment data beginning with the FY 2019 LTCH QRP.

We invited public comments on this proposal. We did not receive any comments on this proposal. Therefore, we are finalizing our proposal to revise the regulatory text at § 412.560(d) to extend these policies to the submission of standardized patient assessment data beginning with the FY 2019 LTCH QRP.

16. Application of the LTCH QRP Data Completion Thresholds to the Submission of Standardized Patient Assessment Data Beginning With the FY 2019 LTCH QRP

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50311 through 50314), we finalized LTCH QRP thresholds for completeness of LTCH data submissions. To ensure that LTCHs are meeting an acceptable standard for completeness of submitted data, we finalized the policy that, beginning with the FY 2016 LTCH QRP, LTCHs must meet or exceed two separate data completeness thresholds: One threshold set at 80 percent for completion of measures data collected using the LTCH CARE Data Set submitted through the QIES ASAP system, and a second threshold set at 100 percent for measures data collected and submitted using the CDC NHSN. The term ''measures'' refers to quality measures, resource use, and other measures.

Under our finalized policy, some assessment data will not invoke a response and, in those circumstances, are not ''missing'' nor is the data incomplete. For example, in the case of a patient who does not have any of the medical conditions in a ''check all that apply'' listing, the absence of a response of a health condition indicates that the condition is not present, and it would be incorrect to consider the *absence* of such data as missing in a threshold determination. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20118), we proposed to extend our current LTCH QRP data completion requirements to the reporting of standardized patient assessment data. We invited public comment on this proposal.

We also proposed to codify these LTCH QRP data completion thresholds at a new § 412.560(f) for measures data collected using the LTCH CARE Data Set, beginning with the FY 2016 LTCH QRP, and standardized patient assessment data elements collected using the LTCH CARE Data Set, beginning with the FY 2019 LTCH QRP. Under this section, we proposed to codify that LTCHs must meet or exceed two separate data completeness thresholds: 80 Percent for completion of measures data and standardized patient assessment data collected using the LTCH CARE Data Set submitted through the QIES; and 100 percent for measures data collected and submitted using the CDC NHSN. These thresholds would apply to all measures and data elements adopted into LTCH QRP. A LTCH must meet or exceed both thresholds to avoid receiving a 2 percentage point reduction to its annual payment update for a given fiscal year, beginning with the FY 2016 LTCH QRP for measures data and beginning with the FY 2019 LTCH QRP for standardized patient assessment data elements.

We invited public comment on our proposal to extend our current LTCH QRP data completion requirements to the reporting of standardized patient assessment data. We also invited public comment on our proposal to codify the LTCH QRP data completion thresholds at § 412.560(f) for measures and standardized patient assessment data elements collected using the LTCH CARE Data Set.

Comment: A commenter raised concerns regarding the addition of standardized patient assessment data that would be applied to the data completion threshold policy. The commenter suggested waiting a year to

impose the data completion threshold policy to the standardized patient assessment data so that providers have the opportunity to receive confidential feedback on their data from CMS.

Response: We appreciate the commenter's suggestions pertaining to the application of the data completion threshold policy to the standardized patient assessment data elements. Providers generally have 135 days following the end of each CY quarter to review and submit corrections to their data. Therefore, we believe that providers have the sufficient tools and time to manage the addition of the standardized patient assessment data to the data completion threshold policy.

After consideration of the public comments we received, we are finalizing our proposal as proposed to extend our current LTCH QRP data completion requirements to the reporting of standardized patient assessment data. We are also finalizing our proposal as proposed to codify the LTCH QRP data completion thresholds at § 412.560(f) for measures and standardized patient assessment data elements collected using the LTCH CARE Data Set.

17. Policies Regarding Public Display of Measure Data for the LTCH QRP

Section 1886(m)(5)(E) of the Act requires the Secretary to establish procedures for making the LTCH QRP data available to the public after ensuring that an LTCH has the opportunity to review its data prior to public display. Measure data is currently displayed on the Long-Term Care Hospital Compare Web site, which is an interactive web tool that assists individuals by providing information on LTCH quality of care including those who need to select an LTCH. For more information on *LTCH Compare,* we refer readers to: *https://www.medicare.gov/longtermcarehospitalcompare/*. In addition, for a more detailed discussion about the provider's confidential review process prior to public display of quality measures we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57231 through 57236).

We also finalized the process we use to publish a list of LTCHs that successfully meet the reporting requirements for the applicable LTCH QRP year on the LTCH QRP Web site in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57231). The list of compliant LTCHs is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Data-Submission-Deadlines.html*.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57231 through 57236), we finalized the public display of measure data on the *LTCH Compare* Web site in CY 2017 for the following 4 quality measures pending the availability of data: (1) NHSN Facility-wide Inpatient Hospital-onset MRSA Bacteremia Outcome Measure (NQF #1716); (2) NHSN Facility-wide Inpatient Hospital-onset CDI Outcome Measure (NQF #1717); (3) Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431); and (4) Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (NQF #0680).

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57232), we stated that ''pending the availability of data,'' the public display of NHSN Facility-wide Inpatient Hospital-onset MRSA Bacteremia Outcome Measure (NQF #1716) and NHSN Facility-wide Inpatient Hospital-onset CDI Outcome Measure (NQF #1717) would initially be based on data collected from January 1, 2015 through December 31, 2015 and would be displayed based on 4 rolling quarters. We would like to clarify that the initial public display of data for these two quality measures (MRSA and CDI) will be based on data collected from January 1, 2016 through December 31, 2016 (CY 2016), as the CY 2015 data is not available for display using the Standardized Infection Ratio (SIR) metric. Rather, this data (CY 2015) was used by the CDC to calculate the ''predicted'' number of infections (the number of infections that would be expected to occur based on previously reported data) for each LTCH, so that subsequent data could be used to calculate the SIR for each of these quality measures.

The SIR is a summary statistic that compares the ''predicted'' number of infections to the ''observed'' or actual number of infections for a given LTCH. This process or ''rebaselining'' of data occurs periodically when the CDC determines that referent period of data or ''baseline'' is no longer meaningful due to changes in the quality measure protocols or changes in provider populations. When the CDC uses a specific year's data to inform newly calculated ''predicted'' number of infections, CMS is unable to use that specific year of data to calculate the SIR, and for this reason, we are unable to display the MRSA and CDI performance data using the CY 2015 LTCH NHSN data, and will use the CY 2016 data to inform the SIR calculations when we publicly display the SIRs for these measures in fall 2017.

The Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) and Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (NQF #0680) will be based on the influenza vaccination season from October 1, 2015 through March 31, 2016 and will be updated annually. We refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57231 through 57233) for details on the calculations and display of these quality measures.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20118 through 20120), pending the availability of data, we proposed to publicly report data in CY 2018 for the following 3 assessment-based measures: (1) Percent of LTCH Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631); (2) Application of Percent of LTCH Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631); and (3) Application of Percent of Residents Experiencing One or More Falls with Major Injury (NQF #0674). In addition, pending the availability of data, we proposed to publicly report data in CY 2020 for the assessment-based measure Functional Outcome Measure: Change in Mobility Among Patients Requiring Ventilator Support (NQF #2632). Data collection for these 4 new assessment-based measures began on April 1, 2016. We proposed to display data for the assessment-based measures based on four rolling quarters of data and would initially use discharges from January 1, 2017 through December 31, 2017, with the exception of Functional Outcome Measure: Change in Mobility Among Patients Requiring Ventilator Support (NQF #2632) which would be based on eight rolling quarters of data and would initially use discharges from January 1, 2017 through December 31, 2018.

In addition, we proposed to publicly report 3 claims-based measures: (1) Medicare Spending Per Beneficiary-PAC LTCH QRP; (2) Discharge to Community-PAC LTCH QRP; and (3) Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP.

These measures were adopted for the LTCH QRP in the FY 2017 IPPS/LTCH PPS final rule to be based on data from 2 consecutive calendar years. As previously adopted in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57233 through 57236), confidential feedback reports for these 3 claims-based measures will be based on calendar years 2015 and 2016 and data collected

for discharges beginning January 1, 2015 through December 31, 2016. However, our current proposal revises the dates for public reporting, and we proposed to transition from calendar year to fiscal year to make these measure data publicly available by October 2018. Thus, we proposed public reporting beginning in CY 2018 for these claims-based measures based on fiscal years 2016 and 2017 and data collected from discharges beginning October 1, 2015 through September 30, 2017.

We proposed to remove the following claims-based measure ''All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from LTCHs'' from the LTCH QRP and public reporting by October 2018. We refer readers to section IX.C.8. of the preamble of this final rule for additional information regarding the proposed removal of this measure from quality reporting and public display. We also proposed to remove the following assessment-based measure ''Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678)'' and to replace it with a modified version of the measure entitled ''Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury'' from the LTCH QRP and public reporting by October 2020. We refer readers to section IX.C.7.a. of the preamble of this final rule for additional information regarding the proposed replacement of this measure from quality reporting and public display.

For the assessment-based measures: Percent of LTCH Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631); Application of Percent of LTCH Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631); and Application of Percent of Residents Experiencing One or More Falls with Major Injury (NQF #0674), to ensure the statistical reliability of the measures, we proposed to assign LTCHs with fewer than 20 eligible cases during a performance period to a separate category: ''The number of cases/patient stays is too small to report.'' If an LTCH had fewer than 20 eligible cases, the LTCH's performance would not be publicly reported for the measure for that performance period.

For the claims-based measures: Discharge to Community-PAC LTCH QRP and Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP, to ensure the statistical reliability of the measures, we proposed to assign LTCHs with fewer than 25 eligible cases during a performance period to a separate category: ''The number of cases/patient stays is too small to report.'' If an LTCH had fewer than 25 eligible cases, the LTCH's performance would not be publicly reported for the measure for that performance period. For Medicare Spending Per Beneficiary-PAC LTCH QRP, to ensure the statistical reliability of the measure, we proposed to assign LTCHs with fewer than 20 eligible cases during a performance period to a separate category: ''The number of cases/patient stays is too small to report.'' If an LTCH had fewer than 20 eligible cases, the LTCH's performance would not be publicly reported for the measure for that performance period.

PREVIOUSLY FINALIZED AND PROPOSED MEASURES FOR CY 2018 PUBLIC DISPLAY AND CONFIDENTIAL FEEDBACK REPORTS

Previously Finalized Measures:
Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678).
National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138).
National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Measure (NQF #0139).
NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716).
NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717).
Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431).
Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (NQF #0680).
Proposed Measures:
Percent of Long-Term Care Hospital (LTCH) Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).
Application of Percent of Long-Term Care Hospital (LTCH) Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).
Application of Percent of Residents Experiencing One or More Falls with Major Injury (NQF #0674).
Medicare Spending Per Beneficiary-PAC LTCH QRP.
Discharge to Community-PAC LTCH QRP.
Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP.

PROPOSED ADDITIONAL MEASURE FOR CY 2020 PUBLIC DISPLAY AND CONFIDENTIAL FEEDBACK REPORTS

Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital (LTCH) Patients Requiring Ventilator Support (NQF #2632).

We invited public comment on the proposal for the public display of the four assessment-based measures and three claims-based measures, the removal of the All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from LTCHs from the LTCH QRP and public display, and the replacement of ''Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678)'' with a modified version of the measure entitled ''Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury'' as described above.

Comment: A commenter supported CMS' efforts to display regional comparison rates. The commenter also requested state comparison data in addition to regional comparison data for the LTCH quality measures.

Response: We appreciate the commenter's support. We also note that we addressed this issue in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57233), and we refer the reader to that final rule for a detailed response regarding the display of regional and state comparison rates.

Comment: A commenter supported CASPER monthly updates to the data and the provision of detailed instructions on how to obtain their confidential feedback reports.

Response: We acknowledge the commenter's support for the current process of providing monthly updates to the confidential feedback reports. We will continue to provide detailed instructions on how to obtain CASPER reports on the LTCH QRP Web site and will continue to offer trainings to help providers understand how to utilize the reports available to them.

Comment: A commenter suggested that CMS provide consultative opportunities to assist LTCHs in their measure improvements.

Response: We note that providers can use their confidential feedback and other CASPER reports to address their internal processes to improve quality outcomes. Further, there are established help desks for our public reporting and quality reporting programs that providers can submit questions about the measures and performance results that CMS reviews and responds to. Additional information about the help desks can be found on the LTCH QRP Web site: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Help.html*. Finally, we also provide training opportunities and updated guidance which can be accessed by means of the LTCH QRP Web pages.

Comment: A few commenters expressed concern that similar or overlapping quality measures would be publicly reported at the same time on the *LTCH Compare* Web site (for example, both pressure ulcer measures, both readmission measures).

Response: We plan to remove the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) and All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Long-Term Care Hospitals from the *LTCH Compare* Web site prior to when we begin to publicly display the Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury and Potentially Preventable 30-Day Post-Discharge Readmission Measure for Long-Term Care Hospital Quality Reporting Program, respectively.

Comment: A few commenters recommended enhancements to the *LTCH Compare* Web site to further explain quality measure data and results in a way that is interpretable to patients, their families, and providers. One of these commenters also suggested convening a multi-stakeholder panel to review and provide guidance on the various Compare Web sites including *LTCH Compare.*

Response: We appreciate the commenters' suggestions and will take these suggestions into consideration as we continue to enhance the *LTCH Compare* Web site, including making quality measure information interpretable for LTCH patients, families, and providers. Of note, when developing the *LTCH Compare* Web site, consumer testing of the Web site did occur during the development stages with members of the public including Medicare beneficiaries.

Comment: A commenter expressed concerns about the ability of providers to review and correct the accuracy of measure data generated by the CDC NHSN and claims-based models prior to their display on the *LTCH Compare* Web site as mandated by the IMPACT Act. The commenter further stated that results for two of the four required measures, CLABSI and CAUTI, were not posted on the *Compare* Web site due to calculation issues while the unplanned readmission rate cannot be reviewed for accuracy by providers because they are not provided the raw source data or the model.

Response: We recognize the commenter's concerns regarding the CDC NHSN CAUTI and CLABSI and claims-based All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Long-Term Care Hospitals. Providers are required to submit accurate HAI data to CDC and are given the opportunity to review and correct any data submitted. Providers have approximately 4.5 months after the reporting quarter to correct their assessment-based and NHSN data used to calculate the measures as detailed in FY 2017 IPPS/LTCH PPS final rule (81 FR 57234 through 57236). Also, as stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57234), CMS can suppress data on *LTCH Compare* if it is determined that the measure performance on the Provider Preview reports contains a calculation error. We intend to display data on the CDC NHSN CAUTI and CLABSI measures for the most recent quarter when the data is corrected. We will continue to work with the CDC to ensure the accuracy of measure results. CDC measure specifications can be found on the CDC NHSN Web site (*http://www.cdc.gov/nhsn/index.html*).

Regarding the claims-based All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Long-Term Care Hospitals measure, CMS appreciates commenter's concern regarding the accuracy of the measure because they are not provided the raw source data or the model. CMS is exploring the feasibility of making additional patient level data available to providers as well as posting updated information on the risk model results used for measure calculation. We intend to continue to display results for The All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Long-Term Care Hospitals (NQF #2512) until the removal of the measure from public display by October 2018.

Comment: A commenter expressed concerns regarding the ability of CDC NHSN HAI and claims-based All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Long-Term Care Hospitals measures to accurately reflect changing patient populations.

Response: We appreciate the commenter's concerns about the CDC NHSN HAI CAUTI and CLABSI measures and the claims-based All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Long-Term Care Hospitals. We will continue to update and refine measure specifications based on ongoing analysis of the data and patient populations. National averages are not stagnant but are calculated on an ongoing basis to reflect results based on the data from the time period reported.

After consideration of the public comments we received, we are finalizing our proposal as proposed to begin publicly reporting in CY 2018 the following assessment-based measures pending the availability of the data: ''Percent of Long-Term Care Hospital (LTCH) Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function'' (NQF #2631), ''Application of Percent of Long-Term Care Hospital (LTCH) Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function'' (NQF #2631), ''Application of Percent of Residents Experiencing One or More Falls with Major Injury'' (NQF #0674), as well as the following claims-based measures: ''Medicare Spending Per Beneficiary-PAC LTCH QRP,'' ''Discharge to Community-PAC LTCH QRP,'' and ''Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP.'' In addition, we will publicly report data in CY 2020 the assessment-based measure: ''Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital (LTCH) Patients Requiring Ventilator Support'' (NQF #2632) pending availability of data.

We are finalizing our proposal to remove the claims-based measure ''All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Long-Term Care Hospitals'' from the LTCH QRP and public reporting by October 2018. We are also finalizing our proposals to remove the following assessment-based measure ''Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678)'' and to replace it with a modified version of the measure entitled ''Changes in Skin Integrity Post-Acute Care: Pressure

Ulcer/Injury'' from the LTCH QRP and public reporting by October 2020.

18. Mechanism for Providing Feedback Reports to LTCHs

Section 1899B(f) of the Act requires the Secretary to provide confidential feedback reports to PAC providers on their performance on the measures specified under sections 1899B(c)(1) and (d)(1) of the Act, beginning one year after the specified application date that applies to such measures and PAC providers. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57233 through 57236), we finalized processes to provide LTCHs the opportunity to review their data and information using confidential feedback reports that will enable LTCHs to review their performance on the measures required under the LTCH QRP. Information on how to obtain these and other reports available to the LTCH can be found at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Public-Reporting.html*.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20120), we did not propose any changes to this policy.

D. Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program

1. Background

a. Statutory Authority

Section 1886(s)(4) of the Act, as added and amended by sections 3401(f) and 10322(a) of the Patient Protection and Affordable Care Act, requires the Secretary to implement a quality reporting program for inpatient psychiatric hospitals and psychiatric units. Section 1886(s)(4)(A)(i) of the Act requires that, for fiscal year (FY) 2014 [457] and each subsequent fiscal year, the Secretary must reduce any annual update to a standard Federal rate for discharges occurring during the fiscal year by 2.0 percentage points for any inpatient psychiatric hospital or psychiatric unit that does not comply with quality data submission requirements with respect to an applicable fiscal year.

As provided in section 1886(s)(4)(A)(ii) of the Act, the application of the reduction for failure to report under section 1886(s)(4)(A)(i) of the Act may result in an annual update of less than 0.0 percent for a fiscal year, and may result in payment rates under section 1886(s)(1) of the Act being less than the payment rates for the preceding year. In addition, section 1886(s)(4)(B) of the Act requires that the application of the reduction to a standard Federal rate update be noncumulative across fiscal years. Thus, any reduction applied under section 1886(s)(4)(A) of the Act will apply only with respect to the fiscal year rate involved and the Secretary may not take into account the reduction in computing the payment amount under the system described in section 1886(s)(1) of the Act for subsequent years.

Section 1886(s)(4)(C) of the Act requires that, for FY 2014 (October 1, 2013 through September 30, 2014) and each subsequent year, each psychiatric hospital and psychiatric unit must submit to the Secretary data on quality measures as specified by the Secretary. The data must be submitted in a form and manner and at a time specified by the Secretary. Under section 1886(s)(4)(D)(i) of the Act, unless the exception of subclause (ii) applies, measures selected for the quality reporting program must have been endorsed by the entity with a contract under section 1890(a) of the Act. The National Quality Forum (NQF) currently holds this contract.

Section 1886(s)(4)(D)(ii) of the Act provides an exception to the requirement for NQF endorsement of measures: In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

Section 1886(s)(4)(E) of the Act requires the Secretary to establish procedures for making public the data submitted by inpatient psychiatric hospitals and psychiatric units under the IPFQR Program. These procedures must ensure that a facility has the opportunity to review its data prior to the data being made public. The Secretary must report quality measures that relate to services furnished by the psychiatric hospitals and units on the CMS Web site.

b. Covered Entities

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53645), we established that the IPFQR Program's quality reporting requirements cover those psychiatric hospitals and psychiatric units paid under Medicare's Inpatient Psychiatric Facility Prospective Payment System (IPF PPS) (42 CFR 412.404(b)). Generally, psychiatric hospitals and psychiatric units within acute care and critical access hospitals that treat Medicare patients are paid under the IPF PPS. Consistent with prior rules, we continue to use the term ''inpatient psychiatric facility'' (IPF) to refer to both inpatient psychiatric hospitals and psychiatric units. This usage follows the terminology in our IPF PPS regulations at 42 CFR 412.402. For more information on covered entities, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53645).

c. Considerations in Selecting Quality Measures

We strive to put patients first, ensuring they are empowered to make decisions about their own healthcare along with their clinicians using information from data-driven insights that are increasingly aligned with meaningful quality measures. We support technology that reduces burden and allows clinicians to focus on providing high-quality healthcare for their patients. We also support innovative approaches to improve quality, accessibility, and affordability of care while paying particular attention to improving clinicians' and beneficiaries' experience when interacting with our programs. In combination with other efforts across the Department of Health and Human Services, we believe the IPFQR program helps to incentivize facilities to improve healthcare quality and value while giving patients and providers the tools and information needed to make the best decisions for them. Consistent with these goals, our objective in selecting quality measures is to balance the need for information on the full spectrum of care delivery and the need to minimize the burden of data collection and reporting. We have primarily focused on measures that evaluate critical processes of care that have significant impact on patient outcomes and support CMS and HHS priorities for improved quality and efficiency of care provided by IPFs. When possible, we also seek to

[457] The statute uses the term ''rate year'' (RY). However, beginning with the annual update of the inpatient psychiatric facility prospective payment system (IPF PPS) that took effect on July 1, 2011 (RY 2012), we aligned the IPF PPS update with the annual update of the ICD codes, effective on October 1 of each year. This change allowed for annual payment updates and the ICD coding update to occur on the same schedule and appear in the same **Federal Register** document, promoting administrative efficiency. To reflect the change to the annual payment rate update cycle, we revised the regulations at 42 CFR 412.402 to specify that, beginning October 1, 2012, the RY update period would be the 12-month period from October 1 through September 30, which we refer to as a ''fiscal year'' (FY) (76 FR 26435). Therefore, with respect to the IPFQR Program, the terms ''rate year,'' as used in the statute, and ''fiscal year'' as used in the regulation, both refer to the period from October 1 through September 30. For more information regarding this terminology change, we refer readers to section III of the RY 2012 IPF PPS final rule (76 FR 26434 through 26435).

incorporate measures that directly evaluate patient outcomes. We refer readers to section VIII.F.4.a of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53645 through 53646) for a detailed discussion of the considerations taken into account in selecting quality measures.

(1) Measure Selection Process

Before being proposed for inclusion in the IPFQR Program, measures are placed on a list of measures under consideration, which is published annually by December 1 on behalf of CMS by the NQF. In compliance with section 1890A(a)(2) of the Act, measures proposed for the IPFQR Program were included in a publicly available document: ''List of Measures under Consideration for December 1, 2016'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Quality Measures/Downloads/Measures-under-Consideration-List-for-2016.pdf*. The Measure Applications Partnership (MAP), a multi-stakeholder group convened by the NQF, reviews the measures under consideration for the IPFQR Program, among other Federal programs, and provides input on those measures to the Secretary. The MAP's 2017 recommendations for quality measures under consideration are captured in the following documents: ''Process and Approach for MAP Pre-Rulemaking Deliberations, 2016–2017,'' available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=84455* and ''2016–2017 Spreadsheet of Final Recommendations to HHS and CMS'' available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=84452*. We considered the input and recommendations provided by the MAP in selecting all measures for the IPFQR Program, including those discussed below.

(2) Accounting for Social Risk Factors in the IPFQR Program

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20121), we discussed accounting for social risk factors in the IPFQR Program. We understand that social risk factors such as income, education, race and ethnicity, employment, disability, community resources, and social support (certain factors of which are also sometimes referred to as socioeconomic status (SES) factors or socio-demographic status (SDS) factors) play a major role in health. One of our core objectives is to improve beneficiary outcomes including reducing health disparities, and we want to ensure that all beneficiaries, including those with social risk factors, receive high quality care. In addition, we seek to ensure that the quality of care furnished by providers and suppliers is assessed as fairly as possible under our programs while ensuring that beneficiaries have adequate access to excellent care.

We have been reviewing reports prepared by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) [458] and the National Academies of Sciences, Engineering, and Medicine on the issue of measuring and accounting for social risk factors in CMS' value-based purchasing and quality reporting programs, and considering options on how to address the issue in these programs. On December 21, 2016, ASPE submitted a Report to Congress on a study it was required to conduct under section 2(d) of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. The study analyzed the effects of certain social risk factors in Medicare beneficiaries on quality measures and measures of resource use used in one or more of nine Medicare value-based purchasing programs.[459] The report also included considerations for strategies to account for social risk factors in these programs. In a January 10, 2017 report released by the National Academies of Sciences, Engineering, and Medicine, that body provided various potential methods for measuring and accounting for social risk factors, including stratified public reporting.[460]

As noted in the FY 2017 IPPS/LTCH PPS final rule, the NQF undertook a 2-year trial period in which new measures, measures undergoing maintenance review, and measures endorsed with the condition that they enter the trial period could be assessed to determine whether risk adjustment for selected social risk factors is appropriate for these measures. This trial entailed temporarily allowing inclusion of social risk factors in the risk-adjustment approach for these measures. The trial period ended in April 2017 and a draft report is available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*.

As we continue to consider the analyses and recommendations from these reports and await the results of the NQF trial on risk adjustment for quality measures, we are continuing to work with stakeholders in this process. As we have previously communicated, we are concerned about holding providers to different standards for the outcomes of their patients with social risk factors because we do not want to mask potential disparities or minimize incentives to improve the outcomes for disadvantaged populations. Keeping this concern in mind, while we sought input on this topic previously, we continue to seek public comment on whether we should account for social risk factors in the IPFQR Program, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors. Examples of methods include: Confidential reporting to providers of measure rates stratified by social risk factors; public reporting of stratified measure rates; and potential risk adjustment of a particular measure as appropriate based on data and evidence.

In addition, in the proposed rule, we sought public comment on which social risk factors might be most appropriate for reporting stratified measure scores and/or potential risk adjustment of a particular measure. Examples of social risk factors include, but are not limited to, dual eligibility/low-income subsidy, race and ethnicity, and geographic area of residence. We also sought comments on which of these factors, including current data sources where this information would be available, could be used alone or in combination, and whether other data should be collected to better capture the effects of social risk. We will take commenters' input into consideration as we continue to assess the appropriateness and feasibility of accounting for social risk factors in the IPFQR Program. We note that any such changes would be proposed through future notice-and-comment rulemaking.

We look forward to working with stakeholders as we consider the issue of accounting for social risk factors and reducing health disparities in CMS programs. Of note, implementing any of the above methods would be taken into consideration in the context of how this and other CMS programs operate (for example, data submission methods, availability of data, statistical considerations relating to reliability of

[458] Office of the Assistant Secretary for Planning and Evaluation. 2016. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs*.

[459] Office of the Assistant Secretary for Planning and Evaluation. 2016. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. 21 Dec. 2016. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs*.

[460] National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

data calculations, among others), so we also welcomed comment on operational considerations. CMS is committed to ensuring that its beneficiaries have access to and receive excellent care, and that the quality of care furnished by providers and suppliers is assessed fairly in CMS programs.

Comment: Many commenters expressed support for the concept of accounting for social risk factors in the IPFQR Program; however, these commenters expressed concern that chart-abstracted process measures, with data submitted in aggregate, are inappropriate for risk adjustment or stratified reporting. These commenters observed that to properly risk-adjust or stratify data for the IPFQR Program, the program would benefit from collection of patient-level outcome measures data. One commenter cautioned that collecting information to stratify measures could increase burden on IPFs and reduce the amount of data publicly reported due to small sample sizes. Several commenters encouraged CMS to ensure that providers can confidentially view reports of measures data stratified by social risk factors.

One commenter expressed appreciation that CMS is dedicating time and attention to this issue, but requested that CMS improve transparency of the process by developing a work plan and timeline. One commenter encouraged CMS to collaborate with Medicare Advantage and Medicaid health plans in understanding the impact of social risk factors.

Many commenters expressed concern that incentives for reducing disparities could lead to a reduction in quality for patients who are not at risk, and recommended that CMS consider this or other unintended consequences in any program design.

Several commenters urged CMS to ensure that data are publicized in a way that is meaningful to consumers, with some commenters specifically recommending that CMS convene consumer focus groups to provide input on the data presentation.

Response: We will consider all suggestions as we continue to assess the feasibility of accounting for social risk factors and will actively perform additional research and monitor for trends to prevent unintended consequences. We intend to explore options including but not limited to measure stratification by social risk factors in a consistent manner across our quality reporting and value-based purchasing programs when appropriate. Future proposals would be made after further research and continued stakeholder engagement.

We are committed to ensuring that CMS beneficiaries have access to and receive excellent care and the quality of care furnished by providers and suppliers is assessed fairly in CMS quality reporting and value-based purchasing programs. We thank the commenters, and we will consider their views as we develop further policy regarding social risk factors in the IPFQR Program.

(3) IPFQR Program Measures Adopted in Previous Payment Determinations

The current IPFQR Program includes 18 mandatory measures. For more information on these measures, we refer readers to the following final rules:

- The FY 2013 IPPS/LTCH PPS final rule (77 FR 53646 through 53652);
- The FY 2014 IPPS/LTCH PPS final rule (78 FR 50889 through 50895);
- The FY 2015 IPF PPS final rule (79 FR 45963 through 45974);
- The FY 2016 IPF PPS final rule (80 FR 46694 through 46714); and
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 57236 through 57249).

2. Factors for Removal or Retention of IPFQR Program Measures

a. Background

The Hospital IQR Program adopted formal policies regarding measure retention and removal in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50185). We believe that it is important to be consistent between programs to the extent possible. Therefore, to align with the policies adopted in this and other quality reporting programs, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20122), we proposed to adopt similar policies within the IPFQR Program. In the past, we have retained measures from each previous year's IPFQR Program measure set for subsequent years' measure sets, except when we specifically proposed to remove or replace a measure. For example, we removed HBIPS–6 and HBIPS–7 and replaced these measures with Transition Record with Specified Elements Received by Discharged Patients (NQF #0647) and Timely Transmission of Transition Record (NQF #0648) respectively in the FY 2016 IPF PPS final rule (80 FR 46701 through 46709). In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20122), we proposed factors to consider in removing or retaining measures effective upon finalization of the proposed rule, anticipated to be effective October 1, 2017 and for subsequent years.

We will continue to use the notice-and-comment rulemaking process to propose measures for removal or replacement.

b. Considerations in Removing or Retaining Measures

With respect to measure removal, we believe it is important to be transparent in identifying factors that we would take into consideration on a case-by-case basis as guidelines to evaluate a measure for potential removal from the IPFQR Program. We believe that these factors should be aligned between our programs whenever possible. Therefore, we refer readers to the Hospital IQR Program (80 FR 49641 through 49642) factors we consider in removing or retaining measures. We intend to align our policies in the IPFQR Program with those in the Hospital IQR Program. Thus, in the proposed rule, we proposed: (1) Measure removal factors; (2) criteria for determining when a measure is ''topped-out;'' and (3) measure retention factors. These proposals are discussed in more detail below.

We proposed the following measure removal factors for the IPFQR Program:

- Measure performance among IPFs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures);
- Measure does not align with current clinical guidelines or practice;
- Measure can be replaced by a more broadly applicable measure (across settings or populations) or a measure that is more proximal in time to desired patient outcomes for the particular topic;
- Measure performance or improvement does not result in better patient outcomes;
- Measure can be replaced by a measure that is more strongly associated with desired patient outcomes for the particular topic;
- Measure collection or public reporting leads to negative unintended consequences other than patient harm; and
- Measure is not feasible to implement as specified.

For the purposes of considering measures for removal from the program, we also proposed to align our criteria for determining that a measure is ''topped-out'' with the Hospital IQR Program's criteria (80 FR 49642), which states that a measure is ''topped-out'' if there is statistically indistinguishable performance at the 75th and 90th percentiles and the truncated coefficient of variation is less than or equal to 0.10.

Furthermore, we recognize that there may be times when measures may meet some of the outlined factors for removal,

but continue to bring value to the program. Therefore, we also proposed the following factors for consideration in determining whether to retain a measure in the IPFQR Program, which also are based on factors established in the Hospital IQR Program (80 FR 49641 through 49642):

- Measure aligns with other CMS and HHS policy goals, such as those delineated in the National Quality Strategy or CMS Quality Strategy;
- Measure aligns with other CMS programs, including other quality reporting programs; and
- Measure supports efforts to move IPFs towards reporting electronic measures.

We reiterate that these removal and retention factors are considerations that we take into account in balancing the benefits and drawbacks of whether or not to remove measures on a case-by-case basis.

We invited public comment on our proposals to adopt: (1) Measure removal factors; (2) criteria for determining when a measure is ''topped out;'' and (3) measure retention factors as discussed above. These factors and criteria will become effective upon finalization of this rule, anticipated to be effective October 1, 2017 and for subsequent years; measures identified as appropriate for removal would be proposed through notice-and-comment rulemaking subsequent to that date.

Comment: Many commenters supported CMS' proposal to adopt measure removal factors. Many of these commenters also expressed a desire to see measure performance data and for CMS to define and report on the outcomes that CMS believes are impacted by each process measure. One commenter supported the criteria for determining that a measure is ''topped out.''

Response: We thank the commenters for their support of our proposed measure removal factors. We publish data collected through the IPFQR Program on a publicly available CMS Web site (specifically, *Hospital Compare—https://www.medicare.gov/hospitalcompare/psych-measures.html*) to allow the public to make informed healthcare decisions; these data can also be used to assess national performance levels on specific measures. We also note that when we propose measures for the IPFQR Program, we provide explanations of how we believe these measures impact patient outcomes, we report these data to the extent possible (through our reporting on *Hospital Compare*), and we continue to be committed to adopting applicable outcomes measures into the IPFQR Program.

Comment: One commenter requested that CMS add ''implementation puts patients at greater risk of harm'' and ''measure has not been specified or tested in the IPF setting'' to this list of removal factors.

Response: While we agree with the commenter that the potential for increased patient harm requires removing a measure from the IPFQR Program, this was not included on the list because the list is for routine measure maintenance, and an increase in patient harm would most likely require immediate action. To clarify, if evidence suggests that a measure results in an increase in patient harm, we would take immediate action, as opposed to waiting for the notice and comment rulemaking cycle.

We disagree with the commenter's assertion that measures must have been specified or tested in the IPF setting for adoption in the IPFQR Program. We believe that measures should address the overall care provided to patients while they are inpatients and that to accomplish this, for example, some measures which have been tested in general acute care facilities are appropriate for the IPF setting.

Comment: Many commenters did not support CMS' proposed measure retention factors. These commenters believed that only measures specific to psychiatric care should be retained in the IPFQR Program. One commenter expressed that the measure retention factors do not appear to outweigh the benefit of removing measures that meet at least one removal factor.

Response: We disagree with the commenters' assertion that only measures specific to psychiatric care should be included in the IPFQR Program. We believe IPFs should consider the overall health of the patient throughout the length of his/her episode of care, in addition to the patient's psychiatric condition. We also disagree with the assertion that the measure retention factors do not outweigh the measure removal factors. We believe that selecting measures for this or any of the CMS quality reporting program requires multiple considerations, which is why we have aligned these measure removal and retention factors with those in use in other programs which must also balance multiple considerations. We refer readers to the Hospital IQR Program (80 FR 49641 through 49642), the PCHQR Program (81 FR 57182 through 57183), the Hospital OQR Program (79 FR 66942), and the ASCQR Program (79 FR 66968 through 66969) as examples of programs with similar needs to balance multiple considerations.

Comment: Several commenters expressed concern that if CMS adopts measures that ''support efforts to move IPFs towards reporting electronic measures,'' it may require IPFs to make extensive infrastructure investments to participate in the IPFQR Program. Some commenters stated that measures should not be retained to support efforts to move IPFs toward reporting electronic measures.

Response: We understand the commenters' concern regarding the adoption of infrastructure to support electronic measure reporting. We do believe that EHRs have a role in quality reporting programs, including the IPFQR Program and, as discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53660) and the 2014 IPPS/LTCH PPS final rule (78 FR 50903) we are interested in increasing the use of EHRs for data collection in the future. However, we note that the only measure currently in the IPFQR Program that addresses the adoption of Electronic Health Records is the attestation measure ''Use of an Electronic Health Record,'' which does not require any infrastructure investment. We originally adopted this measure to assess the state of adoption of EHRs among IPFs because the use of EHRs for the collection, use, and transmission of medical information has been demonstrated to impact the quality of care. However, data collected from this measure also provides insight into the operational barriers to adopting future electronic clinical quality measures (eCQMs) as well as the potential burden posed by individual eCQMs. We would propose any future measures that address adoption of EHRs through the notice and comment rulemaking process which allows us to seek public comment on these measures.

Comment: Several commenters requested that CMS evaluate the current measures using the proposed removal and retention factors. One commenter further encouraged CMS to evaluate the measures individually and as a set.

Response: We will evaluate the effectiveness of the measures currently in the IPFQR Program, individually and as a set, using these factors for this evaluation upon finalization of this rule.

Comment: One commenter recommended that CMS also identify a set of principles to use in selecting measures for inclusion in the IPFQR Program. The commenter recommended the following principles for selecting measures: (1) Measures improve the effectiveness and efficiency of patient care; (2) measures focus on indicators

that provide the most useful clinical and operational data possible; (3) measures focus on indicators that support actionable steps that fall within the scope of responsibility and accountability of the organization being measured; (4) measures provide value in the data generated that is in proportion to the intensity of the data-collection effort; and (5) measures have the potential for being used to measurably improve the processes, outcomes, efficiency, and patient experiences of the care being delivered.

Response: We have previously described our considerations in the development and selection of measures, which include addressing the six priorities of the National Quality Strategy (NQS) while minimizing burden, publicly reporting on measures that are close to the patient centered outcome of interest, focusing on gaps of quality, reflecting important areas of service, weighing the importance of the measure versus the burden of collection, seeking measures which are endorsed by multistakeholder organizations, and supporting the HHS Strategic Plan. For a detailed discussion, we refer readers to section VIII.F.4.a. of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53645 through 53646). However, we will take into consideration commenter's suggestions for the future.

Comment: One commenter expressed concern that the definition of ''topped out'' is not standardized across private and public payers. This commenter also expressed concern that removing ''topped out'' measures may worsen performance on the processes that these measures evaluate.

Response: We seek to align definitions and criteria with other programs wherever possible. However, as the commenter noted there are multiple definitions of ''topped out'' across private and public payers. We wish to align definitions and criteria with other programs to the extent possible, however because of the non-standardization of the definition, it is not possible to align with all payers. We proposed ''topped out'' criteria that align with those in use in other CMS quality reporting programs to ensure our ability to continue to be in alignment with these programs. Such quality reporting programs include the Hospital IQR Program (80 FR 49641 through 49642), the PCHQR Program (81 FR 57182 through 57183), the Hospital OQR Program (79 FR 66942), and the ASCQR Program (79 FR 66968 through 66969).

We agree with the commenter that there may be times that retaining a ''topped out'' measure is beneficial, as the measure continues to encourage high levels of performance and we intend to evaluate each measure on a case-by-case basis in accordance with our removal and retention policy to address this concern.

After consideration of the public comments we received, we are adopting the measure removal factors, ''topped-out'' criteria, and measure retention factors as proposed.

3. Proposal for New Quality Measure for the FY 2020 Payment Determination and Subsequent Years—Medication Continuation Following Inpatient Psychiatric Discharge (NQF #3205)

a. Background

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20122 through 20126), we proposed one new measure, Medication Continuation Following Inpatient Psychiatric Discharge (NQF #3205), for the FY 2020 payment determination and subsequent years. The measure uses Medicare fee-for-service (FFS) claims to identify whether patients admitted to IPFs with diagnoses of major depressive disorder (MDD), schizophrenia, or bipolar disorder had filled at least one evidence-based medication within 2 days prior to discharge through 30 days post-discharge. We believe that medication continuation is important for patients discharged from the inpatient psychiatric setting with MDD, schizophrenia, or bipolar disorder because of significant negative outcomes associated with non-adherence to medication regimens. For example, patients with MDD who do not remain on prescribed medications are more likely to have negative health outcomes such as relapse and readmission, decreased quality of life, and increased healthcare costs.[461] [462] Patients with schizophrenia who do not adhere to their medication regimen are more likely to be hospitalized, use emergency psychiatric services, be arrested, be victims of crimes, and consume alcohol or drugs compared to those who adhere to their medication regimen.[463] Patients with bipolar disorder who do not adhere to their medications have increased suicide risk.[464] For these reasons, guidelines from the American Psychiatric Association (APA) and the Department of Veterans Affairs/Department of Defense (VA/DoD), which are based on extensive literature, recommend pharmacotherapy as the primary form of treatment for patients with these conditions.[465] [466] [467] [468] [469]

Interventions that can be applied in the inpatient setting that increase medication compliance and prevent the negative outcomes associated with nonadherence have been identified. These interventions include patient education, enhanced therapeutic relationships, shared decision-making, and text-message reminders, with multidimensional approaches resulting in the best outcomes.[470] [471] [472] [473] [474] [475] Furthermore, patients and caregivers interviewed during the development of this measure indicated the importance of the facility's role in communicating

[461] Geddes JR, Carney SM, Davies C, et al. Relapse prevention with antidepressant drug treatment in depressive disorders: a systematic review. Lancet. 2003;361(9358):653–661.

[462] Glue P, Donovan MR, Kolluri S, Emir B. Meta-analysis of relapse prevention antidepressant trials in depressive disorders. The Australian and New Zealand journal of psychiatry. 2010;44(8):697–705.

[463] Gilmer TP, Dolder CR, Lacro JP, et al. Adherence to treatment with antipsychotic medication and health care costs among Medicaid beneficiaries with schizophrenia. The American journal of psychiatry. 2004;161(4):692–699.

[464] Gonzalez-Pinto A, Mosquera F, Alonso M, et al. Suicidal risk in bipolar I disorder patients and adherence to long-term lithium treatment. Bipolar disorders. 2006;8(5 Pt 2):618–624.

[465] American Psychiatric Association. (2002). Practice guideline for the treatment of patients with bipolar disorder, second edition. Retrieved from: *http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/bipolar.pdf.*

[466] American Psychiatric Association. (2010). Practice guideline for the treatment of patients with major depressive disorder, 3rd ed. Retrieved from: *http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf.*

[467] American Psychiatric Association. (2010). Practice guideline for the treatment of patients with schizophrenia: 2nd ed. Retrieved from: *http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/schizophrenia.pdf.*

[468] U.S. Department of Veterans Affairs, & U.S. Department of Defense. (2016). Management of major depressive disorder (MDD). Retrieved from: *http://www.healthquality.va.gov/guidelines/MH/mdd/VADoDMDDCPGFINAL82916.pdf.*

[469] U.S. Department of Veterans Affairs & U.S. Department of Defense. (2010) VA/DOD clinical practice guideline for management of bipolar disorder in adults. Retrieved from: *http://www.healthquality.va.gov/guidelines/MH/bd/bd_305_full.pdf.*

[470] Douaihy AB, Kelly TM, Sullivan C. Medications for substance use disorders. Social work in public health. 2013;28(3–4):264–278.

[471] Haddad PM, Brain C, Scott J. Nonadherence with antipsychotic medication in schizophrenia: challenges and management strategies. Patient related outcome measures. 2014;5:43–62.

[472] Hung CI. Factors predicting adherence to antidepressant treatment. Current opinion in psychiatry. 2014;27(5):344–349.

[473] Lanouette NM, Folsom DP, Sciolla A, Jeste DV. Psychotropic medication nonadherence among United States Latinos: a comprehensive literature review. Psychiatric services (Washington, DC). 2009;60(2):157–174.

[474] Mitchell AJ. Understanding Medication Discontinuation in Depression. BMedSci Psychiatric Times. 2007;24(4).

[475] Sylvia LG, Hay A, Ostacher MJ, et al. Association between therapeutic alliance, care satisfaction, and pharmacological adherence in bipolar disorder. Journal of clinical psychopharmacology. 2013;33(3):343–350.

information about medications to the patient, pharmacy, and outpatient providers.[476]

b. Appropriateness for the IPFQR Program

In compliance with section 1890A(a)(2) of the Act, this measure was included in a publicly available document: ''List of Measures under Consideration for December 1, 2016'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/Measures-under-Consideration-List-for-2016.pdf.* The MAP Hospital Workgroup concluded that the measure addressed a critical quality objective, was evidence-based, and would contribute to efficient use of resources.[477] One Workgroup member commented that it was appropriate to hold IPFs accountable for patients filling a prescription for an evidence-based medication post-discharge, further remarking that the measure was moving in the right direction.[478]

The MAP Hospital Workgroup classified the measure as ''Refine and Resubmit Prior to Rulemaking.'' [479] The measure received this classification because the MAP recommended that measure testing be completed to demonstrate reliability and validity at the facility level in the hospital setting and that the measure be submitted to NQF for review and endorsement.[480] The MAP also requested additional details on the measure, such as: (1) The definition of medication dispensation; (2) how the facility would know whether the medication was dispensed; and (3) how the measure would be impacted if Medicare Part D coverage is optional. The MAP also recommended that this measure be submitted to NQF for review and endorsement. The final methodology report includes the results of reliability and validity testing, and additional measure updates that occurred between the MAP review and NQF submission in December 2016.[481] This methodology report also provides the additional details requested by MAP at the December meeting.

Reliability and validity testing completed in 2016 using the final measure specifications demonstrates that the measure, as specified, provides reliable and valid facility-level scores of medication continuation.[482]

Reliability was established using a method of mean denominator and volume categories. Using that approach, a minimum denominator size of 75 discharges was established to attain an overall reliability score of at least 0.7; this reliability score is within acceptable norms and indicates sufficient signal strength to discriminate performance between facilities.[483] This means that it is possible to distinguish good performance from poor performance based on measure scores among facilities with at least 75 cases in the denominator.

Validity was established by evaluating the correlations of medication continuation scores with the conceptually related IPFQR Program measures. The medication continuation scores were moderately correlated with the scores for 7- and 30-day follow-up after hospitalization for mental illness scores as expected (rho = 0.35 and 0.45, where rho is the Spearman's rank correlation coefficient). In other words, the positive correlation between scores of these two types of measures is expected because high follow-up rates with mental health providers and high follow-up rates of medication continuation both indicate a high-quality transition from the inpatient to the outpatient setting. The medication continuation scores were negatively correlated with readmission scores as expected (rho = -0.27). This negative correlation is expected because patients that do not continue their medications are more likely to relapse and be readmitted.[484] [485] [486] All correlations are statistically significant at p-value <0.0001. After reviewing these results and the proposed measure specifications, all of the 10 TEP members who were present for the face validity vote agreed that the measure score had face validity.

This measure was submitted to NQF for endorsement on December 16, 2016, and the measure received endorsement from the NQF Consensus Standards Approval Committee (CSAC) following the June 21 CSAC meeting, pending a 30 day appeals process that closes on August 2, 2017.[487] The new version of the specifications referenced on the NQF Web site is consistent with the version reviewed and approved by the CSAC. Under section 1886(s)(4)(D)(i) of the Act, measures selected for the IPFQR Program must have been endorsed by the entity with a contract under section 1890(a) of the Act. The NQF currently holds this contract. However, section 1886(s)(4)(D)(ii) of the Act provides that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We have reviewed NQF-endorsed measures related to medication continuation in this patient population and did not identify any equivalent measures. We believe this measure is consensus-based because of the extensive measure development process, including the solicitation of expert and patient opinion and public comments (discussed in more detail below).

In addition, this measure addresses several aspects of the CMS Quality Strategy goals and objectives. The measure supports the CMS Quality Strategy Goal to ''promote effective prevention and treatment of chronic disease,'' which includes an objective to improve behavioral health access and quality of care by using evidence-based practices.[488] The measure also supports the CMS Quality Strategy Goal to

[476] Health Services Advisory Group. Final Methodology Report: Medication Continuation Following Inpatient Discharge. Tampa, FL; 2016.

[477] MAP Hospital Workgroup, Preliminary Analysis Worksheet. December 2017.

[478] National Quality Forum, Measure Applications Partnership. Meeting Transcript, Day 1 of 2—In-Person Meeting. 2016.

[479] *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=84452.*

[480] National Quality Forum, Measure Application Partnership. MAP 2017 Considerations for Implementing Measures in Federal Programs: Hospitals. 2017.

[481] Health Services Advisory Group. Final Methodology Report: Medication Continuation Following Inpatient Discharge. Tampa, FL; 2016. *https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.* To access the report, click on the zip file titled ''Inpatient Psychiatric Facility Medication Continuation Measure.''

[482] Health Services Advisory Group. Final Methodology Report: Medication Continuation Following Inpatient Discharge. Tampa, FL; 2016.

[483] Adams J. The reliability of provider profiling: a tutorial. Santa Monica, CA: RAND; 2009.

[484] Glue P, Donovan MR, Kolluri S, Emir B. Meta-analysis of relapse prevention antidepressant trials in depressive disorders. The Australian and New Zealand journal of psychiatry. 2010;44(8):697–705.

[485] Geddes JR, Carney SM, Davies C, et al. Relapse prevention with antidepressant drug treatment in depressive disorders: a systematic review. Lancet. 2003;361(9358):653–661.

[486] Gilmer TP, Dolder CR, Lacro JP, et al. Adherence to treatment with antipsychotic medication and health care costs among Medicaid beneficiaries with schizophrenia. The American journal of psychiatry. 2004;161(4):692–699.

[487] *http://www.qualityforum.org/QPS/3205.*

[488] Centers for Medicare & Medicaid Services. CMS Quality Strategy 2016. Baltimore, MD: U.S. Department of Health and Human Services; 2015. *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

''promote effective communication and coordination of care.''[489] Specifically, the measure addresses three objectives within the goal of ''promoting effective communication and coordination of care:'' (1) ''to reduce admissions and readmissions''[490] as patients with these conditions who do not adhere to their medication regimens are at an increased risk of relapse and readmission;[491] [492] [493] (2) ''to embed best practices to enable successful transitions between all settings of care,''[494] because ensuring medication continuation following discharge is a critical component of transitioning from the IPF to the home or home health care; and (3) ''to enable effective healthcare system navigation,''[495] as we believe that this measure will encourage IPFs to provide information to patients regarding the importance of medication continuation and guidance on how to fill prescriptions following discharge.

The measure would complement the portfolio of facility-level measures in the IPFQR Program that assess the transition from the inpatient to outpatient setting: Follow-Up After Hospitalization for Mental Illness; Thirty-day All Cause Unplanned Readmission Following Psychiatric Hospitalization in an Inpatient Psychiatric Facility; Transition Record with Specified Elements Received by Discharged Patients; and Timely Transmission of Transition Record.

More detailed information about the development of this measure as well as final measure specifications can be downloaded from the CMS Web site at: *https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. To access the report, click on the zip file titled ''Inpatient Psychiatric Facility Medication Continuation Measure.''

c. Measure Calculation

The measure is calculated by dividing the number of admissions that meet the numerator criteria (described below) by the number of admissions that meet the denominator criteria (also described below).

(1) Numerator

The numerator for the measure includes discharges for patients with a principal diagnosis of MDD, schizophrenia, or bipolar disorder in the denominator who were dispensed at least one evidence-based outpatient medication within 2 days prior to discharge through 30 days post-discharge. The evidence-based medications that define the numerator are based on the practice guidelines for each condition from the APA and VA/DoD.[496] [497] [498] [499] [500] Furthermore, we sought to align the medications with evidence-based medications from existing quality measures including the Antidepressant Medication Management measure from the Healthcare Effectiveness Data and Information Set (HEDIS) 2015 for MDD, the Adherence to Antipsychotic Medications for Individuals with Schizophrenia measure (NQF #1879) for schizophrenia, and the Adherence to Mood Stabilizers for Individuals with Bipolar I Disorder measure (NQF #1880) for bipolar disorder. Staff pharmacists reviewed these lists of medications for completeness and appropriateness in the IPF setting. The finalized lists of evidence-based medications are available in the measure methodology report at: *https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospital QualityInits/Measure-Methodology.html*. To access the report, click on the zip file titled ''Inpatient Psychiatric Facility Medication Continuation Measure.''

We considered the appropriate number of days prior to discharge and post-discharge to include in the follow-up period for the numerator. Clinical experts noted that discharge planning may start as early as 2 days prior to discharge and that some facilities may help patients fill their outpatient prescriptions prior to discharge. Therefore, the numerator includes outpatient medications filled up to 2 days prior to discharge (Day −2 through Day −1). The follow-up period extends 30 days post-discharge (Day 0 through Day 30) to align with other care coordination measures, such as the 30 day follow-up period in Follow-Up After Hospitalization for Mental Illness (FUH) (NQF #0576) which we finalized for the IPFQR Program in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50893 through 50895). To further support a 30-day follow-up period, we confirmed that over 93 percent of the evidence-based prescriptions filled prior to the admission were for a 30-day supply, which indicates that most patients would need to fill a medication within 30 days of discharge to avoid gaps in treatment even if they had some medications at home.

(2) Denominator

The denominator for the measure includes Medicare FFS beneficiaries aged 18 years and older who were discharged from an IPF to home or home health care[501] with a principal diagnosis of MDD, schizophrenia, or bipolar disorder. The denominator excludes discharges for patients who:

- Received Electroconvulsive Therapy (ECT) during the inpatient stay or follow-up period because some patients who receive ECT during the inpatient stay or follow-up period may

[489] Centers for Medicare & Medicaid Services. CMS Quality Strategy 2016. Baltimore, MD: U.S. Department of Health and Human Services; 2015. *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiatives GenInfo/Downloads/CMS-Quality-Strategy.pdf*.

[490] Centers for Medicare & Medicaid Services. CMS Quality Strategy 2016. Baltimore, MD: U.S. Department of Health and Human Services; 2015. *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiatives GenInfo/Downloads/CMS-Quality-Strategy.pdf*.

[491] Glue P, Donovan MR, Kolluri S, Emir B. Meta-analysis of relapse prevention antidepressant trials in depressive disorders. The Australian and New Zealand journal of psychiatry. 2010;44(8):697–705.

[492] Geddes JR, Carney SM, Davies C, et al. Relapse prevention with antidepressant drug treatment in depressive disorders: a systematic review. Lancet. 2003;361(9358):653–661.

[493] Gilmer TP, Dolder CR, Lacro JP, et al. Adherence to treatment with antipsychotic medication and health care costs among Medicaid beneficiaries with schizophrenia. The American journal of psychiatry. 2004;161(4):692–699.

[494] Centers for Medicare & Medicaid Services. CMS Quality Strategy 2016. Baltimore, MD: U.S. Department of Health and Human Services; 2015. *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiatives GenInfo/Downloads/CMS-Quality-Strategy.pdf*.

[495] Centers for Medicare & Medicaid Services. CMS Quality Strategy 2016. Baltimore, MD: U.S. Department of Health and Human Services; 2015. *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiatives GenInfo/Downloads/CMS-Quality-Strategy.pdf*.

[496] American Psychiatric Association. (2010). Practice guideline for the treatment of patients with major depressive disorder, 3rd ed. Retrieved from: *http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf*.

[497] American Psychiatric Association. (2002). Practice guideline for the treatment of patients with bipolar disorder, second edition. Retrieved from: *http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/bipolar.pdf*.

[498] American Psychiatric Association. (2010). Practice guideline for the treatment of patients with schizophrenia: 2nd ed. Retrieved from: *http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/schizophrenia.pdf*.

[499] U.S. Department of Veterans Affairs & U.S. Department of Defense. (2016). Management of major depressive disorder (MDD). Retrieved from: *http://www.healthquality.va.gov/guidelines/MH/mdd/VADoDMDDCPGFINAL82916.pdf*.

[500] U.S. Department of Veterans Affairs & U.S. Department of Defense. (2010) VA/DOD clinical practice guideline for management of bipolar disorder in adults. Retrieved from: *http://www.healthquality.va.gov/guidelines/MH/bd/bd_305_full.pdf*.

[501] The measure specifications, as submitted to the MAP, did not include home health care. For details of this addition, please see the measure methodology report: *https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. To access the report, click on the zip file titled ''Inpatient Psychiatric Facility Medication Continuation Measure.''

have failed pharmacotherapy and would not fill an evidence-based prescription post-discharge;

- Received Transcranial Magnetic Stimulation (TMS) during the inpatient stay or follow-up period because some patients who receive TMS during the inpatient stay or follow-up period may have failed pharmacotherapy and would not fill an evidence-based prescription post-discharge;
- Were pregnant during the inpatient stay because some of the evidence-based medications for the treatment of MDD, schizophrenia, and bipolar disorder are contraindicated during pregnancy;
- Had a secondary diagnosis of delirium because some of the evidence-based medications for the treatment of MDD, schizophrenia, and bipolar disorder are contraindicated for patients with delirium; or
- Had a principal diagnosis of schizophrenia and secondary diagnosis of dementia because many FDA-approved medications for the treatment of schizophrenia have a Boxed Warning due to an increased risk of mortality in elderly patients with dementia-related psychosis treated with antipsychotic drugs.[502]

All patients in the measure denominator are enrolled in Medicare Parts A, B, and D during the measurement and follow-up periods. Therefore, these patients have prescription drug coverage for evidence-based medications in the measure. While patients are responsible for some out-of-pocket medication costs after Part D has been applied, low income patients qualify for additional support through both Medicare and Medicaid to help mitigate the cost of prescriptions and ensure that patients do not face financial barriers to filling necessary medications.

We refer readers to the measure specifications for more details about measure inclusions and exclusions at: *https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. To access the report, click on the zip file titled ''Inpatient Psychiatric Facility Medication Continuation Measure.''

d. Data Sources

The measure will be implemented using Medicare FFS Parts A, B, and D claims and enrollment data to calculate the measure results. Valid prescription drug claims from Medicare Parts B and D provide the data necessary to calculate this measure. Therefore, no data collection will be required from IPFs. The measure will be reported as a combined facility-level rate across all three conditions. The measurement period is 2 years to maximize the number of facilities with a minimum of 75 discharges, which is necessary for calculation of reliable facility-level scores.[503] We will inform stakeholders of the claims data collection period through a subregulatory process, such as on a CMS Web site and/or on our applicable listservs.

e. Public Comment

During the measure development process, we solicited public comments on the measure via the CMS Quality Measures Public Comment Page.[504] We provided the draft measure information form [505] and draft measure justification form [506] to the public for review. We accepted public comments from August 25, 2016 through September 15, 2016. Numerous commenters expressed support for the Medication Continuation Following Inpatient Psychiatric Discharge (NQF #3205) measure (with only 6 of 53 commenters expressing reluctance to support the measure) and commented on the importance of measuring medication continuation as this is an important component of care transitions and reduces the risk of readmissions. We received public comments about denominator specifications, numerator specifications, data collection, attribution of the measure to the IPF, and the relevance of the proposed measure. After review and evaluation of all the public comments received, we expanded the follow-up period from day of discharge (Day 0) through 30 days post discharge to include outpatient prescriptions filled up to 2 days prior to discharge as described above. For specific information regarding the comments we received, we refer readers to the public comment summary at: *https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. To access the report, click on the zip file titled ''Inpatient Psychiatric Facility Medication Continuation Measure.''

We believe this measure evaluates a process with a demonstrated quality gap and has the potential to benefit patients. For these reasons and the reasons stated above, we proposed the Medication Continuation Following Inpatient Psychiatric Discharge (NQF #3205) measure described in this section for the FY 2020 payment determination and subsequent years.

In summary, we proposed one measure for the FY 2020 payment determination and subsequent years, as shown in the table below.

NEWLY PROPOSED IPFQR PROGRAM MEASURE FOR THE FY 2020 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

National quality strategy priority	NQF #	Measure ID	Measure
Communication/Care Coordination	3205	N/A	Medication Continuation Following Inpatient Psychiatric Discharge.

We welcomed public comment on our proposal to adopt the Medication Continuation Following Inpatient Psychiatric Discharge (NQF #3205) measure.

Comment: Several commenters supported adoption of the Medication Continuation Following Inpatient Psychiatric Discharge (NQF #3205) measure. Other commenters expressed appreciation for CMS developing claims-based measures to limit the burden on IPFs.

Response: We thank these commenters for their input and appreciate this support.

[502] U.S. Food and Drug Administration. Public Health Advisory: Deaths with Antipsychotics in Elderly Patients with Behavioral Disturbances. 2005. Accessed at: *https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm053171.htm*.

[503] Health Services Advisory Group. Final Methodology Report: Medication Continuation Following Inpatient Discharge. Tampa, FL; 2016.

[504] CMS Quality Measure Public Comment Page: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html#44* In the ''Downloads'' section of this page, please select ''Recently Archived Call for Public Comments Files.'' The information regarding the Medication Continuation following Inpatient Psychiatric Discharge information is available in the ''Inpatient-Psychiatric-Facility-IPF-Outcome-and-Process-Measure-Development-and-Maintenance'' zip file.

[505] *Ibid.*

[506] *Ibid.*

Comment: Many commenters expressed concerns that the Medication Continuation Following Inpatient Psychiatric Discharge (NQF #3205) measure will pose undue burden on facilities, which are still updating processes to account for previously adopted measures. Several commenters expressed the concern that IPFs have limited control of medication continuation once their patients are discharged. These commenters observed that patients may experience social or geographical barriers to filling medication prescriptions that are beyond the control of IPFs.

Response: We recognize that there are factors external to the IPF that influence filling prescriptions post-discharge in the psychiatric population. While it may not be possible to achieve complete post-discharge compliance with pharmacotherapy, there is evidence that improvements to the quality of care for patients in the IPF setting, including the discharge processes, can help to increase medication continuation rates. We discussed this evidence in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20123). However, depending on a facility's current state of performance and the implicit requirements of this measure, process changes (such as updates to clinical procedures or adoption of new workflows) to achieve higher performance may be significant and sometimes require a considerable period after initial implementation to realize measurable improvement. This may particularly be true for a measure such as the Medication Continuation Following Inpatient Psychiatric Discharge (NQF #3205) measure, which assesses the degree to which facilities address a critical element of successful care transition following discharge, a component of quality care that some facilities have not traditionally attended to. We agree with commenters that updating processes to achieve high performance, which likely requires multiple and innovative efforts related to patient communication, and coordination and communication with outpatient providers, creates burden on IPFs. While we believe this is an important measure because of the clinical benefits of appropriate pharmacotherapy post discharge and the current performance gap on the measure, we would like to be sensitive to facilities, especially small, rural facilities, that may not have sufficient resources to meet the burden this measure could bring.

To accommodate the need for facilities to develop and implement innovative efforts for this measure, we are not adopting it at this time. However, we will consider re-proposing this measure in future rulemaking.

Comment: Many commenters expressed concerns that the NQF has not completed the endorsement review of the measure.

Response: This measure was submitted to NQF for endorsement on December 16, 2016, and the measure received endorsement from the NQF Consensus Standards Approval Committee (CSAC) following the June 21 CSAC meeting, pending a 30 day appeals process that closes on August 2, 2017.

Comment: Many commenters expressed concerns that limitation of the measure to patients enrolled in Medicare Parts A, B, and D may result in an impacted population that is both too small to be meaningful for public reporting and one that does not experience the same access to medications barriers as other inpatient psychiatric patients.

Response: We thank the commenters for expressing their concerns, but we disagree with the commenters that limiting the measure to patients with Medicare Parts A, B, and D for use in the IFPQR program limits the utility of the measure. While we agree that the patients included in the measure may not experience the same barriers to access to medications that some other patients encounter because low income Medicare patients qualify for additional support to help pay for medications, we note that the evidence based interventions to improve medication adherence would apply to all patients. Further, considering that the Medicare population may have lower barriers to access, we would expect to see higher medication continuation rates and less variation in performance across facilities. As described in the measure technical report,[507] the claims data from 1,694 IPFs demonstrated ample opportunity for improvement. The mean medication continuation rate was 79 percent across all facilities, with variation of 22 percent between the 10th and 90th percentile.

Comment: Many commenters expressed concerns that IPFs may not receive feedback with sufficient time to improve processes prior to public reporting of the data since they will not be able to independently calculate measure results (as they do not have access to Part D claims).

Response: We thank the commenters for providing these comments, and we will consider their views if we decide to propose this measure in the future.

Comment: Some commenters believed that the link between measure performance and patient outcomes has not been adequately demonstrated. Commenters further expressed the belief that the measure may not generate information that is meaningful to consumers in making healthcare choices.

Response: We thank the commenters for their comments, but disagree with them. We believe that information on medication continuation is important for patients discharged from the inpatient psychiatric setting with MDD, schizophrenia, or bipolar disorder because of significant negative outcomes associated with patients not adhering to recommended medication. We note that the MAP Hospital Workgroup concluded that the measure addressed a critical quality objective, was evidence-based, and would contribute to efficient use of resources. Further, performance on this measure in testing showed that improved performance on this measure was associated with reduced unplanned readmissions, indicating that performance on this measure is linked with patient outcomes.

Comment: Many commenters expressed the concern that filling a prescription does not always indicate compliance to treatment. They suggested that patient compliance, not claims for prescriptions, should be the target of quality measurement.

Response: We acknowledge that increasing patient compliance is the ultimate goal of quality improvement informed by the measure but disagree with the comment that a medication continuation measure assessed from prescription claims does not indicate gaps in compliance. The filling of a prescription is a critical step in improving compliance. We observed ample opportunity for improvement based on a mean medication continuation rate of 79 percent across 1,694 IPFs, with variation of 22 percent between the 10th and 90th percentile. Therefore, we know that at a minimum, approximately 20 percent of patients are not compliant because they are not in possession of their outpatient psychiatric medications following discharge. Measuring actual compliance would be burdensome for both facilities and patients and therefore is not feasible to measure.

Comment: Some commenters expressed the belief that technical questions regarding denominator inclusion and exclusion criteria and measure calculation methods have not been sufficiently answered. Commenters

[507] Health Services Advisory Group. Final Methodology Report: Medication Continuation Following Inpatient Discharge. Tampa, FL; 2016.

were specifically concerned regarding how prescriptions filled for patients without Part D would be identified, how free samples provided at or before discharge would be identified, and whether facilities without inpatient pharmacies would be at a disadvantage for this measure.

Response: Patients who do not have Medicare Part D coverage are excluded from the denominator of this measure. We anticipate that few patients in the population for this measure would be eligible for samples because low income Medicare patients qualify for additional support to help pay for medication copays. Finally, this measure does not include medications filled at inpatient pharmacies in the measure numerator. This measure gives facilities the flexibility to determine which interventions are most appropriate for their patient populations, including filling prescriptions for patients prior to discharge through outpatient pharmacies. However, the measure does not encourage any particular intervention over another because interventions to improve medication continuation should be tailored to meet each patient's needs and circumstances.

After consideration of the public comments we received, we are not finalizing adoption of the Medication Continuation Following Inpatient Psychiatric Discharge (NQF #3205) measure for the reasons discussed above. If we decide to propose this measure in the future, we will consider information and recommendations provided by commenters at that time.

4. Summary of Previously Finalized Measures for the FY 2020 Payment Determination and Subsequent Years

The number of measures for the FY 2020 payment determination and subsequent years totals 18 as set forth in the table below.

PREVIOUSLY FINALIZED MEASURES FOR THE FY 2020 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF #	Measure ID	Measure
640	HBIPS–2	Hours of Physical Restraint Use.
641	HBIPS–3	Hours of Seclusion Use.
560	HBIPS–5	Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification.
576	FUH	Follow-up After Hospitalization for Mental Illness.
1661	SUB–1	Alcohol Use Screening.
1663	SUB–2 and SUB–2a	Alcohol Use Brief Intervention Provided or Offered and SUB–2a Alcohol Use Brief Intervention.
1664	SUB–3 and SUB–3a	Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and SUB–3a Alcohol and Other Drug Use Disorder Treatment at Discharge.
1651	TOB–1	Tobacco Use Screening.
1654	TOB–2 and TOB–2a	Tobacco Use Treatment Provided or Offered and TOB–2a Tobacco Use Treatment.
1656	TOB–3 and TOB–3a	Tobacco Use Treatment Provided or Offered at Discharge and Tob–3a Tobacco Use Treatment at Discharge.
1659	IMM–2	Influenza Immunization.
647	N/A	Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care).
648	N/A	Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care).
N/A	N/A	Screening for Metabolic Disorders.
431	N/A	Influenza Vaccination Coverage Among Healthcare Personnel.
N/A	N/A	Assessment of Patient Experience of Care.
N/A	N/A	Use of an Electronic Health Record.
2860*	N/A	Thirty-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an Inpatient Psychiatric Facility.

*Since this measure was finalized in the FY 2017 IPPS/LTCH PPS final rule (57239 through 57246), NQF endorsement has been received.

5. Possible IPFQR Program Measures and Topics for Future Consideration

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20126 through 20127), we discussed possible IPFQR Program measures and topics for future consideration. As we have previously indicated (79 FR 45974 through 45975), we seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the IPF setting. Therefore, through future rulemaking, we intend to propose new measures for development or adoption that will help further our goals of achieving better healthcare and improved health for individuals who obtain inpatient psychiatric services through the widespread dissemination and use of quality information. As noted on the ''List of Measures under Consideration for December 1, 2016'' [508] published by the NQF on behalf of CMS, we are considering a measure of Medication Reconciliation on Admission and a measure of Identification of Opioid Use Disorder among Patients Admitted to Inpatient Psychiatric Facilities. We welcomed comments on these measure concepts for future inclusion in the IPFQR Program. In addition, we have identified several areas which we believe are important to stakeholders, but which are not currently sufficiently covered by IPFQR Program measures. These areas are:

- Family and caregiver engagement;
- Patient experience of care;
- Opioid use and treatment;
- Access to care; and
- Inpatient assaults and violence.

We welcomed public comments on possible new measures in these or other areas.

Comment: Many commenters expressed support for measures in the areas of: (1) Family and caregiver engagement; (2) patient experience of care; (3) access to care; and (4) inpatient assaults and violence. These commenters further encouraged CMS to consider clinical outcomes measures. Finally, the commenters urged CMS to engage with stakeholders during

[508] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/Measures-under-Consideration-List-for-2016.pdf.*

measure development and implementation.

Response: We thank these commenters for their support of these measure topic areas and will continue to engage with stakeholders in measure development and implementation.

Comment: Many commenters urged CMS to develop and implement a patient experience of care survey and measure specific to the inpatient psychiatric setting. One commenter further recommended that this survey include questions regarding the patient's understanding of diagnoses, treatment plans, and follow-up care.

Response: We believe that patient experience of care is an important measure gap in the IPFQR Program and are actively evaluating ways to address this topic. We will take commenters' suggestions into consideration as we develop future program policy.

Comment: Several commenters urged CMS to develop and implement measures that address suicide. Some of these commenters specifically recommended a measure to address hospital processes to help patients manage suicidal ideation in the hospital and post discharge.

Response: We will consider this input as we develop and select measures for the IPFQR Program.

Comment: Many commenters recommended that CMS develop and implement claims-based measures that evaluate clinical outcomes.

Response: We believe that clinical outcomes measures are an important part of quality reporting, and that claims-based measures are effective for reducing reporting burden on facilities. We will take commenters' suggestions into consideration as we develop and select measures for the IPFQR Program.

Comment: One commenter recommended that CMS adopt measures related to opioid treatment to determine if there are access issues associated with this treatment.

Response: We believe that the current opioid epidemic is a significant public health issue, and we are striving to address it in the IPFQR Program to the extent possible, including adoption of the SUB–3 & 3a Measure (Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and SUB–3a Alcohol and Other Drug Use Disorder Treatment at Discharge) in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57239 through 57241) and inclusion of Identification of Opioid Use Disorder among Patients Admitted to Inpatient Psychiatric Facilities on the List of Measures Under Consideration for December 1, 2016. We will continue to consider ways to address this issue as we develop and select measures for the IPFQR Program.

Comment: Many commenters recommended that CMS identify a method for data validation as part of the measure development and adoption process.

Response: We will consider this input as we develop and select measures for the IPFQR Program. We are currently seeking to identify a means to implement data validation in the IPFQR Program.

We thank the commenters and we will consider their views as we develop further measures for use in the IPFQR Program.

6. Public Display and Review Requirements

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53653 through 53654), in which we finalized that we would publicly display the submitted data on the CMS Web site beginning in the first quarter of the calendar year following the respective payment determination year. We also finalized that IPFs would have the opportunity to preview their data between September 20 and October 19 of the respective payment determination year. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50897 through 50898), we finalized policies on public display and review of data stating that we would publicly display the data in April of the calendar year following the start of the payment determination year and that the preview period would be 30 days approximately twelve weeks prior to the public display of the data. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57248 through 57249), we finalized changes to how we specify the timeframes for the IPFQR Program, including that we would: (1) No longer specify the exact dates of the preview period or data publication in rulemaking; (2) make the data for the IPFQR Program available as soon as possible; (3) announce the exact timeframes through subregulatory guidance; and (4) continue our policy that the time period for review will be approximately 30 days. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20127), we did not propose any changes to the public display and review policies.

7. Form, Manner, and Timing of Quality Data Submission for the FY 2019 Payment Determination and Subsequent Years

a. Procedural Requirements for FY 2019 Payment Determination and Subsequent Years

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53654 through 77 FR 53655), we finalized procedural requirements for the IPFQR Program, including the requirements that facilities must do the following to participate in the IPFQR Program:

- Register with QualityNet before the IPF begins reporting;
- Identify a QualityNet Administrator who follows the registration process listed on the QualityNet Web site;
- Complete a Notice of Participation (NOP) within a specified time period; and,
- Submit aggregate numerator and denominator data for all age groups, for all measures.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50901), we clarified that the policy we adopted for the FY 2016 payment determination also applies to the FY 2017 payment determination and subsequent years, unless we change it through future rulemaking. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20127), we proposed to make changes related to the Notice of Participation (NOP) and withdrawals for the FY 2019 payment determination and subsequent years.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53654 through 53655), we finalized our policies that IPFs participating in the IPFQR Program must comply with several procedural requirements. In that rule, one of the policies we finalized was that the time frame for completing an online NOP form is between January 1 and August 15 before each respective payment determination year (for example, for the FY 2017 payment determination year, IPFs would be required to submit an NOP between January 1, 2016 and August 15, 2016). Similarly, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53654), we also finalized that withdrawals from the IPFQR Program will be accepted no later than August 15 before the beginning of each respective payment determination year.

As described in section IX.D.7.b. of the preamble of this final rule, there have been times that we have updated the data submission period through subregulatory means; this has led to a data submission period that is not aligned with the submission period for the NOP or program withdrawal. To ensure these dates align, in the

proposed rule, we proposed to change the submission timeframes for both NOPs and withdrawals from between January 1 and August 15 before each respective payment determination year to prior to the end of the data submission period before each respective payment determination year. This means that we proposed to accept NOPs and withdrawals any time prior to the end of the data submission period before the payment determination year. For example, for the FY 2019 payment determination year, the end of the data submission period would be a date on or after June 15, 2018 (which we would announce via subregulatory means). This date will coincide with the deadline to submit an NOP or withdraw from the program. In addition, we proposed to provide precise dates that define the end of the data submission period/NOP/withdrawal submission deadline through subregulatory means, such as on a CMS Web site and/or on our applicable listservs, beginning with the FY 2019 payment determination.

We invited public comment on our proposals to: (1) Change the submission timeframes for both NOPs and withdrawals to the end of the data submission period before each respective payment determination year; and (2) provide precise dates that define the end of the data submission period/NOP/withdrawal submission deadline through subregulatory means for the FY 2019 payment determination and subsequent years.

Comment: Several commenters supported CMS' proposal to align the submission period for NOPs and withdrawals with the end of the data submission period, which will be provided through subregulatory means.

Response: We thank the commenters for this support.

After consideration of the public comments we received, we are finalizing our proposals to: (1) Change the submission timeframes for both NOPs and withdrawals to the end of the data submission period before each respective payment determination year; and (2) provide precise dates that define the end of the data submission period/NOP/withdrawal submission deadline through subregulatory means for the FY 2019 payment determination and subsequent years as proposed.

b. Data Submission Requirements for the FY 2019 Payment Determination and Subsequent Years

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53655 through 53656) and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50901) for our previously finalized policies regarding quality data submission requirements. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20127 through 20128), we proposed to make changes related to the data submission period for the FY 2019 payment determination and subsequent years.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53655 through 53657) we finalized our policies related to reporting periods and submission timelines for data required by the IPFQR Program. IPFs are required to submit their aggregated data on the measures on an annual basis, beginning in FY 2014 (77 FR 53655). In that rule, we specified that data must be submitted between July 1 and August 15 of the calendar year preceding a given payment determination year (for example, between July 1, 2015 and August 15, 2015 for the FY 2016 payment determination (77 FR 53655 through 53657)). In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50899), we clarified that this policy applies to all future years of data submission for the IPFQR Program unless we change the policy through future rulemaking.

Because there have been times that the submission period has been updated through the subregulatory process (for example, due to systems issues impacting data collection in the specified timeframe), in order to avoid contradictory guidance between dates established in the **Federal Register** and dates established through subregulatory guidance, in the proposed rule, we proposed to no longer specify the exact dates of the submission period through rulemaking. We proposed to provide these exact dates through a subregulatory process instead, beginning with the FY 2019 payment determination. We proposed to shift to a 45-day submission period beginning at least 30 calendar days following the end of the data collection period. For example, for the FY 2019 payment determination, the latest reporting period for a measure for which IPFs must submit data through the QualityNet Secure Portal ends on March 31, 2018 for the IMM–2 measure. In this example, the submission period would begin at least 30 days after March 31, 2018 (that is, no earlier than May 1, 2018). IPFs then would have 45 days from May 1 to submit their data, which would result in a June 15, 2018 submission deadline for this example. Because the exact dates could vary from year to year, for the FY 2019 payment determination and subsequent years, we also proposed to provide notification of the exact dates of the 45-day submission period through subregulatory means, such as on a CMS Web site and/or on our applicable listservs.

We welcomed public comments on our proposals to: (1) Change the specification of the submission deadline from exact dates (that is, July 1–August 15) to a 45-day submission period beginning at least 30 days following the end of the data collection period; and (2) provide notification of the exact dates of the 45-day submission period through subregulatory means for the FY 2019 payment determination and subsequent years.

Comment: Several commenters supported CMS' proposal to change the specification of the submission deadline and provide notification of the exact dates through subregulatory means.

Response: We thank these commenters for this support.

Comment: One commenter asked for clarification whether this proposal pertains only to data submitted via the QualityNet Secure Portal, as opposed to through the NHSN Web site.

Response: This proposal only applies to data submitted via the QualityNet Secure Portal.

Comment: Many commenters expressed concerns that the data submission period, as proposed, may not allow adequate time to abstract and audit the data prior to submission. These commenters were also concerned that IPFs may have insufficient warning regarding the data submission timeframe for appropriate resource planning.

Response: We recognize that IPFs must plan for appropriate resources for data collection and submission. We will strive to give as much notice as possible. It is our intent to continue the July 1 to August 15 data reporting period. However, because there are instances where adherence to these dates would not be possible, we wish to provide more flexibility and communicate the dates of reporting periods (or confirmation of the July 1 through August 15 timeframe) through subregulatory means. We expect that in most, if not all, cases, changes in the July 1 to August 15 reporting period will be to delay and/or extend the reporting period, rather than to move it forward.

After consideration of the public comments we received, we are finalizing our proposals as proposed to: (1) change the specification of the submission deadline from exact dates (that is, July 1–August 15) to a 45-day submission period beginning at least 30 days following the end of the data collection period; and (2) provide notification of the exact dates of the 45-day submission period through subregulatory means for the FY 2019

payment determination and subsequent years

c. Reporting Requirements for the FY 2019 Payment Determination and Subsequent Years

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53655 through 53657), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50901 through 50902), and the FY 2016 IPF PPS final rule (80 FR 46715 and 46716), for information about data reporting periods. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20128) we did not propose any changes to these policies.

d. Population and Sampling

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53657 through 53658), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50902), FY 2015 IPF PPS final rule (79 FR 45973), the FY 2016 IPF PPS final rule (80 FR 46717 through 46719), for information about population, sampling, and minimum case thresholds. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20128), we did not propose any changes to the population and sampling methodology or to the minimum case thresholds.

e. Data Accuracy and Completeness Acknowledgement (DACA) Requirements

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20128), we did not propose any changes to the DACA requirements and refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53658) for more information on these requirements.

8. Reconsideration and Appeals Procedures

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53658 through 53660), FY 2014 IPPS/LTCH PPS final rule (78 FR 50953), and 42 CFR 412.434 for details on our reconsideration and appeals procedures. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20128), we did not propose any changes to these policies.

9. Extraordinary Circumstances Exceptions (ECE) Policy for the IPFQR Program

a. Background

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53659 through 53660), we finalized policies for facilities to request waivers, now called ''exceptions'' (79 FR 45978), from quality reporting requirements for the FY 2014 payment determination and subsequent years. We stated that in the event of extraordinary circumstances not within the control of IPFs, such as a natural disaster, IPFs may request a reporting extension or a complete waiver of the requirement to submit quality data for one or more quarters for the FY 2014 payment determination and subsequent years. In that rule, we also finalized that facilities would be required to submit a request form with the following information:

- The IPF's CMS Certification Number (CCN);
- The IPF's name;
- Contact information for the IPF's Chief Executive Officer (CEO) and any other designated personnel, including name, email address, telephone number, and mailing address (the address must be a physical address, not a post office box);
- The IPF's reason for requesting an extension or waiver;
- Evidence of the impact of extraordinary circumstances, including but not limited to photographs, newspaper and other media articles; and
- A date when the IPF will again be able to submit IPFQR Program data, and a justification for the proposed date.

In addition, we finalized that the form must be signed by the IPF's CEO and submitted within 30 days of the date that the extraordinary circumstance occurred. We also finalized that following the receipt of the request form, we would: (1) Provide a written acknowledgement, using the contact information provided in the request, to the CEO and any additional designated IPF personnel, notifying them that the IPF's request has been received; and (2) provide a formal response to the CEO and any designated IPF personnel, using the contact information provided in the request, notifying the IPF of our decision. Furthermore, in that rule, we discussed that the above policy does not preclude us from granting waivers or extensions to IPFs that have not requested them when we determine that an extraordinary circumstance has affected an entire region or locale. We stated that if we make the determination to grant such a waiver or extension, we would communicate this decision through routine communication channels (77 FR 53659). In the FY 2014 IPPS/LTCH PPS final rule, we did not make any changes to this policy (78 FR 50903).

In the FY 2015 IPF PPS final rule (79 FR 45978), we clarified that the term ''exception'' is synonymous with the term ''waiver'' used in previous rules and renamed our policy to ''Extraordinary Circumstances Exception'' in order to align with similar exceptions in other CMS quality reporting programs. In that rule, we also finalized that that we may grant a waiver or extension to IPFs if we determine that a systemic problem with one of our data collection systems directly affects the ability of the IPFs to submit data. We stated that because we do not anticipate that these types of systemic errors will occur often, we do not anticipate granting a waiver or extension on this basis frequently (79 FR 45978). We noted that if we make the determination to grant a waiver or extension, we would communicate this decision through routine communication channels to IPFs, vendors, and quality improvement organizations (QIOs) by means of, for example, memoranda, emails, and notices on the QualityNet Web site (79 FR 45978).

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20128 through 20130), we proposed to modify aspects of our current ECE policy to align with those of other CMS quality reporting programs. Many of our quality reporting and value-based purchasing programs share common processes for requesting an exception from program reporting due to an extraordinary circumstance not within a provider's control. We refer readers to the Hospital IQR Program (76 FR 51651 through 51652, 78 FR 50836 through 50837, 79 FR 50277, 81 FR 57181 through 57182, and 42 CFR 412.140(c)(2)), Hospital OQR Program (77 FR 68489, 78 FR 75119 through 75120, 79 FR 66966, and 80 FR 70524), and ASCQR Program (77 FR 53642 through 53643 and 78 FR 75140 through 75141) as well as the HAC Reduction Program (80 FR 49579 through 49581), Hospital Readmissions Reduction Program (80 FR 49542 through 49543), and PCHQR Program (78 FR 50848) for program specific information about extraordinary circumstances exceptions requests. In reviewing the policies for these programs, however, we found five areas in which these programs have variance: (1) Contact Information and Signature on ECE Form—there is inconsistency regarding whether the program requires contact information and a signature on the ECE form from the facility's or hospital's CEO versus CEO or designated personnel; (2) Submission deadline—there is inconsistency in requiring the form be submitted within 90 days following the date that the extraordinary circumstance occurred versus within 30 days following the date the extraordinary circumstance occurred; (3) CMS' response following an ECE request—there is inconsistency regarding specification of a timeline for us to provide our formal response notifying the facility or hospital of our decision; (4) CMS system issues—there is

inconsistency regarding whether programs make explicit the ability to grant ECEs specific for systemic issues with CMS data collection systems that directly affect the ability of hospitals/facilities to submit data; and (5) Policy name—there is inconsistency in the names used to refer to the policy, with some programs using ''extraordinary circumstances extensions/exemptions'' and some using ''extraordinary circumstances exceptions.''

We believe aligning these five areas across the programs will improve administrative efficiencies for affected facilities or hospitals. We note that, in the FY 2018 IPPS/LTCH PPS proposed rule, we also proposed to update ECE policies in the Hospital Readmissions Reduction Program (in section V.I.12. of the preamble of the proposed rule); the HAC Reduction Program (in section V.K.8. of the preamble of the proposed rule), Hospital IQR Program (in section IX.A.15. of the preamble of the proposed rule), and the PCHQR Program (in section IX.B.10. of the preamble of the proposed rule) in order to align policies. We refer readers to these sections for more details.

b. ECE Policy Modifications

The IPFQR Program currently includes policies to: (1) Make explicit the ability to grant ECEs specific for systemic issues with CMS data collection systems that directly affect the ability of hospitals/facilities to submit data; and (2) refer to the ECE policy as ''extraordinary circumstances exceptions.'' Therefore did not make proposals related to these two items. However, to improve cross-program alignment, in the proposed rule, we proposed to update the IPFQR Program's ECE policy by: (1) Allowing designated personnel to sign the ECE request form that IPFs currently submit with contact information for the CEO and designated personnel and the signature from the CEO; (2) extending the deadline from 30 days following the date that the extraordinary circumstance occurred to 90 days following the date the extraordinary circumstance occurred; and (3) specifying that we will strive to provide our formal response to an ECE request notifying the IPF of our decision within 90 days of receipt of the IPF's request. We proposed that these policies would apply beginning with extraordinary circumstances that occur on or after the effective date of the 2018 IPPS/LTCH PPS final rule, anticipated to be October 1, 2017. These proposals are discussed in more detail below.

(1) Signature of Either Designated Personnel or CEO

As discussed above, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53659 through 53660) we finalized ECE requests for the IPFQR Program must submitted with contact information for the CEO and any designated personnel, and be signed by the IPF's CEO. However, we now believe that there may be circumstances in which it is not feasible for an IPF's CEO to sign the ECE request form, such as in cases where the CEO has become disabled or is deceased. Also, in the event that the CEO of a facility affected by an extraordinary circumstance, such as a natural disaster, is unavailable to sign the ECE request form, we believe that the affected facility should be able to submit ECE form despite the CEO's inability to sign. Therefore, we proposed that ECE forms may be signed by either the CEO or the designated personnel as listed on the ECE form.

(2) ECE Request Submission Deadline

As discussed above, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53659 through 53660) we finalized that ECE requests for the IPFQR Program must be submitted within 30 days of the date that the extraordinary circumstance occurred. However, we believe that it may be difficult for some IPFs to timely evaluate the impact of a certain extraordinary circumstance within 30 calendar days. Therefore, we proposed to change the ECE request form submission deadline from within 30 days of the date that the extraordinary circumstance occurred to within 90 days of the date that the extraordinary circumstance occurred.

We believe that extending the deadline to 90 calendar days would allow IPFs more time to determine whether it is necessary and appropriate to submit an ECE request and to provide a more comprehensive account of the extraordinary circumstance in their ECE request form to CMS. As an example, if an IPF suffers damage due to a hurricane on October 1, 2017, it would have until December 30, 2017, 90 calendar days after the hurricane, to submit an ECE form via the QualityNet Secure Portal, mail, email, or secure fax as instructed on the ECE form.

(3) Clarification of CMS Response Timeframe

As stated above, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53659 through 53660), we finalized that following the receipt of the request form, we would provide: (1) A written acknowledgement, using the contact information provided in the request, to the CEO and any additional designated IPF personnel, notifying them that the IPF's ECE request has been received; and (2) a formal response to the CEO and any designated IPF personnel, using the contact information provided in the request, notifying the IPF of our decision. We believe that it is important for IPFs to receive timely feedback in a predictable time frame regarding the status of ECE requests. We strive to complete our review of each ECE request as quickly as possible. However, the number of requests we receive and the complexity of the information provided affect the timeframe that we need to make ECE determinations. Therefore, in an effort to provide facilities with a predictable timeframe, we are clarifying that we will strive to complete our review of ECE requests within 90 days of receipt, depending on the number of requests and the complexity of the information provided by facilities.

We welcomed public comments on our proposals to: (1) Specify that ECE forms can be signed by either the CEO or the designated personnel as listed on the ECE form; and (2) change the ECE request form submission deadline to within 90 days of the date that the extraordinary circumstance occurred. We also invited public comments on our intent to clarify that we will strive to complete our review of ECE requests within 90 days of receipt.

Comment: Several commenters supported CMS' proposals to update the ECE policies to align with other programs.

Response: We thank these commenters for their support.

After consideration of the public comments we received, we are finalizing our proposals as proposed to: (1) Specify that ECE forms can be signed by either the CEO or the designated personnel as listed on the ECE form; and (2) change the ECE request form submission deadline to within 90 days of the date that the extraordinary circumstance occurred.

E. Clinical Quality Measurement for Eligible Hospitals and Critical Access Hospitals (CAHs) Participating in the EHR Incentive Programs

1. Background

The HITECH Act (Title IV of Division B of the ARRA, together with Title XIII of Division A of the ARRA) authorizes incentive payments under Medicare and Medicaid for the adoption and meaningful use of certified electronic health record (EHR) technology (CEHRT). Incentive payments under

Medicare were available to eligible hospitals and CAHs for certain payment years (as authorized under sections 1886(n) and 1814(l) of the Act, respectively) if they successfully demonstrated meaningful use of CEHRT, which includes reporting on clinical quality measures (CQMs or eCQMs) using CEHRT.

Sections 1886(b)(3)(B)(ix) and 1814(l)(4) of the Act also establish downward payment adjustments under Medicare, beginning with FY 2015, for eligible hospitals and CAHs that do not successfully demonstrate meaningful use of CEHRT for certain associated reporting periods. Section 1903(a)(3)(F)(i) of the Act establishes 100 percent Federal financial participation (FFP) to States for providing incentive payments to eligible Medicaid providers (described in section 1903(t)(2) of the Act) to adopt, implement, upgrade and meaningfully use CEHRT.

Under sections 1814(l)(3)(A), 1886(n)(3)(A), and 1903(t)(6)(C)(i)(II) of the Act and the definition of ''meaningful EHR user'' under 42 CFR 495.4, eligible hospitals and CAHs must report on CQMs selected by CMS using CEHRT, as part of being a meaningful EHR user under the Medicare and Medicaid EHR Incentive Programs.

2. Modifications to the CQM Reporting Requirements for the Medicare and Medicaid EHR Incentive Programs for CY 2017

a. Background

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57255), we stated the CQM reporting periods in CY 2017 for the Medicare and Medicaid EHR Incentive Programs as outlined below. For the Medicare EHR Incentive Program, we finalized the following submission periods for eligible hospitals and CAHs reporting CQMs by attestation and eligible hospitals and CAHs electronically reporting CQMs (81 FR 57255). In regard to the Medicaid EHR Incentive Program, we provided States with the flexibility to determine the submission periods for reporting CQMs.

• *Eligible Hospitals and CAHs Reporting CQMs by Attestation:*

++ For eligible hospitals and CAHs demonstrating meaningful use for the first time in 2017, the reporting period is any continuous 90-day period within CY 2017. The submission period for attestation is the 2 months following the close of the calendar year, ending February 28, 2018.

++ For eligible hospitals and CAHs that demonstrated meaningful use in any year prior to 2017, the reporting period is the full CY 2017 (consisting of four quarterly data reporting periods). The submission period for attestation is the 2 months following the close of the calendar year, ending February 28, 2018.

• Eligible Hospitals and CAHs Reporting CQMs Electronically: For eligible hospitals and CAHs demonstrating meaningful use for the first time in 2017 or that have demonstrated meaningful use in any year prior to 2017, the reporting period is the full CY 2017 (consisting of four quarterly data reporting periods). The submission period for reporting CQMs electronically begins in late spring 2017 and continues through the 2 months following the close of the calendar year, ending February 28, 2018.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57251 through 57255), we finalized the following reporting criteria regarding the number of CQMs eligible hospitals and CAHs are required to report for the reporting periods in CY 2017:

• *For Attestation:* If only participating in the EHR Incentive Program, report on all 16 available CQMs.

• *For Electronic Reporting:* If only participating in the EHR Incentive Program, or participating in both the EHR Incentive Program and the Hospital IQR Program (81 FR 57150 through 57159), report on 8 of the available CQMs.

For further information on the policies applicable for CQM reporting for the EHR Incentive Program in 2017, we refer readers to the discussion in the FY 2017 IPPS/LTCH PPS final rule at 81 FR 57249 through 57257.

Since the publication of the FY 2017 IPPS/LTCH PPS final rule, we have continued to receive frequent feedback from hospitals and health IT vendors about the ongoing challenges of implementing CQM reporting capabilities. A summary of the main concerns identified by these data submitters is as follows:

• The timing of the transition to a new EHR system during 2017 (system upgrades or new health IT vendor) may influence hospitals' ability to report in a timely manner;

• The current timeframe for the implementation of new EHR requirements presents challenges due to the varying 6 to 24-month cycles needed for vendors to code new measures, test and institute measure updates, train hospital staff, and rollout other upgraded features;

• Hospitals have had difficulty identifying applicable measures that reflect their patient population, given the reduction in the number of available CQMs (from 29 to 16) for CY 2017;

• Hospitals have had challenges with data mapping and workflow because of the need to collect CY 2017 data while still reporting CY 2016 data; and

• Hospitals have identified challenges in implementing annual updates and new editions of certified health IT because of significant impacts on workflow, staffing, and connected technology systems. (We note that this information was inadvertently omitted in the proposed rule at 82 FR 20130.)

In addition, there have been other recent issues related to the CMS data receiving system not being able to process QRDA Category I files, and as a result, the system is not generating notifications confirming for providers that their files have been received and processed by the system. The aforementioned issues and challenges being experienced by hospitals and health IT vendors are impacting the capability of hospitals to meet the requirements for CY 2017. As a result, we proposed modifications to the CY 2017 final policies in the proposed rule, which would reduce CQM reporting requirements in order for hospitals and health IT vendors to address these issues.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20130 through 20131), we proposed two modifications to our CY 2017 electronic CQM reporting policies for the Medicare and Medicaid EHR Incentive Programs. For eligible hospitals and CAHs reporting CQMs electronically in CY 2017, we proposed to: (1) Decrease the number of calendar quarters for which such hospitals are required to submit data; and (2) decrease the number of CQMs for which such hospitals must submit data (further discussion below). These proposals are made in conjunction with our proposals discussed in sections IX.A.8. and IX.A.10.d. of the preamble of this final rule to align requirements for the Medicare and Medicaid EHR Incentive Programs and the Hospital IQR Program. In making these proposals, we believe that eligible hospitals and CAHs would have additional time to upgrade their systems and processes in preparation for the transition to electronic reporting on additional CQMs for additional quarters in future years.

As we continue to make strides with electronic reporting, we want to ensure we provide eligible hospitals and CAHs with a robust selection of CQMs. As noted above, hospitals have expressed concerns with identifying applicable measures that reflect their patient population; thus, we believe that the

addition of new CQMs in the future will offer more clinically relevant CQMs that facilitate reporting and help drive quality improvement. In section IX.A.9.d. of the preamble of the proposed rule, we discussed and sought feedback on future potential CQMs for the Hospital IQR Program and the Medicare and Medicaid EHR Incentive Programs for eligible hospitals and CAHs.

b. Changes to Policies Regarding Electronic Reporting of CQMs for CY 2017

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20131), in response to concerns from stakeholders, we proposed to modify the CQM reporting period for eligible hospitals and CAHs reporting CQMs electronically for the Medicare and Medicaid EHR Incentive Programs in CY 2017—for eligible hospitals and CAHs demonstrating meaningful use for the first time in 2017 or that have demonstrated meaningful use in any year prior to 2017, the reporting period would be two self-selected quarters of CQM data in CY 2017.

In addition, we proposed to modify the reporting criteria regarding the required number of CQMs for eligible hospitals and CAHs that are reporting electronically for the reporting periods in CY 2017 under the Medicare and Medicaid EHR Incentive Programs—if only participating in the EHR Incentive Program, or participating in both the EHR Incentive Program and the Hospital IQR Program, eligible hospitals and CAHs would report on at least 6 (self-selected) of the available CQMs. For a list of the available CQMs for reporting periods in CY 2017, we refer readers to the table in the FY 2017 IPPS/LTCH PPS final rule at 81 FR 57255.

It should be noted that we did not propose to modify any other aspects of the policies for reporting CQMs electronically for CY 2017, including the submission periods, nor did we propose any changes to our policies for reporting CQMs by attestation.

Through our proposals for CY 2017, we intend to continue to maintain alignment between the Medicare and Medicaid EHR Incentive Programs and the Hospital IQR Program to reduce confusion and reporting burden among participants in the Medicare and Medicaid EHR Incentive Programs that also participate in the Hospital IQR Program. As noted above, we are retaining the submission period for reporting CQMs electronically under the Medicare EHR Incentive Program, in which such submission period begins in late spring 2017 and continues through the 2 months following the close of the calendar year, ending February 28, 2018. In addition, we are continuing to provide States with the flexibility to determine the submission periods for reporting CQMs under the Medicaid EHR Incentive Program. For more details on the aligned reporting requirements for the Hospital IQR and Medicare and Medicaid EHR Incentive Programs, we refer readers to section IX.A.10.d. of the preamble of this final rule.

We believed that reducing the number of CQMs required to be electronically reported from 8 to 6 would ease the burden on data submitters, allowing them to shift resources to support system upgrades, map data, and train staff on CQMs. Similarly, we proposed reducing the number of data reporting periods to 2 quarters, rather than 4 quarters, and allowing eligible hospitals and CAHs to select which two quarters of CY 2017 to electronically report would offer greater reporting flexibility and allow eligible hospitals, CAHs, and health IT vendors more time to plan for reporting. We recognized that eligible hospitals and CAHs were concerned about their ability to meet the CY 2017 requirements established in the FY 2017 IPPS/LTCH PPS final rule and believed that the proposed modified reporting requirements for CY 2017 would account for the challenges stakeholders are experiencing while requiring the electronic reporting on a portion of CQMs, which is consistent with our goal to transition to electronic reporting (81 FR 57254).

We invited public comment on our proposals to modify the CY 2017 CQM reporting requirements for the Medicare and Medicaid EHR Incentive Programs as described above.

Comment: A majority of commenters supported CMS' proposals to reduce the number of CQMs required to be electronically reported from 8 to 6 available CQMs and reduce the reporting period from one full calendar year of data to two, self-selected quarters of data for CY 2017 electronic reporting. The commenters encouraged CMS to continue to take into account the operational implications of the electronic CQM submission requirements for smaller hospitals that have resource limitations. The commenters noted that as currently proposed, the requirements align with the CY 2017 Joint Commission reporting standards. A few commenters requested CMS to finalize requirements as proposed as soon as possible in order for hospitals to prepare and educate appropriate staff.

Several commenters indicated that the modified reporting period from one full calendar year of data to two, self-selected quarters of data would provide eligible hospitals and CAHs with sufficient time to adequately transition their EHR systems and allow them to avoid a reporting period that overlaps with the quarter in which they transition EHR systems. One commenter indicated that even if facilities were already collecting data on 8 CQMs, the reduction in the number of CQMs required to electronically report and the reporting period would give facilities that have limited resources or difficulties reporting for an entire calendar year the opportunity to be more successful.

Response: We thank the commenters for their support regarding our proposal to reduce the number of CQMs required to be electronically reported from 8 to 6 available CQMs and reduce the reporting period from one full calendar year of data to two, self-selected quarters of data for CY 2017 electronic reporting. CMS remains committed to engaging with stakeholders to address their concerns, including hospitals of varying sizes.

Comment: Several commenters supported the proposed policies for CY 2017 that reduce the reporting period from one full calendar year of data to two, self-selected quarters of data and the number of CQMs required to electronically report from 8 to 6, but recommended that CMS further reduce the CY 2017 requirements by retaining the CY 2016 established policies that required the electronic reporting of 4 CQMs for one quarter of data. The commenters indicated that maintaining the CY 2016 CQM reporting requirements for electronic submission would provide certified health IT vendors and CMS with additional time to work on measure specification and data validation, while giving hospitals more time to focus on incorporating system upgrades, data mapping, staff training, planning for data processing for CMS reporting and other issues.

In addition, some commenters expressed concern that the incremental increase in CQM electronic reporting requirements would impact the ability of eligible hospitals and CAHs to effectively meet current CQM reporting requirements and concurrently prepare for increased CQM electronic reporting requirements in the following program year. As a result, additional burden would be placed on hospitals by limiting available time for testing prior to production file submission. These commenters indicated that recent updates to measure specifications have

required labor-intensive updates to complete terminology mapping, which has limited the ability of hospitals to expand reporting on additional CQMs. The commenters noted that implementation of electronic CQM reporting is a multi-year, incremental process that requires significant capital and operating expenditure, and a significant investment of time and energy by staff.

Response: We appreciate commenters' feedback regarding the challenges associated with the electronic reporting of CQMs. As previously noted, in response to hospital and health IT vendor concerns, we proposed to modify previously finalized policies by reducing CQM reporting requirements. Based upon continued feedback from commenters, we are finalizing a modification to our proposal which reduces the CQM reporting requirements for the CY 2017 reporting period further than initially proposed. For the CY 2017 reporting period, we are requiring eligible hospitals and CAHs to report one, self-selected calendar quarter of data for 4 self-selected, available CQMs, instead of reporting two, self-selected calendar quarters of data for 6 available CQMs. We believe that these modified reporting requirements will provide eligible hospitals, CAHs, and health IT vendors with additional time to plan for data processing, report quality data to CMS, and focus on system upgrades, data mapping, staff training, and other issues, while also providing CMS with more time to address data validation. We will continue to monitor the progress of hospitals implementing the CQM reporting requirements and to engage hospitals regarding their experiences as we develop future CQM policy.

In regard to the impact of the incremental increase in CQM electronic reporting requirements and recent updates to measure specifications on the ability of eligible hospitals and CAHs to meet current CQM reporting requirements and concurrently prepare for increased CQM reporting requirements in the following program year, we believe that the modified policies that we are finalizing will address these commenters' concerns. Specifically, we decided to finalize for CY 2017 the same CQM reporting requirements established for CY 2016 (80 FR 49757 and 49758) (eligible hospitals and CAHs will be required to report one, self-selected quarter of data (for CY 2016, either Q3 or Q4) for 4 self-selected, available CQMs), which we believe will provide eligible hospitals and CAHs additional experience reporting CQMs electronically, incorporating annual measure specification updates, and reviewing the results of CQM data collection efforts prior to an incremental increase in the CQM reporting requirements.

For the CY 2017 reporting period, eligible hospitals and CAHs will be able to self-select 4 CQMs from the available 16 CQMs in the EHR Incentive Program measure set and meet the reporting requirements by submitting data via QRDA I files, zero denominator declaration, or case threshold exemption. In addition, we are continuing to allow manual aggregation of data for those eligible hospitals and CAHs experiencing issues with data aggregation in the process of upgrading EHR systems or changing health IT vendors. In order to provide eligible hospitals and CAHs with maximum flexibility, they may self-select which calendar quarter of data to report for the CY 2017 reporting period.

We note that hospitals have reported data electronically for several years to both the Medicare EHR Incentive Program and the Hospital IQR Program (3 prior years of pilot reporting and 3 prior years of voluntary reporting) and believe that the majority of hospitals should be ready to successfully report on at least 4 electronic CQMs beginning with the CY 2017 reporting period. However, we believe that the modification to our proposal regarding the CQM reporting requirements for CY 2017 that we are finalizing is responsive to stakeholder feedback, including feedback from small, rural, tribal, and Indian Health Service hospitals that have expressed the need for additional time and flexibility to successfully implement all of the CQM reporting requirements. Lastly, CMS is aligning the requirement for the reporting of one, self-selected calendar quarter of data for 4 CQMs between the Hospital IQR Program and the Medicare and Medicaid EHR Incentive Programs in order to streamline the electronic submission of quality data for hospitals.

Although we are not finalizing our proposal to require the electronic reporting of 6 CQMs for two, self-selected calendar quarters of data in CY 2017, we encourage eligible hospitals and CAHs to continue refining their electronic reporting implementation activities in order to successfully achieve electronic data capture and reporting. In addition, we encourage early testing and the use of pre-submission testing tools to reduce errors and inaccurate data submissions in electronic CQM reporting. As time progresses, we expect that eligible hospitals and CAHs will continue to build and refine their EHR systems and gain more familiarity with electronic reporting of more CQM data, resulting in more accurate data submissions with fewer errors. It is critical that we maintain a balance between the pace of evolving electronic standards and the timing cycle for the regulatory adoption of standards when adopting policies for the Medicare and Medicare EHR Incentive Programs.

Comment: One commenter believed that clinical staff may have difficulty inputting patient information into the appropriate structured fields during a patient encounter due to competing clinical demands.

Response: An EHR may allow clinicians or administrative staff to update patient information at a later time if clinical staff cannot record patient information at the time of the encounter without compromising patient care, or if additional information needs to be added to the medical record. We recommend that eligible hospitals and CAHs and their health IT vendors work together to implement EHR functionalities that will successfully support clinical activities, documentation, and quality measure reporting and that are consistent with the policies and procedures of the eligible hospital or CAH. We believe that recording patient information in structured fields for the purpose of reporting CQMs electronically is more accurate and less prone to errors than using unstructured fields since it relies less on interpretation, and ultimately reduces burden on eligible hospitals and CAHs.

Comment: A few commenters expressed concern that hospitals may be penalized more than once for failing to successfully report CQMs electronically in both the Hospital IQR and EHR Incentive Programs and as a result, a significant portion of their annual payment update hinges on the maturity of health IT vendor capabilities and the ability of the CMS QualityNet Secure Portal to manage and appropriately support the volume of incoming data submissions. Commenters noted that hospitals continue to report barriers to successfully submitting CQM data electronically, including health IT vendor failures during the submission of production data (which were not present during test submissions) and limitations of the QualityNet Secure Portal, such as: (1) An inability to accept QRDA I files over a certain size; (2) an inability to run reports verifying that data have been submitted to CMS; and (3) frequent periods when the system is down due to it not being able to accommodate more than a certain

number of users at one time. The commenters also expressed concern regarding CQM measure specification.

Response: We disagree with commenters that failing to successfully report CQMs electronically in both the Hospital IQR and EHR Incentive Programs may result in duplicate payment adjustments for hospitals. Section 1886(n)(3)(B)(iii) of the Act encourages the coordination of reporting of information across CMS programs and specifically directs the Secretary to seek to avoid redundant or duplicative reporting with reporting otherwise required, including reporting under the Hospital IQR Program, in selecting measures and in establishing the form and manner for reporting measures for the EHR Incentive Program. Therefore, we have established policies that have enabled hospitals to satisfy the CQM reporting requirements of both the Medicare EHR Incentive Program and the Hospital IQR Program without duplicative reporting. In the event an eligible hospital or CAH is unable to meet the electronic CQM reporting requirements, for CY 2017, it would be able to report CQMs by attestation for purposes of the EHR Incentive Program, and if it satisfies all other program requirements, it would avoid the EHR Incentive Program downward payment adjustment under sections 1886(b)(3)(B)(ix) and 1814(l)(4) of the Act. Also, we encourage eligible hospitals or CAHs that are unable to meet the electronic CQM reporting requirements under the EHR Incentive Program to review the EHR Incentive Program's hardship exception policy.

Regarding the limitations of the QualityNet Secure Portal and QRDA I file submission difficulties that commenters described, we acknowledge that at certain times of high submission volume, some data submitters reported longer file processing times and an inability to timely run feedback reports. We are actively taking steps to improve the data submission experience for the CY 2017 reporting period, including working to increase system throughput and increase responsiveness should further issues arise. In addition, we are working to identify potential efficiencies in our EHR Incentive Program system source code which could reduce the time it takes to receive submission confirmation and run reports.

We are finalizing a modified version of our proposals regarding the previously finalized CQM reporting requirements for the CY 2017 reporting period, such that eligible hospitals and CAHs are required to electronically report on 4 self-selected available CQMs (instead of 8 available CQMs) for one, self-selected calendar quarter of data (instead of a full calendar year (consisting of four quarterly data reporting periods)), whether reporting only for the EHR Incentive Program or reporting for both the Hospital IQR Program and the EHR Incentive Program.

Comment: One commenter did not support CMS' proposal to reduce the number of CQMs required to be electronically reported from 8 to 6 and reduce the reporting period from one full calendar year of data to two, self-selected quarters of CY 2017, and recommended that the number of CQMs and the reporting period reflect the previously finalized CY 2017 CQM reporting requirements for electronic reporting. The commenter indicated that capturing and exporting the data for a QRDA Category I file is part of the ONC EHR certification program and if a hospital is not capturing data in such a way that a QRDA I file can be generated, then this implies that either the EHR is violating its certification or the hospital is not using its EHR appropriately. Rather than modifying the CQM reporting requirements, the commenter suggested that the existing regulations be enforced and penalties be applied to health IT vendors with EHRs violating their certification. In addition, the commenter suggested that measure specifications could be published in advance to enable hospitals to view them before the reporting period begins. The commenter recognized the challenges some hospitals face, but indicated that these issues should be addressed directly rather than by changing the CQM reporting requirements.

Response: We thank the commenter for their support regarding our previously finalized CY 2017 CQM reporting requirements. We have found that many hospitals are able to successfully meet the CQM electronic reporting requirements and would be capable of successfully reporting additional measures. However, we seek to be responsive to the concerns and challenges expressed by hospitals, particularly smaller hospitals with fewer resources. In the present case we are seeking balance between hospitals' requests for more time to improve their CQM electronic reporting capabilities and furthering our goal to expand electronic data reporting. We appreciate the commenter's suggestion that measure specifications could be published further in advance to enable hospitals to view them before the reporting period begins and note that measure specifications are typically published in the spring of the year prior to the start of the applicable reporting period.

Comment: A few commenters recommended that CMS clarify the definitions used for the terms ''workflow'' and ''data submission,'' in the context of electronic measure reporting. Specifically, the commenters suggested that while ''workflow'' is related to technical challenges, the term is not appropriate in defining the process of data extraction and QRDA I submission.

Response: We thank the commenters for their suggestions. Our references of the terms ''data submission'' and ''workflow'' depend on the context in which the terms are used, the parties exchanging data, and the purpose for which data is exchanged. In the context of the electronic reporting of CQMs, hospitals may experience challenges modifying their internal workflow for clinical care, corresponding documentation and data capture, such that clinical staff enter patient information into the appropriate fields of an EHR at the time of the patient encounter. A clinician, medical assistant, scribe, or other staff member entering data into an EHR may find it simpler to enter patient information in the ''free text'' section of the EHR, even though specific fields exist in the EHR to record data so it maps appropriately for CQM reporting purposes. In suggesting that hospitals may need to make changes to their internal workflow, we expected that hospitals would train the appropriate staff to effectively capture patient data correctly in the EHR and make such efforts a priority. We further encourage hospitals to innovate and design workflows that fit their unique needs to make the best use of both clinical and non-clinical staff resources to maintain patient health information in the EHR. In addition, if clinical staff enter patient information in the ''free text'' sections of an EHR, clinical or administrative staff could go back after a patient encounter has completed and enter that information into the appropriate fields. This could be considered part of the hospital's ''workflow'' under the definition provided by the commenter. Data submission in the context of eCQM reporting would refer to the sending and subsequent receiving of clinical data corresponding to eCQM specifications through the QualityNet Secure Portal for purposes of the Hospital IQR Program and EHR Incentive Program eCQM submissions.

Comment: One commenter urged CMS to suspend all regulatory requirements regarding the electronic

reporting of CQMs, citing a lack of improvement in patient care despite the expenditure of significant time and resources to meet the CQM reporting requirements for the CY 2016 reporting period.

Response: We disagree with the commenter that the electronic reporting of CQMs does not benefit patients. We do not believe that suspending all electronic reporting of CQMs would be an appropriate approach. We recognize the need to continue to improve the electronic reporting of CQMs and establish a more seamless process to minimize burden on eligible hospitals and CAHs in meeting CQM reporting requirements. We understand that eligible hospitals and CAHs have spent resources to refine certified EHR technology to meet the electronic CQM reporting requirements. However, we also believe that CQMs will promote better quality of care as eligible hospitals and CAHs and their health IT vendors continue to refine EHR systems and integrate them into the clinical work flow. This will lead to improved accuracy, reliability, and completeness of the CQM data and promote higher quality, improved health outcomes for patients, and lower costs, while ultimately decreasing reporting burden on hospitals, and the associated operational, administrative, and financial burdens.

We will continue to monitor the progress of eligible hospitals and CAHs implementing CQM reporting requirements and encourage eligible hospitals and CAHs to continue sharing their experiences in meeting reporting requirements. In addition, we will routinely evaluate the CQMs available to report and consider new electronic measures as they become available for potential use in the Medicare and Medicaid EHR Incentive Programs and the Hospital IQR Program.

After consideration of the public comments we received, we are finalizing modifications to our proposals regarding the previously finalized CY 2017 CQM reporting requirements for electronic reporting. For the CY 2017 reporting period, eligible hospitals and CAHs that choose to report CQMs electronically are required to report one, self-selected calendar quarter of data for 4 self-selected CQMs of the available CQMs.

3. CQM Reporting for the Medicare and Medicaid EHR Incentive Programs in 2018

a. Background

In the 2015 EHR Incentive Programs Final Rule (80 FR 62892 through 62893), beginning in CY 2017 and for subsequent years, we established a CQM reporting period of one full calendar year (consisting of four quarterly data reporting periods) for the reporting of CQMs by eligible hospitals and CAHs participating in the Medicare and Medicaid EHR Incentive Programs, with an exception for providers demonstrating meaningful use for the first time under the Medicaid EHR Incentive Program, for whom the CQM reporting period is any continuous 90-day period within the calendar year. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57250), we noted that one full calendar year of data will result in more complete and accurate data, and hospitals will be able to submit one full calendar year of data for both the Medicare and Medicaid EHR Incentive Programs and the Hospital IQR Program, thereby reducing the reporting burden.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57250 through 57255), we removed 13 CQMs from the set of CQMs available for eligible hospitals and CAHs to report under the Medicare and Medicaid EHR Incentive Programs, beginning with the reporting periods in CY 2017. All 16 of the remaining measures listed in Table 10 of the EHR Incentive Program Stage 2 final rule (77 FR 54083 through 54087) are available for eligible hospitals and CAHs to report for the Medicare and Medicaid EHR Incentive Programs. The following table lists the 16 CQMs available for eligible hospitals and CAHs to report for the Medicare and Medicaid EHR Incentive Programs beginning in CY 2017 (81 FR 57255).

CQMs for Eligible Hospitals and CAHs Beginning with CY 2017

Short name	Measure name	NQF #
Electronic Clinical Quality Measures (eCQMs)		
AMI–8a	Primary PCI Received Within 90 Minutes of Hospital Arrival	0163
ED–3	Median Time from ED Arrival to ED Departure for Discharged ED Patients	0496
CAC–3	Home Management Plan of Care Document Given to Patient/Caregiver	+
ED–1	Median Time from ED Arrival to ED Departure for Admitted ED Patients	0495
ED–2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
EHDI–1a	Hearing Screening Prior to Hospital Discharge	1354
PC–01	Elective Delivery (Collected in aggregate, submitted via web-based tool or electronic clinical quality measure).	0469
PC–05	Exclusive Breast Milk Feeding *	0480
STK–02	Discharged on Antithrombotic Therapy	0435
STK–03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK–05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK–06	Discharged on Statin Medication	0439
STK–08	Stroke Education	+
STK–10	Assessed for Rehabilitation	0441
VTE–1	Venous Thromboembolism Prophylaxis	0371
VTE–2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372

+ NQF endorsement has been removed.
* Measure name has been shortened. We refer readers to annually updated measure specifications on the CMS eCQI Resource Center Web page for further information: *https://www.healthit.gov/newsroom/ecqi-resource-center*.

For CY 2018 and future calendar years, we plan to continue to align the CQM reporting requirements for the Medicare and Medicaid EHR Incentive Programs and the Hospital IQR Program. As we expect to expand the current measures to align with the National Quality Strategy, the CMS Quality Strategy [509] and incorporate updated

[509] Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/*

Continued

standards and terminology in current CQMs, including updating the electronic specifications for these CQMs, and creating de novo CQMs, we also plan to expand the set of CQMs available for reporting under the EHR Incentive Programs in future years. We will continue to engage stakeholders to provide input on future proposals for CQMs as well as request comment on future electronic specifications for new and updated CQMs.

b. CQM Reporting Period for the Medicare and Medicaid EHR Incentive Programs in CY 2018

(1) Background

Our goal is to continue to move toward increased electronic reporting while also addressing stakeholder concerns. With the CY 2017 final policies reducing electronic reporting requirements and providing additional time for eligible hospitals, CAHs, and health IT vendors to make EHR upgrades and system transitions in CY 2017, we believe that stakeholders will be able to address some of the issues and challenges they face prior to CY 2018, but recognize that certain challenges and issues (for example, EHR upgrade and system transition challenges associated with the development cycle of technology and the timeframe to develop and execute work flows and processes and train staff based on EHR upgrades and system transitions) may not be fully resolved and as a result, may persist in CY 2018. As established in the 2015 EHR Incentive Programs Final Rule (80 FR 62894), reporting CQMs by attestation will no longer be an option for eligible hospitals and CAHs starting with the reporting periods in CY 2018, except in circumstances in which electronic reporting is not feasible.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20132 and 20133), for CY 2018, we proposed the following CQM reporting period for the Medicare and Medicaid EHR Incentive Programs and the following submission period for the Medicare EHR Incentive Program—for eligible hospitals and CAHs reporting CQMs electronically that demonstrate meaningful use for the first time in 2018 or that have demonstrated meaningful use in any year prior to 2018, the reporting period would be the first 3 quarters of CY 2018, and the submission period would be the 2 months following the close of the calendar year, ending February 28, 2019.

For eligible hospitals and CAHs that report CQMs by attestation under the Medicare EHR Incentive Program as a result of electronic reporting not being feasible, and for eligible hospitals and CAHs that report CQMs by attestation under their State's Medicaid EHR Incentive Program, we established a CQM reporting period of the full CY 2018 (consisting of 4 quarterly data reporting periods) (80 FR 62893). We also established an exception to this full-year reporting period for eligible hospitals and CAHs demonstrating meaningful use for the first time under their State's Medicaid EHR Incentive Program; under this exception, the CQM reporting period is any continuous 90-day period within CY 2018 (80 FR 62893).

In the FY 2018 IPPS/LTCH PPS proposed rule, we proposed the submission period for eligible hospitals and CAHs reporting CQMs by attestation under the Medicare EHR Incentive Program would be the 2 months following the close of the CY 2018 CQM reporting period, ending February 28, 2019.

In regard to the Medicaid EHR Incentive Program, we provide States with the flexibility to determine the method of reporting CQMs (attestation or electronic reporting) and the submission periods for reporting CQMs, subject to prior approval by CMS.

(2) CQM Reporting Criteria for the Medicare and Medicaid EHR Incentive Programs in CY 2018

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20132 through 20133), we proposed the following reporting criteria under the Medicare and Medicaid EHR Incentive Program for eligible hospitals and CAHs reporting CQMs electronically for the reporting period in CY 2018—for eligible hospitals and CAHs participating only in the EHR Incentive Program, or participating in both the EHR Incentive Program and the Hospital IQR Program, report on at least six (self-selected) of the available CQMs from the table in the FY 2017 IPPS/LTCH PPS final rule at 81 FR 57255.

We proposed the following reporting criteria for eligible hospitals and CAHs that report CQMs by attestation under the Medicare EHR Incentive Program because electronic reporting is not feasible, and for eligible hospitals and CAHs that report CQMs by attestation under their State's Medicaid EHR Incentive Program, for the reporting period in CY 2018—report on all 16 available CQMs from the table in the FY 2017 IPPS/LTCH PPS final rule at 81 FR 57255.

In developing these proposals, we considered several alternatives. Specifically, we considered aligning the requirements for CY 2018 with the proposed requirements for CY 2017 outlined in the proposed rule, such that eligible hospitals and CAHs would report on 6 (self-selected) available CQMs for two self-selected quarters of data in both CY 2017 and CY 2018. We also considered the final policy in the FY 2017 IPPS/LTCH PPS final rule for the Hospital IQR Program (81 FR 57150 through 57159), which would require hospitals to report one full calendar year of data for at least 8 (self-selected) CQMs out of the available CQMs for both the CY 2017 reporting period/FY 2019 payment determination and the CY 2018 reporting period/FY 2020 payment determination. However, we proposed changes to this previously adopted policy in the Hospital IQR Program and refer readers to section IX.A.8. of the preamble of this final rule for more details. Ultimately, we believed that our proposal balanced our goal to transition to more robust electronic reporting of quality measure data with concerns from stakeholders regarding an increased burden to meet CQM reporting requirements. We believe the electronic collection and reporting of quality data using health IT will ultimately simplify and streamline reporting for various CMS quality reporting programs, and hospitals will experience decreased financial and administrative burden as we continue to align program reporting requirements and adopt a more streamlined set of clinical quality measures with electronic specifications.

In addition, the proposal provided eligible hospitals and CAHs the opportunity to have several years of experience reporting data electronically for the Hospital IQR and Medicare and Medicaid EHR Incentive Programs. Therefore, we believed that eligible hospitals and CAHs will be better prepared to submit an additional quarter of data for the CY 2018 reporting period compared to the number of quarters we proposed for the CY 2017 reporting period. This proposal was made in conjunction with our proposals discussed in section IX.A.10.d. of the preamble of the proposed rule to align requirements for the Medicare and Medicaid EHR Incentive Programs and the Hospital IQR Program.

We invited public comment on our proposals regarding the CY 2018 reporting requirements for eligible hospitals and CAHs reporting CQMs under the Medicare and Medicaid EHR Incentive Programs.

QualityInitiativesGenInfo/CMS-Quality-Strategy.html.

Comment: A majority of commenters supported CMS' proposal to require eligible hospitals and CAHs to electronically report 6 CQMs for the first three calendar quarters of data for the CY 2018 reporting period. A few commenters requested CMS maintain the requirement to electronically report 6 CQMs beyond the CY 2018 reporting period while increasing the reporting period to one full calendar year and then gradually increasing the number of required CQMs to electronically report in future years. The commenters believed such approach would allow hospitals to adapt to the increased CQM reporting requirements.

Response: We thank the commenters for their support, and will consider their comments in future policymaking.

Comment: Many commenters supported requiring eligible hospitals and CAHs to electronically report 6 CQMs, but requested that CMS retain the proposed modified CY 2017 CQM reporting period for electronic reporting, which would require eligible hospitals and CAHs to report two, self-selected quarters of data for the CY 2018 reporting period instead of the first three calendar quarters of data for the CY 2018 reporting period. Some commenters noted that smaller hospitals with fewer resources require more time to become proficient in all of the parameters (mapping, new work flows, staff education, etc.) associated with electronic reporting.

A few commenters indicated that if hospitals would be able to continue to self-select two quarters of data for the CY 2018 reporting period, it would provide the necessary time for quality, health IT, and clinical teams to improve performance without significantly impairing CMS' ability to review and analyze data generated through CQM reporting.

Response: We appreciate the support from commenters regarding our proposal to require eligible hospitals and CAHs to electronically report 6 available CQMs for the CY 2018 reporting period and their suggestion that we retain the proposed CY 2017 reporting period (two, self-selected quarters of data) for CY 2018.

In response to stakeholder concerns regarding the burden associated with meeting the CQM reporting requirements (including updating EHR systems, data mapping, refining work flows, and staff education and training), we recognize that eligible hospitals and CAHs may require more time and flexibility to meet the electronic reporting requirements. Therefore, we are finalizing modifications to our proposals regarding the CQM reporting requirements for the CY 2018 reporting period. Under the modified version of our proposals which we are finalizing for CY 2018, eligible hospitals and CAHs will be required to electronically report 4 self-selected CQMs of the available 16 CQMs under the Medicare and Medicaid EHR Incentive Programs. In addition, under the modified version of our proposals which we are finalizing, for the CY 2018 reporting period, eligible hospitals and CAHs are required to report one, self-selected calendar quarter of data for the 4 self-selected available CQMs.

By finalizing these modifications to our proposal, the CQM reporting requirements for electronic reporting for the CY 2018 reporting period will be the same as the CQM reporting requirements finalized for the CY 2017 reporting period, as discussed above. We believe that having the same reporting requirements for three reporting years will offer the consistency requested by stakeholders and allow hospitals and their health IT vendors to improve CQM reporting capabilities. We intend to establish requirements for the CY 2019 reporting period/FY 2021 payment determination and future years in future rulemaking.

We will continue to monitor the progress of eligible hospitals and CAHs implementing CQM reporting requirements and encourage hospitals to continue sharing their experiences. In addition, we encourage early testing and the use of pre-submission testing tools to reduce errors and inaccurate data submissions in electronic CQM reporting. As time progresses, we expect that eligible hospitals and CAHs will continue to build and refine their EHR systems and gain more familiarity with electronic reporting of more CQM data, resulting in more accurate data submissions with fewer errors.

Comment: Several commenters supported CMS' proposal to require eligible hospitals and CAHs to electronically report 6 CQMs for the CY 2018 reporting period, but requested that CMS allow eligible hospitals and CAHs to self-select the three quarters of data for which they would report. The commenters noted implementing requirements that differ from one calendar year to the next is time consuming and cumbersome, which includes changes and updates to CQM logic definitions, vendor relations, schemas for running reports, and XML files. Some commenters indicated that they would support reporting data from the first quarter reporting period when the year-end process is more established and predictable.

Response: We thank the commenters for their support of our proposal to require eligible hospitals and CAHs to electronically report 6 CQMs for the CY 2018 reporting period and suggestion to allow eligible hospitals and CAHs to self-select the three quarters of data for which they would report.

However, with stakeholders expressing concerns regarding eligible hospitals and CAHs experiencing an increased burden in meeting CQM reporting requirements, we are finalizing modifications to our proposals regarding the CQM reporting requirements for the CY 2018 reporting period. For CY 2018, eligible hospitals and CAHs are required to electronically report one, self-selected calendar quarter of data for 4 self-selected CQMs of the available 16 CQM under the Medicare and Medicaid EHR Incentive Programs. The CQM reporting requirements for CY 2017 and CY 2018 are the same.

Comment: Several commenters supported the proposed policies for CY 2018 reporting period that would require eligible hospitals and CAHs to electronically report the first three quarters of data for 6 self-selected available CQMs, but recommended that CMS further reduce the CY 2018 requirements by retaining the CY 2016 established policies that required the electronic reporting of 4 CQMs for one quarter of data.

In addition, some commenters expressed concern that the incremental increase in CQM electronic reporting requirements would impact the ability of eligible hospitals and CAHs to effectively meet current CQM electronic reporting requirements and concurrently prepare for increased CQM reporting requirements in the following program year. As a result, additional burden would be placed on hospitals by limiting available time for testing prior to production file submission. A few commenters expressed concern about the considerable burden required to map the necessary data elements from the EHR to the appropriate QRDA file format and noted that some health IT vendors are not properly equipped to collect and transmit such data through the CMS QualityNet Secure Portal. The commenters stated that until these issues are sufficiently addressed, CMS should not increase the required CQM reporting requirements for electronic reporting.

Response: We appreciate commenters expressing their concerns regarding the challenges associated with the electronic reporting of CQMs. As previously noted, in response to hospital and health IT vendor feedback,

we are modifying our proposed CY 2018 reporting requirements by reducing CQM reporting requirements. For the CY 2018 reporting period, we are requiring eligible hospitals and CAHs to report one, self-selected calendar quarter of data for 4 available CQMs. We believe that the modified, reduced reporting requirements will provide eligible hospitals, CAHs, and health IT vendors with additional time to plan for data processing, report quality data to CMS, and focus on system upgrades, data mapping, staff training, and other issues. We will continue to monitor the progress of hospitals in implementing CQM reporting requirements and engage in discussions with hospitals and health IT vendors regarding their experiences as we consider the establishment of CQM policies in future rulemaking.

In response to concerns from commenters that the incremental increase in CQM electronic reporting requirements would impact the ability of eligible hospitals and CAHs to both effectively execute current CQM electronic reporting requirements and concurrently prepare for increased CQM reporting requirements in the following program year, we believe that the modifications to our proposals requiring eligible hospitals and CAHs to report one, self-selected calendar quarter of data for 4 available CQMs reduce reporting requirements and provide eligible hospitals and CAHs with additional time to prepare to meet CQM reporting requirements. We believe that modestly increasing the requirements for eligible hospitals and CAHs to report CQMs electronically is consistent with our goal to make progress toward more robust electronic reporting of CQMs in the EHR Incentive Program, but recognize that some eligible hospitals and CAHs may benefit from additional time to become proficient in all of the aspects associated with electronic reporting and improving upon CQM reporting capabilities prior to increasing the number of quarters of data and number of CQMs eligible hospitals and CAHs are required to report electronically. We believe the electronic collection and reporting of quality data using health IT will ultimately simplify and streamline reporting for various CMS quality reporting programs, and hospitals will experience decreased financial and administrative burden as we continue to align program reporting requirements and adopt a more streamlined set of clinical quality measures with electronic specifications.

For the CY 2018 reporting period, eligible hospitals and CAHs will be able to self-select 4 CQMs from the available 16 CQMs in the EHR Incentive Program measure set and meet the reporting requirements by submitting data via QRDA I files, zero denominator declaration, or case threshold exemption. In addition, we are continuing to allow abstraction of data into structured fields since some eligible hospitals and CAHs are still in the process of upgrading EHR systems and changing health IT vendors. In an effort to provide eligible hospitals and CAHs with maximum flexibility, we are finalizing a policy which permits them to self-select the one calendar quarter of data they report for the CY 2018 reporting period.

In considering what the reporting period and number of CQMs to report electronically should be, we decided to implement for CY 2018 the same CQM reporting requirements established for CY 2016 (80 FR 49757 and 49758) and finalized in this final rule for CY 2017 (eligible hospitals and CAHs will be required to report one, self-selected quarter of data (for CY 2016, either Q3 or Q4) for 4 available CQMs), which we believe will provide eligible hospitals and CAHs with additional time gaining experience reporting CQMs electronically and reviewing the results of CY 2016 CQM data collection prior to increasing the number of quarters of data and number of CQMs eligible hospitals and CAHs are required to report electronically. We note that hospitals have reported data electronically for several years to both the Medicare EHR Incentive Program and the Hospital IQR Program (3 prior years of pilot reporting and 3 prior years of voluntary reporting) and believe that the majority of hospitals should be ready to successfully report on at least 4 electronic CQMs beginning with the CY 2018 reporting period. However, we believe that the finalized modification to our proposal regarding the CQM reporting requirements for CY 2018 is responsive to stakeholder feedback, including feedback from small, rural, tribal, and Indian Health Service hospitals that have expressed the need for additional time and flexibility to successfully implement all of the CQM reporting requirements.

Comment: One commenter supported CMS' proposal that would require eligible hospitals and CAHs to electronically report 6 CQMs for the CY 2018 reporting period, but suggested that CMS retain the requirement to report one full calendar year of data. Further, the commenter suggested gradually increasing the number of required CQMs in future years. The commenter believed that such approach would allow hospitals to adapt to the increased CQM requirements.

Response: We thank the commenter for their support. For future years, we will consider requiring hospitals to report more quarters of data and to gradually increase the electronic reporting of quality measure data in the Medicare and Medicaid EHR Incentive Programs.

Comment: One commenter recommended the submission deadline be moved to the end of the first quarter of 2019 instead of February 28, 2019, which would allow for final ICD–10 coding and corrections potentially needed after receiving final documentation from physicians.

Response: We thank the commenter for the recommendation to adjust the CQM submission deadline for the Medicare EHR Incentive Program from February 28, 2019 to the end of the first quarter of 2019. We will take this suggestion into consideration; however, at this juncture, we are finalizing the submission deadline for the 2018 reporting period as proposed.

After consideration of the public comments we received, we are finalizing the CY 2018 reporting requirements as proposed, except for our proposals pertaining to the electronic reporting of CQM reporting period and reporting criteria, which we are finalizing with modifications. For CY 2018, the CQM reporting period for the Medicare and Medicaid EHR Incentive Programs and the submission period for the Medicare EHR Incentive Program are as follows—for eligible hospitals and CAHs reporting CQMs electronically that demonstrate meaningful use for the first time in 2018 or that have demonstrated meaningful use in any year prior to 2018, the reporting period is one, self-selected calendar quarter of CY 2018 data, and the submission period is the 2 months following the close of the calendar year, ending February 28, 2019.

For eligible hospitals and CAHs that report CQMs by attestation under the Medicare EHR Incentive Program as a result of electronic reporting not being feasible, and for eligible hospitals and CAHs that report CQMs by attestation under their State's Medicaid EHR Incentive Program, we established a CQM reporting period of the full CY 2018 (consisting of 4 quarterly data reporting periods) (80 FR 62893). We also established an exception to this full-year reporting period for eligible hospitals and CAHs demonstrating meaningful use for the first time under their State's Medicaid EHR Incentive Program. Under this exception, the CQM reporting period is any continuous 90-day period within CY 2018 (80 FR 62893). The submission period for

eligible hospitals and CAHs reporting CQMs by attestation under the Medicare EHR Incentive Program is the 2 months following the close of the CY 2018 CQM reporting period, ending February 28, 2019. In regard to the Medicaid EHR Incentive Program, we provide States with the flexibility to determine the method of reporting CQMs (attestation or electronic reporting) and the submission periods for reporting CQMs, subject to prior approval by CMS.

For the CY 2018 reporting period, the reporting criteria under the Medicare and Medicaid EHR Incentive Program for eligible hospitals and CAHs reporting CQMs electronically is as follows—for eligible hospitals and CAHs participating only in the EHR Incentive Program, or participating in both the EHR Incentive Program and the Hospital IQR Program, report on at least 4 self-selected CQMs of the available CQMs from the table in the FY 2017 IPPS/LTCH PPS final rule at 81 FR 57255, which is also in section IX.E.3.a. of the preamble to this final rule.

The reporting criteria for eligible hospitals and CAHs that report CQMs by attestation under the Medicare EHR Incentive Program as a result of electronic reporting not being feasible, and for eligible hospitals and CAHs that report CQMs by attestation under their State's Medicaid EHR Incentive Program, for the reporting period in CY 2018—report on all 16 available CQMs from the table in the FY 2017 IPPS/LTCH PPS final rule at 81 FR 57255.

c. CQM Reporting Form and Method for the Medicare EHR Incentive Program in 2018

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49759 through 49760), we removed the QRDA–III as an option for reporting under the Medicare EHR Incentive Program for eligible hospitals and CAHs. For the reporting periods in 2016 and future years, we are requiring QRDA–I for CQM electronic submissions for the Medicare EHR Incentive Program. As noted in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49760), States would continue to have the option, subject to our prior approval, to allow or require QRDA–III for CQM reporting.

As noted in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49759), we encourage health IT developers to test any updates, including any updates to the CQMs and CMS reporting requirements based on the CMS Implementation Guide for Quality Reporting Document Architecture (QRDA) Category I and Category III (CMS Implementation Guide for QRDA) for Hospital Quality Reporting (HQR), on an annual basis.

The form and method of electronic submission are further explained in subregulatory guidance and the certification process. For example, the following documents are updated annually to reflect the most recent CQM electronic specifications: The CMS Implementation Guide for QRDA; program specific performance calculation guidance; and CQM electronic specifications and guidance documents. These documents are located on the eCQI Resource Center Web page at: *https://ecqi.healthit.gov/*. For further information on CQM reporting, we refer readers to the EHR Incentive Program Web site where guides and tip sheets are located at: *http://www.cms.gov/ehrincentive programs*. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20133), for the CY 2018 reporting period, we proposed the following for CQM submission under the Medicare EHR Incentive Program:

- Eligible hospital and CAH participating in the Medicare EHR Incentive Program (single program participation)—electronically report CQMs through QualityNet Portal.
- Eligible hospital and CAH options for electronic reporting for multiple programs (that is, EHR Incentive Program and Hospital IQR Program participation)—electronically report through QualityNet Portal.

As noted in the 2015 EHR Incentive Programs Final Rule (80 FR 62894), starting in 2018, eligible hospitals and CAHs participating in the Medicare EHR Incentive Program must electronically report CQMs where feasible; and attestation to CQMs will no longer be an option except in certain circumstances where electronic reporting is not feasible.

For the Medicaid EHR Incentive Program, States continue to be responsible for determining whether and how electronic reporting of CQMs would occur, or if they wish to allow reporting through attestation. Any changes that States make to their CQM reporting methods must be submitted through the State Medicaid Health IT Plan (SMHP) process for CMS review and approval prior to being implemented.

For CY 2018, we proposed to continue our policy regarding the electronic submission of CQMs, which would require the use of the most recent version of the CQM electronic specification for each CQM to which the EHR is certified. For the CY 2018 electronic reporting of CQMs, this means eligible hospitals and CAHs would be required to use the Spring 2017 version of the CQM electronic specifications and any applicable addenda available on the eCQI Resource Center Web page at: *https://ecqi.healthit.gov/*. In addition, we proposed to require that an eligible hospital or CAH would need to have its EHR technology certified to all 16 available CQMs from the table in the FY 2017 IPPS/LTCH PPS final rule at 81 FR 57255 in order to meet the reporting requirements for CY 2018. In the 2015 EHR Incentive Programs Final Rule (80 FR 62767), we established that starting in CY 2018, eligible hospitals and CAHs are required to have EHR technology certified to the 2015 Edition, although as discussed in section IX.G.4 of the preamble of this final rule, we are changing that requirement for the EHR reporting period in CY 2018.

Starting in CY 2018, we proposed to require the use of EHR technology certified to the 2015 Edition for CQM reporting. Furthermore, we proposed that an EHR certified for CQMs under the 2015 Edition certification criteria would not need to be recertified each time it is updated to a more recent version of the CQMs. We believe it is not necessary for an EHR certified for CQMs under the 2015 Edition certification criteria to be recertified each time it is updated to the most recent version of the CQMs because the EHR technology continues to meet the 2015 Edition certification criteria and any updates to the CQM specifications do not impact or change any elements regarding certification and thus, we proposed that recertification is not necessary. For further discussion regarding EHR certification requirements for 2018, we refer readers to section IX.G.4. of the preamble of this final rule. We invited public comment on these proposals.

Comment: Many commenters did not support the proposal requiring EHR technology to be certified to the 2015 Edition for the CY 2018 reporting period. Several commenters supported the options described in the FY 2018 IPPS/LTCH PPS proposed rule that would allow hospitals to use 2014 Edition CEHRT or a combination of 2014 and 2015 Edition CEHRT for the CY 2018 CQM reporting period.

A few commenters recommended CMS delay the requirement for EHR technology to be certified to the 2015 Edition until the CY 2019 reporting period. The commenters indicated that additional time is necessary since the certification requirements for the 2015 Edition are extensive and expensive, and noted that health IT vendors will continue to struggle with completing the

certification process by January 1, 2018. One commenter mentioned that turn over in the industry has caused a backlog in the certification process. Another commenter expressed concern that the slow pace of certification, the number of upgrades that need to be performed, and the number of trainings yet to be held makes it highly unlikely that health systems and medical practices will be prepared to submit CQMs using EHR technology certified to the 2015 Edition for the CY 2018 reporting period. Another commenter noted that implementing the 2015 Edition of CEHRT does not automatically create the ability to submit appropriate or complete quality data.

Response: We recognize that there is burden associated with the development and deployment of each new edition of CEHRT, but we believe it is important to continue to encourage the use of the most recent edition of CEHRT, which incorporates updated standards and criteria, as it allows the collection of more relevant and accurate electronic data. We believe there are many benefits associated with upgrading to EHR technology certified to the 2015 Edition. Specifically, the 2015 Edition health IT certification criteria enables health information exchange through new and enhanced certification criteria standards, and implementation specifications for interoperability while incorporating changes that are designed to spur innovation and provide more choices to health care providers and patients for the exchange of electronic health information including new application access (API) certification criteria.

However, based on the comments we received that did not support our proposal, we are also finalizing a modified version of our proposal to require the use of EHR technology certified to the 2015 Edition for the CQM reporting period in CY 2018. For the CY 2018 CQM reporting period, eligible hospitals and CAHs will have the flexibility to use EHR technology certified to the 2014 Edition or 2015 Edition, or a combination of both Editions. We believe this provides sufficient time for eligible hospitals and CAHs to test and deploy the 2015 Edition of CEHRT in subsequent years. The utilization of the most recent version of CEHRT will provide the most relevant data, which is critical for eligible hospitals and CAHs to collect, use, and share data. We believe improved systems interoperability and use of the most current standards will facilitate more robust and accurate quality data reporting. One of the main purposes of the ONC 2015 Edition final rule (80 FR 62603) is to facilitate greater interoperability for several clinical health information purposes and enable health information exchange through new and enhanced certification criteria, standards, and implementation specifications. We note that we have worked closely with ONC to enhance testing and validation of certified technology's ability to capture, exchange, and report electronic patient data, such as improved testing and certification through the Cypress CQM testing and certification tool.

In addition, in response to the concern regarding the burden associated with upgrading EHR technology certified to the 2015 Edition for the CY 2018 CQM reporting period, as discussed in this section of the preamble of this final rule, we are finalizing a modified version of our proposal regarding CQM reporting requirements for the CY 2018 reporting period that require reporting on 4 self-selected CQMs for one, self-selected calendar quarter of data to reduce burden. By allowing eligible hospitals and CAHs to self-select the quarters of data they report, eligible hospitals and CAHs will have more flexibility to meet certification and EHR system upgrades, such as transitioning to the 2015 Edition.

We are also finalizing a modified version of our proposal to require the use of EHR technology certified to the 2015 Edition for the CQM reporting period in CY 2018. For the CY 2018 CQM reporting period, eligible hospitals and CAHs will have the flexibility to use EHR technology certified to the 2014 Edition or 2015 Edition, or a combination of both Editions. We believe this provides sufficient time for eligible hospitals and CAHs to test and deploy the 2015 Edition of CEHRT in subsequent years.

Comment: One commenter expressed concern that allowing the flexibility to use a combination of the 2014 and 2015 Editions of CEHRT for the CY 2018 reporting period may create more problems than it could potentially solve.

Response: We acknowledge the concern from the commenter and note that we do not believe allowing hospitals to use a combination of EHR technology certified to the 2014 and 2015 Editions would make it more difficult for them to meet the CQM reporting requirements in CY 2018. We have allowed this flexibility for the CY 2016 and CY 2017 reporting periods and we are not aware of any specific issues in QRDA I file creation or submission. Based on the comments received, many eligible hospitals, CAHs, and health IT vendors would prefer to have greater time and flexibility to implement upgrades to the 2015 Edition.

Comment: Several commenters supported the proposal to require EHR technology to be certified to all 16 CQMs for the CY 2018 reporting period since all 16 CQMs should be available for submission to allow for reporting flexibility to better reflect the populations served by hospitals.

Response: We thank the commenters for their support regarding our proposal to require EHR technology to be certified to all 16 CQMs for the CY 2018 reporting period.

Comment: Several commenters did not support the proposal to require that EHR technology be certified to all 16 CQMs for the CY 2018 reporting period. A few of these commenters noted that there is not a requirement as a condition of ONC certification for EHR technology to support all CQM reporting options for hospitals, leaving each hospital or health system to work independently with health IT vendors in implementing their measures. The commenters expressed concern that these conditions may result in additional costs and hours of additional work for hospitals, and cause a tremendous waste of limited financial and personnel resources.

In addition, some commenters expressed concern that the proposal to require EHR technology be certified to all 16 CQMs for the CY 2018 reporting period inappropriately places the burden on hospitals, rather than health IT vendors, to meet the requirement, especially for hospitals transitioning to EHR technology certified to the 2015 Edition and preparing for long-planned system upgrades. These commenters urged CMS to work with ONC and health IT vendors to ensure that the 2015 Edition CEHRT is capable of supporting hospital CQM reporting, including the reporting of any of the CQMs available to report in the Medicare and Medicaid EHR Incentive Programs.

One commenter expressed concern that this policy eliminates the opportunity for a specialty product to focus on measures only applicable to its domain, such as a surgical suite product focusing on surgery measures. The commenter also noted its concern that this policy would reduce the availability of CEHRT for hospitals or lead to poorer workflows for capturing quality data.

Response: We appreciate commenters expressing their concerns regarding the proposal to require EHR technology be certified to all available CQMs for the CY 2018 reporting period. We recognize the challenges associated with the electronic reporting of CQMs. We

believe that requiring EHR technology to be certified to all available CQMs is important in allowing us to collect the most relevant electronic data. Further, we believe that requiring EHR technology to be certified to all available CQMs would help streamline the electronic data extrapolation component of hospital workflow in the future. In addition, having EHR technology certified to all available CQMs will prevent hospitals from having to go back and consult their health IT vendors each time they want/need to report on a new or different CQM.

We do not agree that the proposal places the burden on hospitals, rather than health IT vendors, to meet the requirement. We will continue to seek stakeholder input and collaborate with ONC to define standards for EHR organization and structure, which would allow for documentation to fit into the clinical workflow and to ensure our policies are responsive to evolving electronic standards to the greatest extent possible. We also seek to ensure that EHR technology certified to the 2015 Edition is capable of supporting hospital CQM reporting requirements, including the electronic reporting of any of the CQMs that are available to report under the Medicare and Medicaid EHR Incentive Programs. We encourage eligible hospitals and CAHs to work with their health IT vendors to continue refining their electronic reporting implementation activities to successfully achieve electronic data capture and reporting despite mapping and integration issues.

With respect to the concern indicating that this policy eliminates the opportunity for a specialty product to focus on measures only applicable to its domain, such as a surgical suite product focusing on surgery measures and that it would reduce the availability of CEHRT for hospitals or lead to poorer workflows for capturing quality data, we believe focusing first on consistency and alignment across all measures and EHR systems will provide an opportunity for all specialties to report equally within the EHR technology. Focusing on unique and individual specialties is a consideration for future rules once the concept of electronic reporting is fully established. Therefore, requiring EHR technology to be certified to all available CQMs at this time outweighs the potential limitations on specialty products and any impact this might have on their workflow.

After consideration of the public comments we received, we are finalizing the following policies regarding CQM reporting form and method as proposed. For CY 2018, we will continue our policy regarding the electronic submission of CQMs, which requires the use of the most recent version of the CQM electronic specification for each CQM to which the EHR is certified. For the CY 2018 electronic reporting of CQMs, this means eligible hospitals and CAHs are required to use the Spring 2017 version of the CQM electronic specifications and any applicable addenda available on the eCQI Resource Center Web page at: *https://ecqi.healthit.gov/*. In addition, we are requiring that an eligible hospital or CAH will need to have its EHR technology certified to all 16 available CQMs from the table in the FY 2017 IPPS/LTCH PPS final rule at 81 FR 57255 in order to meet the reporting requirements for CY 2018.

In regard to the proposal requiring eligible hospitals and CAHs to utilize EHR technology certified to the 2015 Edition for CQM reporting in CY 2018, we are finalizing a modification to our proposal. As discussed above and in section IX.G.4 of the preamble of this final rule, for the CY 2018 CQM reporting period, eligible hospitals and CAHs will have the flexibility to use EHR technology certified to either the 2014 Edition or 2015 Edition, or a combination of both Editions. We note that an EHR technology certified for CQMs under the 2014 or 2015 Edition certification criteria will not need to be recertified each time it is updated to a more recent version of the CQMs.

F. Clinical Quality Measurement for Eligible Professionals (EPs) Participating in the Medicaid EHR Incentive Program in 2017

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20134 through 20135), we discussed clinical quality measurement for eligible professionals (EPs) participating in the Medicaid EHR Incentive Program in 2017. We explained that the proposals in this section would apply only to EPs participating in the Medicaid EHR Incentive Program. They would not apply to eligible hospitals or CAHs, or to the Medicare EHR Incentive Program.

1. Modifications to the CQM Reporting Period for EPs in 2017

In the 2015 EHR Incentive Programs Final Rule (80 FR 62762), we established for the Medicare and Medicaid EHR Incentive Programs a CQM reporting period of the full CY 2017 for EPs who have demonstrated meaningful use in a prior year and a CQM reporting period of any continuous 90 days within CY 2017 for EPs who are demonstrating meaningful use for the first time (80 FR 62891 through 62892). We also noted that we would continue to allow the States to determine the form and manner in which Medicaid EPs should report CQMs, subject to CMS approval (80 FR 62891, 62894).

In the final rule with comment period titled Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models (81 FR 77008) (referred to as the ''CY 2017 Quality Payment Program final rule with comment period''), we established at § 414.1320(a), for the 2019 MIPS payment year, a minimum of a continuous 90-day performance period within CY 2017, up to and including the full CY 2017, for the quality performance category of the MIPS. We established at § 414.1320(b), for the 2020 MIPS payment year, a performance period of the full CY 2018.

Following the publication of that final rule with comment period, we received feedback from EPs observing that having CQM reporting or performance periods for Medicare professionals under MIPS that are different from the CQM reporting period for EPs under the Medicaid EHR Incentive Program would create administrative burdens for EPs who wish to participate in both programs and to report CQMs electronically. Our goal has always been to align Medicare and Medicaid reporting and quality improvement programs to the extent possible. In addition, while participation in MIPS is required for professionals who are considered ''MIPS eligible clinicians,'' participation in the Medicaid EHR Incentive Program is not required. If the CQM reporting periods and MIPS performance periods are not aligned, we believe it is less likely that MIPS eligible clinicians will also participate as EPs in the remaining years of the Medicaid EHR Incentive Program.

Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20134), we proposed to change the CQM reporting period for EPs who report CQMs electronically in the Medicaid EHR Incentive Program to match the performance period established under MIPS in the quality performance category for MIPS eligible clinicians. We proposed a minimum of a continuous 90-day period during CY 2017 for EPs electronically reporting CQMs for the Medicaid EHR Incentive Program. We note that we consider the reporting periods established through rulemaking to be minimums and would encourage States to accept data from longer reporting periods. We proposed that the

reporting period for CQMs for EPs who choose to attest rather than report electronically, and who have demonstrated meaningful use in a previous program year under the EHR Incentive Program, would remain one full year (CY 2017), which is in alignment with the requirements for eligible hospitals and CAHs for the Medicare and Medicaid EHR Incentive Programs for 2017 (80 FR 62892 through 62893). We noted that reporting CQMs by attestation is not an option for eligible clinicians under MIPS, so the reason for proposing a shortened reporting period for EPs reporting CQMs electronically, which is to align this reporting period with the MIPS performance period, would not exist for EPs who choose not to report electronically. We explained that nothing in this proposal would change the CQM reporting period for EPs demonstrating meaningful use for the first time, which was established in the 2015 EHR Incentive Programs Final Rule to be any continuous 90 day period regardless of the method of CQM submission (80 FR 62892).

We further explained that the CQM reporting period for the Medicaid EHR Incentive Program in 2018 for EPs that have demonstrated meaningful use in a previous program year would remain 1 full year (CY 2018) to align with the corresponding performance period in MIPS for MIPS eligible clinicians. If changes are made to the MIPS performance period through future rulemaking, we will revisit the Medicaid EHR Incentive Program policies to continue our alignment goals.

We explained that we intend to reduce EP burden and simplify the program through this proposal, which is intended to better align CQM reporting periods and CQM reporting for the Medicaid EHR Incentive Program with policies under MIPS. Overall, we believe the proposed alignment at the State attestation system and EP levels would both reduce burden associated with reporting on multiple CMS programs and enhance State and CMS operational efficiency.

We invited public comment on this proposal, including on whether making the proposed change would create burdens for EPs or States.

Comment: The majority of commenters supported our proposal to change the CQM reporting period to any continuous 90-day period during CY 2017 for EPs electronically reporting CQMs for the Medicaid EHR Incentive Program, which would align with the MIPS performance period. Commenters supported aligning the Medicaid EHR Incentive Program with MIPS when possible to reduce EP burden.

Response: We appreciate these comments and will continue to look for ways to align the Medicaid EHR Incentive Program with MIPS when possible. Therefore, we are finalizing the proposal to change the CQM reporting period to any continuous 90-day period during CY 2017 for Medicaid EPs electronically reporting CQMs.

Comment: Several commenters, including representatives of state Medicaid agencies, requested that CMS also change the CQM reporting period for Medicaid EPs who attest to CQMs rather than report electronically in CY 2017. These commenters noted that establishing a 90-day reporting period for all CQM reporting, regardless of submission method, would further reduce EP burden and streamline the Medicaid EHR Incentive Program requirements.

Response: We thank these commenters and agree that establishing a 90-day CQM reporting period during CY 2017 for all Medicaid EPs, regardless of submission method, would reduce burden and streamline the program requirements. Due to the comments we received, the majority of which encouraged us to make this change to the proposed rule, we reconsidered the benefits to all EPs of a 90-day CQM reporting period in CY 2017. Therefore, we are establishing a CQM reporting period of any continuous 90-day period during CY 2017 for all Medicaid EPs, regardless of reporting method.

After consideration of the public comments we received, we are finalizing a CQM reporting period for 2017 of any continuous 90-day period during CY 2017 for all Medicaid EPs, regardless of submission method.

2. Modifications to CQM Reporting Requirements for Medicaid EPs Under the Medicaid EHR Incentive Program

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20134 through 20135), we also proposed to align the specific CQMs available to EPs participating in the Medicaid EHR Incentive Program with those available to clinicians participating in MIPS who submit CQMs through their EHR. In the final rule titled ''Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2,'' we established (77 FR 54058) that EPs are required to report 9 CQMs covering at least 3 of the National Quality Strategy (NQS) domains from a list of 64 CQMs (77 FR 54069, Table 8). Subsequently and in the following years, in general, there has been alignment between the CQMs selected for the Medicaid and Medicare EHR Incentive Programs for EPs and the electronic measures selected for the PQRS Program. Updates to the PQRS measure set were proposed and finalized in the annual Physician Fee Schedule (PFS) rule for purposes such as keeping specifications in line with industry standards and clinical guidelines.

In the CY 2017 Quality Payment Program final rule with comment period (81 FR 77144), we revised the list of CQMs for the 2019 MIPS payment year, based on performance periods within CY 2017, to better reflect updated clinical standards and guidelines. Specifically, we removed a number of CQMs that had not been updated and were no longer clinically relevant (81 FR 77773, Appendix, Table F). In order to keep CQM specifications current, we proposed to align the CQMs for Medicaid EPs with those applicable for MIPS. Specifically, we proposed that the CQMs available for Medicaid EPs in 2017 would consist of the list of available CQMs for reporting from an EHR for MIPS in 2017, available in the Appendix of the CY 2017 Quality Payment Program final rule with comment period under Table A, which are denoted with a CMS e-Measure ID number.

In the CY 2017 Quality Payment Program final rule with comment period (81 FR 77145), we noted that one commenter requested that we engage State Medicaid leaders to maximize measure alignment across Medicare and Medicaid. We responded that we intend to align quality measures among all CMS quality programs where possible, including Medicaid, and would take this comment into account in the future. In addition, States have requested alignment between the CQM set for MIPS and the CQM set for EPs in the Medicaid EHR Incentive Program for consistency and convenience, to reduce burden, and to avoid confusion. In addition, we believe it is more likely that professionals would participate in both programs if the CQM sets are aligned. While participation in MIPS is required for professionals who are considered ''MIPS eligible clinicians,'' participation in the Medicaid EHR Incentive Program is not required. If the CQMs are not aligned across both programs, we believe it is less likely that MIPS eligible clinicians would also participate as EPs in the remaining years of the Medicaid EHR Incentive Program. Finally, as noted above, the CQMs that were removed from MIPS (81 FR 77773, Appendix, Table F) had not been updated and were no longer clinically relevant, and we believe that the revised list of CQMs would better reflect

updated clinical standards and guidelines (81 FR 77144).

We noted in the proposed rule that we anticipate that this proposal would reduce burden for Medicaid EPs, and that the systems changes that would be needed to implement it would not be significant for either States or EPs. The set of 53 CQMs available to MIPS participants is a subset of the 64 CQMs currently available under the Medicaid EHR Incentive Program. In addition, we believe that if EPs also plan to participate in MIPS, they should already be prepared to report on the 53 CQMs. However, we welcomed comments on whether any EPs might be negatively affected by the proposal; for example, on whether any EPs might have EHRs that do not measure enough of the 53 remaining CQMs because they were relying on some of the 11 CQMs that would be removed. We do not anticipate that this would be a common situation because these 11 CQMs are outdated, and the industry is moving away from them as EHRs are upgraded to meet the MIPS requirements.

We also noted in the proposed rule that we anticipate that the proposal to reduce the number of available CQMs would have only a minimal impact on States, which would have to make minor adjustments to State systems to reduce the available measures from 64 to 53. It is our understanding that State systems can turn off or easily exclude CQMs from user visibility on the front end and still easily manage on the back end.

The data submission criteria for the MIPS quality performance category at § 414.1335(a)(1)(i) provide that individual MIPS eligible clinicians and groups who elect to submit data via claims, qualified registry, EHR or qualified clinical data registry must submit data on at least six quality measures, including at least one outcome measure (or, if an applicable outcome measure is not available, one other high priority measure). We refer readers to § 414.1335(a)(2) and (3) for the data submission criteria that apply to individual MIPS eligible clinicians and groups who elect to submit data via other data submission mechanisms.

Instead of requiring MIPS eligible clinicians to report on CQMs across a certain number of NQS domains, MIPS provides individual MIPS eligible clinicians and groups with a variety of alternatives for participating in MIPS, including a variety of data submission mechanisms and scoring criteria. We noted in the proposed rule that we believe that the burden on EPs and States of adopting all of these MIPS alternatives for the Medicaid EHR Incentive Program would outweigh any benefits gained. The alternative reporting options for MIPS are calibrated as part of an overall quality improvement program beyond what the Medicare and Medicaid EHR Incentive Programs are designed to be. We believe it would be inappropriate to apply all of these new requirements to the Medicaid EHR Incentive Program.

We proposed to eliminate the requirement to report on CQMs across 3 of the 6 NQS domains that existed in previous years of the Medicaid EHR Incentive Program, for improved alignment with the data submission criteria for the MIPS quality performance category. The removal of this requirement would provide EPs greater flexibility in selecting CQMs to report and would assure that they could report on the same CQMs from their EHR to both MIPS and the Medicaid EHR Incentive Program.

We proposed that for 2017 Medicaid EPs would be required to report on any six measures that are relevant to the EP's scope of practice. This proposal would better align with the data submission criteria for the MIPS quality performance category in 2017.

We noted that we would continue our policy on allowing zero denominators to be reported to allow EPs to meet the CQM reporting requirements of the EHR Incentive Programs (80 FR 62889). Future years' requirements for reporting CQMs in the Medicaid EHR Incentive Program will be established in future rulemaking, as the policies for MIPS are developed for 2018 and beyond. We will continue to align the quality reporting requirements, as logical and feasible, to reduce EP burden.

We invited public comment on these proposals, specifically on whether making these proposed changes to CQM measures and measure reporting effective for 2017 would create burdens on EPs or States. If so, we stated we would consider making these proposed changes to the CQM reporting requirements effective beginning with the reporting period in 2018.

Comment: The vast majority of commenters supported CMS' proposals to change the CQM reporting requirements for EPs participating in the Medicaid EHR Incentive Program to align with the MIPS requirements for eligible clinicians and groups reporting CQMs through their EHRs. Our proposal to reduce and simplify the reporting requirement, from nine CQMs across 3 NQS domains, to any six CQMs relevant to an EP's scope of practice, received significant support from commenters.

Response: We appreciate the comments and are finalizing the proposals as proposed. In 2017, Medicaid EPs will report any six CQMs relevant to their scope of practice, regardless of whether they report via attestation or electronically.

Comment: One provider group commented that removing CQMs from the list of available CQMs could be an issue for EPs who were expecting to report on the removed measures in 2017.

Response: We did not receive any comments from providers affirmatively stating that this would be an issue. The majority of provider comments were very supportive of aligning the Medicaid EHR Incentive Program CQM reporting requirements with MIPS, stating that it would reduce reporting burden and allow providers to participate in both programs. Reducing the number of required CQMs from 9 to 6, and removing the domain requirements gives EPs greater flexibility to meet program requirements. We believe that all Medicaid EPs will be able to find six CQMs that are relevant to their scope of practice within the updated list of available CQMs. Also, we note our continued policy to allow ''zero denominator'' CQM submissions, which allows EPs to report on a CQM even if they have no data on that CQM in their EHR from the reporting period.

After consideration of the public comments we received, we are finalizing the proposals without modification. For 2017, the CQMs available for Medicaid EPs will consist of the list of 53 available CQMs for reporting from an EHR for MIPS for 2017 performance periods. Also, for 2017, Medicaid EPs are required to report on any six measures that are relevant to the EP's scope of practice.

G. Changes to the Medicare and Medicaid EHR Incentive Programs

1. Summaries of Final Policies Included in This Final Rule

In this final rule, we are adopting final policies based on proposals in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20135–20139) to continue advancement of certified EHR technology utilization, focusing on interoperability and data sharing. For the reasons discussed in section IX.G.2. of the preamble of this final rule, we are finalizing an EHR reporting period of a minimum of any continuous 90-day period in CY 2018 for new and returning participants attesting to CMS or their State Medicaid agency.

As mandated by the 21st Century Cures Act (Pub. L. 114–255, enacted on December 13, 2016), we proposed an

exception from the Medicare payment adjustments for EPs, eligible hospitals, and CAHs who are unable to comply with the requirements for being a meaningful EHR user because their CEHRT has been decertified under ONC's Health IT certification program (82 FR 20136 through 20138). For the reasons discussed in section IX.G.3. of the preamble of this final rule, we are finalizing the exception and application process for EPs, eligible hospitals and CAHs as proposed.

As mandated by the 21st Century Cures Act, in the FY 2018 IPPS/LTCH PPS proposed rule (81 FR 20138 through 20139), we proposed to implement a policy in which no payment adjustments will be made in 2017 and 2018 for eligible professionals who furnish ''substantially all'' of their covered professional services in an Ambulatory Surgical Center (ASC). We proposed to define an ASC-based EP under § 495.4 as an EP who furnishes 75 percent or more (or alternatively, 90 percent or more) of his or her covered professional services in sites of service identified by the codes used in the HIPAA standard transaction as an ASC setting in the calendar year that is two years before the payment adjustment year. In addition, we proposed to use Place of Service (POS) Code 24 to identify services furnished in an ASC and requested public comment on whether other POS codes or mechanisms should be used to identify sites of service in addition to or in lieu of POS code 24. For the reasons discussed in section IX.G.4. of the preamble of this final rule, we are finalizing the definition of an ASC-based EP as an EP who furnishes 75 percent or more of his or her covered professional services in sites of service identified by POS 24.

In the proposed rule, we stated we were working in cooperation with our Federal partners at the ONC to monitor progress on the 2015 Edition upgrade. For the reasons discussed in section IX.G.5. of the preamble of this final rule, we are finalizing a policy to allow EPs, eligible hospitals, and CAHs the flexibility to use EHR technology certified to the 2014 Edition, 2015 Edition, or a combination of the 2014 and 2015 Editions for an EHR reporting period in 2018.

We also note that we received comments specific to the EHR Incentive Programs objectives and measures, audits for meaningful use, Merit-Based Incentive Payment System (MIPS) and allocation of grant funding for CEHRT which are out of scope for this rule.

2. Revisions to the EHR Reporting Period in 2018

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20136), we proposed to change the EHR reporting period in 2018 for new and returning participants attesting to CMS or their State Medicaid agency from the full year (CY 2018) to a minimum of any continuous 90-day period within CY 2018.

Therefore, EPs, eligible hospitals and CAHs would attest to meaningful use for an EHR reporting period of a minimum of any continuous 90-day period from January 1, 2018 through December 31, 2018. The applicable incentive payment year and payment adjustment years for the EHR reporting period in 2018, as well as the deadlines for attestation and other related program requirements, would remain the same as established in prior rulemaking. We proposed corresponding changes to the definition of ''EHR reporting period'' and ''EHR reporting period for a payment adjustment year'' at 42 CFR 495.4.

We invited public comment on our proposal.

Comment: Commenters overwhelmingly supported CMS' proposal to change the EHR reporting period to a minimum of any continuous 90-day period in CY 2018. Some commenters requested an extension of the 90-day EHR reporting period beyond CY 2018. Another commenter stated for the first year of any new ''Stage'' a reduced reporting period should be used. A few commenters stated CMS should adopt a 90-day reporting period for all programs, all submission methods, and all years.

Response: We thank commenters for their support on this proposed policy. We disagree that a 90-day EHR reporting period should be established indefinitely for new and returning participants in the EHR Incentive Programs. We are finalizing a 90-day EHR reporting period in CY 2018 to allow participants additional time for testing and implementation of the 2015 Edition, including the new application programming interface (API) functionality requirement for Stage 3. We previously stated that we believe a full year EHR reporting period is the most effective way to ensure that all actions related to patient safety which leverage CEHRT are fully enabled for the duration of the year. This is one of the primary considerations of our continued push for a full year EHR reporting period. We will take commenters' suggestions under advisement for purposes of future rulemaking.

Comment: A commenter requested CMS clearly define the EHR reporting period. A few commenters requested clarity on whether CMS intends to have a minimum of any continuous 90 days for reporting the meaningful use objectives and measures and the clinical quality measures.

Response: The EHR reporting period is a minimum of any continuous 90-day period within the 2018 calendar year for new and returning participants attesting to CMS or their State Medicaid agency. The EHR reporting period must occur between January 1, 2018 and December 31, 2018. For information regarding the reporting period for clinical quality measures (CQMs) for 2018, we refer readers to section IX.E.3.b. of the preamble of this final rule.

Comment: Several commenters requested clarification on when CEHRT needs to be implemented for the applicable EHR reporting period.

Response: An EP, eligible hospital, or CAH may begin the EHR reporting period and implement their EHR technology before it is certified. Certification need only be obtained prior to the end of the EHR reporting period. We caution that if an EP, eligible hospital or CAH starts the EHR reporting period without the certification complete, it runs the risk of not being a meaningful EHR user for that EHR reporting period. See FAQ2893 (available at: *https://questions.cms.gov/faq.php?isDept=0&search=FAQ2893&searchType=faqId&submitSearch=1&id=5005*).

After consideration of the public comments we received, we are finalizing for new and returning EPs, eligible hospitals, and CAHs attesting to CMS or their State Medicaid agency, an EHR reporting period in CY 2018 as a minimum of any continuous 90 days between January 1, 2018 through December 31, 2018, as proposed. The applicable incentive payment year and payment adjustment years for the EHR reporting period in 2018, as well as the deadlines for attestation and other related program requirements, will remain the same as established in prior rulemaking.

We are finalizing corresponding changes to the definitions of ''EHR reporting period'' and ''EHR reporting period for a payment adjustment year'' in the regulations under 495.4.

3. Exception for Decertified EHR Technology for EPs, Eligible Hospitals, and CAHs Seeking To Avoid the Medicare Payment Adjustment

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20136 through 20138), as mandated by sections

4002(b)(1)(A) and (b)(2) of the 21st Century Cures Act, we proposed to add a new exception for EPs, eligible hospitals and CAHs from the Medicare payment adjustments under sections 1848(a)(7)(A), 1886(b)(3)(B)(ix)(I), and 1814(l)(4) of the Act, respectively, who demonstrate through an application process that compliance with the requirement for being a meaningful EHR user is not possible because the certified EHR technology used has been decertified under ONC's Health IT Certification Program.

We proposed that to be considered for this exception, an EP, eligible hospital and CAH must submit an application in a form and manner specified by CMS and must demonstrate in its application and through supporting documentation if available that they intended to attest to meaningful use for a certain EHR reporting period and made a good faith effort to adopt and implement another CEHRT in advance of that EHR reporting period.

We proposed an EP may qualify for this exception for the CY 2018 payment adjustment year, which is the final year of the payment adjustment for EPs under section 1848(a)(7)(A) of the Act, if their certified EHR technology was decertified at any time during the 12-month period preceding the applicable EHR reporting period for the CY 2018 payment adjustment year or during the applicable EHR reporting period for the CY 2018 payment adjustment year, which under § 495.4 is any continuous 90-day period in CY 2016 or 2017, depending on whether the EP has successfully demonstrated meaningful use in a prior year.

We proposed an EP seeking to qualify for this exception would submit an application in the form and manner specified by us by October 1, 2017, or a later date specified by us. We proposed an eligible hospital may qualify for this exception beginning with the FY 2019 payment adjustment year, if their certified EHR technology was decertified at any time during the 12-month period preceding the applicable EHR reporting period for the payment adjustment year, or during the applicable EHR reporting period for the payment adjustment year.

We proposed an eligible hospital seeking to qualify for this exception would submit an application in the form and manner specified by us by July 1 of the year before the payment adjustment year (for example, for the FY 2019 payment adjustment year, by July 1, 2018), or a later date specified by us.

We proposed a CAH may qualify for this exception beginning with the FY 2018 payment adjustment year if their certified EHR technology was decertified at any time during the 12-month period preceding the applicable EHR reporting period for the payment adjustment year, or during the applicable EHR reporting period for the payment adjustment year. We proposed a CAH seeking to qualify for this exception would submit an application in the form and manner specified by us by November 30 after the end of the applicable payment adjustment year (for example, for the FY 2018 payment adjustment year, by November 30, 2018), or a later date specified by us.

We noted in the proposed rule that sections 1848(a)(7)(B) and 1886(b)(3)(B)(ix)(II) of the Act provide that in no case may an EP, eligible hospital, or CAH be granted an exemption from the payment adjustment based on significant hardship or decertified EHR technology for more than five years.

We proposed to revise § 495.102(d) for EPs, § 412.64(d)(4) for eligible hospitals and § 413.70(a)(6) for CAHs to codify this proposed new exception.

We invited public comment on these proposals.

Comment: Many commenters supported the proposed exception for CEHRT that have been decertified by the ONC Health IT Certification Program stating it would help to mitigate potential financial loss to participants.

Response: We thank the commenters for their support. As we stated in the proposed rule (82 FR 20137), we believe participants in the Medicare EHR Incentive Program will benefit from this additional exception because there is a 6-step process that usually occurs with implementation of a certified EHR technology system. Health care providers would likely have to go through some phases of this cycle again, and we understand that it would be time consuming and may take up to a year to implement. In addition, we note that the decertification of a CEHRT by the ONC Health IT Certification Program would be outside of a health care provider's control, and we agree that additional burden would likely result from decertification. In implementing this new exception, we are attempting to reduce any potential burden while also continuing to further the goal of interoperability.

Comment: To account for the CEHRT requests for proposals (RFP) and selection process, implementation, and a 90-day EHR reporting period, several commenters requested a period of two years rather than 12 months, and one commenter suggested that CMS provide an additional 18-month grace period.

Another commenter believed there should be no requirements in moving to a new CEHRT product and that they should have at least three years to switch to a new EHR system.

A commenter indicated that the use of a 12-month period preceding the applicable EHR reporting period is confusing, stating that CMS should consider applying the exception for decertification that occurred at any time within the full calendar year prior to the EHR reporting period for the payment adjustment year and during the EHR reporting period for the payment adjustment year.

Response: We disagree that the exception should be extended beyond the 12-month period preceding the applicable EHR reporting period as suggested by the commenters. As we stated in the proposed rule at 82 FR 20137, we believe a 12-month period preceding the applicable EHR reporting period for the payment adjustment year is reasonable because it should allow ample time for health care providers to procure and deploy new certified EHR technology. We believe this provides additional flexibilities and may partially alleviate any financial burden placed upon a health care provider for having to procure a new EHR system.

Comment: Several commenters suggested that certain situations where a provider's CEHRT is decertified during the EHR reporting period would prevent them from being able to make a good faith effort to adopt and implement another CEHRT in advance of or during the remainder of the EHR reporting period, and requested clarification.

Response: We agree that acquiring another CEHRT during the applicable EHR reporting period would be difficult. We disagree, however, that a health care provider necessarily would be unable to adopt and implement a new CEHRT during the remainder of the EHR reporting period. We believe a good faith effort is necessary in order to ensure the health care provider is diligently working towards adopting and implementing new CEHRT under the circumstances presented. Health care providers may apply for this exception before or during the applicable EHR reporting period, by the deadlines we establish.

Comment: A commenter requested an extension of the application deadline to December 31st of the year of the EHR reporting period.

Response: At this time it is not feasible to extend the application until December 31st. There are time constraints we must adhere to for system updates and changes, therefore

we are unable to modify the proposed deadlines for application submission as outlined in 82 FR 20137 through 20138.

Comment: A commenter stated the application process was unclear and encouraged CMS to release timely guidance on the application.

Response: We will provide additional guidance regarding the application process after the final rule is published.

After consideration of the public comments we received, we are finalizing the policy as proposed.

We are also finalizing as proposed the corresponding changes to § 495.102(d) for EPs, § 412.64(d)(4) for eligible hospitals and § 413.70(a)(6) for CAHs.

4. Ambulatory Surgical Center (ASC)-Based Eligible Professionals (EPs)

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20138 through 20139), as mandated by section 16003 of the 21st Century Cures Act, we proposed to implement a policy in which no payment adjustments would be made under section 1848(a)(7)(A) of the Act for 2017 and 2018 for eligible professionals who furnish ''substantially all'' of their covered professional services in an ambulatory surgical center (ASC). We proposed to define an ASC-based EP under § 495.4 as an EP who furnishes 75 percent or more (or alternatively, 90 percent or more) of his or her covered professional services in sites of service identified by the codes used in the HIPAA standard transaction as an ASC setting in the calendar year that is two years before the payment adjustment year. The percentages of covered professional services in the primary and alternative proposals were based, respectively, on the percentages used in the definitions of a hospital-based MIPS eligible clinician under the Quality Payment Program (§ 414.1305 and 81 FR 77238 through 77240) and the definition of a hospital-based EP under the EHR Incentive Programs (§ 495.4 and 75 FR 44439 through 44442). In addition, we proposed to use Place of Service (POS) code 24 to identify services furnished in an ASC and requested public comment on whether other POS codes or mechanisms to identify sites of service should be used in addition to or in lieu of POS code 24.

We invited public comment on these proposals.

Comment: The majority of commenters supported the proposal for an ASC-based EP using 75 percent or more to define eligible professionals who furnish ''substantially all'' of their covered professional services in an ambulatory surgical center. The commenters believe the exception from the payment adjustments for ASC-based EPs will significantly reduce burden and promote consistency between the EHR Incentive Program and MIPS, but also ensures EPs who have little control over EHR decisions in their practice are not subject to payment adjustments.

One commenter stated that the definition of ASC-based EP should be as broad as possible.

Response: We thank commenters for their support. We are finalizing the definition of ASC-based EP as proposed using 75 percent or more to define eligible professionals who furnish ''substantially all'' of their covered professional services in an ASC, which aligns with the hospital-based MIPS eligible clinician definition under the Quality Payment Program (§ 414.1305 and 81 FR 77238 through 77240). We also agree that this policy will result in a reduction in burden for ASC-based EPs who have little control over the EHR decisions in the practice.

Comment: A few commenters suggested using 50 percent as the threshold to define ''substantially all'' as some EPs provide more than 50 percent, but less than 75 percent or 90 percent, of their services in an ASC.

Response: The statutory definition of an ambulatory surgical center-based EP provides that to be considered an ambulatory surgical center-based EP, the EP must provide ''substantially all'' of his or her covered professional services in an ambulatory surgical center. Therefore, we must identify the minimum percentage of an EP's covered professional services that must be provided in an ambulatory surgical center in order for the EP to be considered as providing ''substantially all'' of his or her covered professional services in an ASC setting. We do not believe that an EP who furnishes only slightly more than half of his or her covered professional services in an ASC setting is furnishing substantially all of such services in that setting. Based on the hospital-based MIPS eligible clinician definition we previously established under the Quality Payment Program, we believe that 75 percent is an appropriate minimum percentage of an EP's covered professional services.

Comment: One commenter suggested that CMS should change ''substantially all covered professional services'' to ''substantially all ASC covered services.'' The commenter believed that CMS should combine ASC services with all other Medicare Part B services when determining whether the professional is a meaningful user of CEHRT.

Response: We are unable to adopt the commenter's suggestion because the statute refers to ''covered professional services'' furnished by the EP. When determining if an EP qualifies as an ASC-based EP, we would look at all of their Medicare services billed using POS 24, and from that we would be able to determine the percentage of covered professional services that were furnished in an ASC. In addition, we requested comments on whether additional place of service codes or mechanisms should be utilized in addition to or in lieu of POS 24, but did not receive any specific comments on this issue. We are finalizing the use of Place of Service (POS) code 24 to identify services furnished in an ASC.

Comment: One commenter suggested a change in the proposed methodology of using claims for services furnished in the year that is two years before the payment adjustment year to be consistent with methodology used to determine a hospital-based EP.

Response: We disagree with using the same methodology for hospital-based and ASC-based determinations. We determine hospital-based status using claims data from the fiscal year before the year that is 1 year prior to the payment adjustment year and the fiscal year before the year that is 2 years prior to the payment adjustment year (77 FR 54102). We adopted this methodology to ensure EPs are made aware of their hospital-based status in advance of the applicable EHR reporting period for the payment adjustment year, so they would have time to adopt and implement CEHRT and begin their EHR reporting period. In contrast, for ASC-based determinations, the applicable EHR reporting periods under § 495.4 for the 2017 and 2018 payment adjustments years have already occurred or are currently underway in 2017, and thus it is not feasible to notify EPs of their ASC-based status in advance of the EHR reporting period. In addition, we believe our proposed methodology is clear and easy for EPs to understand.

After consideration of the public comments we received, we are finalizing as proposed the definition of ASC-based EP using 75 percent or more to define eligible professionals who furnish ''substantially all'' of their covered professional services in an ASC. In addition, we are finalizing Place of Service (POS) code 24 to identify services furnished in an ASC. We are also finalizing the definition of ''ASC-based EP'' in the regulations under § 495.4.

5. Certification Requirements for 2018

In the 2015 EHR Incentive Program final rule (80 FR 62871 through 62875), we adopted a final policy regarding which Edition of CEHRT must be used

by EPs, eligible hospitals, and CAHs for the EHR Incentive Program, which is reflected in the definition of CEHRT § 495.4.

Starting with 2018, all EPs, eligible hospitals, and CAHs would be required to use technology certified to the 2015 Edition to demonstrate meaningful use for an EHR reporting period in 2018 and subsequent years (80 FR 62873 through 62875).

We received feedback from EPs, eligible hospitals and hospital associations after the 2015 EHR Incentive Program final rule was published expressing concerns regarding the burden that will likely occur as a result of the new functionalities required in the implementation of the Stage 3 requirements.

Based on our past experience with the transition from the 2011 Edition to the 2014 Edition and concerns expressed by stakeholders, we understand that transitioning to technology certified to a new Edition can be complex and can require more resources and time than anticipated, including the time necessary to effectively deploy the upgraded system and make the necessary patient safety, staff training and workflow investments. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20139), we stated that we understood and appreciated these concerns, and were working in cooperation with our Federal partners at ONC to monitor progress on the deployment and implementation status of EHR technology certified to the 2015 Edition. We further stated if we identified a change in the current trends and significant issues with the certification and deployment of the 2015 Edition, we would consider flexibility in 2018, for those EPs that attest directly to a State for the State's Medicaid EHR Incentive Program and eligible hospitals and CAHs attesting to CMS or the State's Medicaid EHR Incentive Program that are not able to implement 2015 Edition CEHRT to attest for an EHR reporting period in 2018. We indicated one possibility was the flexibility to use EHR technology certified to the 2014 Edition or 2015 Edition, or a combination of EHR technologies certified to the 2014 and 2015 Editions, for an EHR reporting period in 2018.

In efforts to track certification readiness for the 2015 Edition, ONC considers the number of health care providers likely to be covered by the individual developers seeking certification under the ONC Health IT Certification Program in real time as the testing and certification process progresses. The ONC considers trends within the industry when projecting for 2015 Edition readiness. The market trend of consolidation was considered as part of the projection model and as of the close of the first quarter this analysis supported an estimate of greater than 85 percent of hospitals will be ready by the end of CY 2017. However, ONC has continued to update this tracking as the testing and certification process continues and this tracking as of the end of the second quarter of 2017 indicates that overall progress is behind the first quarter projections. ONC has therefore updated the overall estimate to reflect an estimate of greater than 75 percent of hospitals will be ready by the end of CY 2017.

This necessitates further consideration, both for adoption of a 90 day reporting period as discussed in IX.G.2 of this final rule and for the adoption of flexibility for the 2018 calendar year in the requirement for eligible hospitals and CAHs to use only the 2015 Edition in CY 2018. While the ONC estimates note that the majority of eligible hospitals and CAHs will be ready at the beginning of January 2018, the tracking indicates that additional flexibility should be allowed for all hospitals to ensure that those hospitals with limited resources to implement upgrades and those hospitals that may face challenges in implementing appropriate and necessary workflows are provided adequate time to successfully implement the upgrade to 2015 Edition.

We invited public comment on options for offering flexibility in CY 2018 with regard to EHR certification requirements.

Comment: A majority of commenters supported the flexibility to use 2014 Edition or 2015 Edition CEHRT in 2018 and stated the cost and administrative burden of upgrading the EHR technology is significant and delaying the requirement to use the 2015 Edition would reduce burden and improve patient-physician interactions.

A commenter requested CMS not to move forward with Stage 3 until further progress is made toward achieving interoperability and health information exchange.

Response: We thank commenters for their feedback and support of CEHRT flexibility in 2018. In an effort to grant more flexibility to health care providers who are experiencing 2015 Edition CEHRT product issues that impact the ability to be a meaningful EHR user in 2018, we are adopting a final policy to allow health care providers to use either 2014 Edition or 2015 Edition CEHRT, or a combination of 2014 Edition and 2015 Edition CEHRT, for their EHR reporting period in 2018. We want to ensure that health care providers have adequate time to effectively deploy the 2015 Edition and make the updates necessary to improve patient safety, staff training, and workflow investments to be a meaningful user. We note that the Stage 3 objectives and measures are designed to promote interoperability with a focus on the advanced use of EHR technology and electronic standards, as well as the interoperable exchange of health information between systems. Therefore, we believe implementing Stage 3 is essential in achieving those goals.

Comment: A few commenters requested CMS finalize a policy allowing for CEHRT flexibility by the end of calendar year 2017, in order to ensure that States have adequate time to update their systems without any delay.

Response: We believe the final policy established in this final rule will provide flexibility with regard to which Edition of CEHRT may be used in 2018.

Comment: Some commenters requested clarification on how CMS would implement flexibility in 2018 and whether providers would have the option to attest to Modified Stage 2 or Stage 3.

Several commenters were confused on how to use a combination of the 2014 and 2015 Editions for an EHR reporting period in 2018.

Response: Under the final policy we are adopting, for an EHR reporting period in CY 2018, health care providers will have the option to attest to the Modified Stage 2 objectives and measures using 2014 Edition CEHRT, 2015 Edition CEHRT, or a combination of 2014 and 2015 Edition CEHRT, as long as the EHR technology they possess can support the objectives and measures to which they plan to attest. Similarly, health care providers will have the option to attest to the Stage 3 objectives and measures using 2015 Edition CEHRT or a combination of 2014 and 2015 Edition CEHRT, as long as their EHR technology can support the functionalities, objectives and measures for Stage 3.

Upon attestation for an EHR reporting period in CY 2018, health care providers may select one of these options and attest to the applicable objectives and measures based on their Edition of CEHRT. The requirements for reporting of CQMs are found in section IX.E.3.b. of the preamble of this final rule.

A health care provider utilizing 2015 Edition CEHRT in CY 2018 could attest to the Stage 3 or the Modified Stage 2 objectives and measures depending on

their ability to fully implement all of the functionalities required of 2015 Edition CEHRT, which may be limited by the timing of product installation, deployment of new processes and workflows, and employee training. A health care provider using a combination of 2014 and 2015 Edition CEHRT could attest to the Stage 3 or the Modified Stage 2 objectives and measures. Health care providers who choose to attest to Modified Stage 2 will attest to only the Modified Stage 2 objectives and measures at § 495.22. Health care providers who choose to attest to Stage 3 will attest to only the Stage 3 objectives and measures at § 495.24. Health care providers who are seeking to attest to Stage 3 in 2018 using a combination of 2014 and 2015 Editions of CEHRT cannot do so without the support of certain functions that are only available for certification as part of the 2015 Edition certification criteria.

Comment: Several commenters requested that CMS not delay the 2015 Edition CEHRT and believed that health IT vendors should be held accountable for upgrading to the 2015 Edition so there is no delay in getting certification from ONC. These commenters believed that the possible delay further hinders the health care providers' ability to adopt and demonstrate meaningful use. In addition the commenters stated they believed the 2015 Edition eases data sharing and offers increased interoperability.

Response: We appreciate those stakeholders who were able to fully implement the 2015 Edition CEHRT. Moreover, we understand the challenges faced in accomplishing the upgrade and wish to recognize the tremendous amount of work from health care providers and health IT vendors in helping to move health IT forward. However, because Stage 3 was optional for CY 2017 and individual circumstances may have prolonged the certification process, we believe that health IT vendors and providers should be given additional time to implement a product that functions as intended utilizing the standards and criteria set forth by the ONC. We received numerous comments that implementation of the 2015 Edition was met with delays related to functionality implementation (including APIs), was administratively burdensome and required more time and resources than anticipated. Our intent in considering these options to provide flexibility in 2018 was not to further complicate the program, or hinder the advancement of health information exchange or interoperability. Rather, we sought to be responsive to stakeholder concerns by considering options for health care providers who were unable to fully implement the 2015 Edition CEHRT for an EHR reporting period in 2018 because of issues related to time constraints, implementation of new functionalities and testing new workflows to support the technology, implementation and training challenges related to new functions and standards, and potential unforeseen delays or updates required throughout the process. For those reasons we considered introducing flexibility in the use of certified EHR technology.

Comment: One commenter believed that CMS should eliminate the requirement for providers to upgrade to 2015 Edition CEHRT.

Response: We disagree that CMS should eliminate this requirement entirely, and we will require use of 2015 Edition CEHRT beginning with the EHR reporting period in 2019. Vendors and health care providers have already invested time and energy in the 2015 Edition, and we believe it will lend to an interoperable nationwide health information infrastructure focusing on the advanced use of EHR technology and electronic standards. In addition, the 2015 Edition facilitates the accessibility and exchange of data and establishes a framework that makes the Health IT Certification Program open and accessible to more types of health IT that can support a variety of care and practice settings, various HHS programs, and public and private interests. We have also heard from many health care providers that they are prepared to move to Stage 3. While this is not the case for all health care providers, we want to give those who are able to successfully attest to the Stage 3 objectives and measures the opportunity to do so.

Comment: One commenter believed that CEHRT requirements should be aligned across all programs where use of CEHRT is required, including the Quality Payment Program. Another commenter suggested that CMS should eliminate all certified EHR technology requirements.

Response: We may not be able to align CEHRT requirements across all programs as each program has different statutory authority and requirements. However, in an effort to reduce burden and promote interoperability, we will continue to align the CEHRT requirements where feasible. We cannot eliminate all requirements of CEHRT as suggested by the commenter because the statute includes certain baseline requirements (see, for example, section 1848(o)(4) of the Act).

Comment: One commenter requested more information on what CMS meant by a health care provider not being able to implement the 2015 Edition of CEHRT as they believed a wide variety of the 2015 Edition CEHRT products already exist.

Another commenter requested clarification on how to implement the 2015 Edition CEHRT and update to all new standards and functionalities for meeting the objectives and measures in Stage 3.

Response: We do acknowledge that some health care providers have successfully updated to the 2015 Edition of CEHRT but this is not the case in every situation. We also note that ONC has advised us that there are some vendors that are delayed in receiving their certification for every EHR module. In addition, as stated above, we received comments indicating a lack of preparedness for the 2015 Edition CEHRT in 2018. For these reasons, we believe that delaying the 2015 Edition of CEHRT is necessary in order to provide additional time to implement those certain elements, such as the API function, that we believe are central to increasing interoperability. For more information about the implementation of the 2015 Edition of CEHRT we refer readers to the 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Program Modifications, Final Rule. 80 FR 62602 through 62759.

Comment: A commenter stated that CMS is too focused on modifying functional requirements and does not emphasize outcomes or interoperability. The commenter indicated that better infrastructure is needed to support interoperability for data management, and to exchange content in a more effective way. The commenter expressed concerns around the expensive workarounds necessary for certified products that do not always function accurately and expressed concern that burden has shifted to staff having to identify codes which they believe is more time consuming and mundane.

Response: We disagree that we are too focused on modifying functional requirements and not enough on outcomes or interoperability. We believe the changes we are finalizing in this rule focus on increasing interoperability and ensure that we are reducing administrative burden in hopes of giving health care providers more time with their patients. In addition, we believe that as we move forward in increasing interoperability by focusing on certain objectives and measures we

will improve the delivery of services and improve patient outcomes. We understand the cost burden that some of the changes have on certain providers, but we believe there is greater benefit in having a truly integrated and interoperable health care system. We will continue to work with stakeholders.

After consideration of the public comments we received, we are finalizing a policy to allow health care providers to use either 2014 Edition or 2015 Edition CEHRT, or a combination of 2014 Edition and 2015 Edition CEHRT, for an EHR reporting period in CY 2018. As discussed above and in section IX.E.3.c. of the preamble of this final rule, for the CY 2018 CQM reporting period, eligible hospitals and CAHs will have the flexibility to use EHR technology certified to either the 2014 Edition or 2015 Edition, or a combination of both Editions.

All new and returning participants attesting to CMS or their State Medicaid agency have the option to attest to the Modified Stage 2 objectives and measures under § 495.22 for the EHR reporting period in 2018 using 2014 Edition CEHRT, 2015 Edition CEHRT, or a combination of 2014 and 2015 Edition CEHRT, as long as the EHR technology they possess can support the objectives and measures to which they plan to attest.

Similarly, all new and returning participants attesting to CMS or their State Medicaid agency have the option to attest to the Stage 3 objectives and measures under § 495.24 for the EHR reporting period in 2018 using 2015 Edition CEHRT or a combination of 2014 and 2015 Edition CEHRT, as long as their EHR technology can support the functionalities, objectives and measures for Stage 3.

Accordingly, we are revising the definition of ''Certified electronic health record technology (CEHRT)'' at § 495.4, the meaningful use criteria at § 495.22 and § 495.24, and the requirements for demonstrating meaningful use under § 495.40 to specify the flexible options for using CEHRT in 2018 and the objectives and associated measures to which health care providers using these options would attest.

X. Revisions of Medicare Cost Reporting and Provider Requirements

A. Electronic Signature and Submission of the Certification and Settlement Summary Page of the Medicare Cost Report

1. Background

Sections 1815(a) and 1833(e) of the Act provide that no payments will be made to a provider unless it has furnished such information, as may be requested by the Secretary, to determine the amount of payments due the provider under the Medicare program. In general, providers submit this information through annual cost reports that cover a 12-month period of time. Under the provisions of 42 CFR 413.20(b) and 413.24(f), providers are required to submit cost reports annually, with the reporting period based on the provider's accounting year. For cost reporting periods beginning on or after October 1, 1989, section 1886(f)(1) of the Act and § 413.24(f)(4) of the regulations require hospitals to submit cost reports in a standardized electronic format, and the same requirement was later imposed for other types of providers.

Currently, under § 413.24(f)(4)(ii), hospitals, skilled nursing facilities, home health agencies, hospices, end-stage renal disease facilities, organ procurement organizations, histocompatibility laboratories, rural health clinics, Federally qualified health centers, and community mental health centers are required to file Medicare cost reports in a standardized electronic format. When preparing the cost report, the provider's electronic program must produce the CMS standardized output file in a form that can be read by the contractor's automated system. This electronic file, also known as the electronic cost report, is forwarded to the contractor for processing through its system. (42 CFR 413.24(f)(4)(ii) and (iii))

Although the Medicare cost report is forwarded to the contractor in electronic format, certain hard copy portions must be separately submitted by the provider to its contractor. Specifically, under § 413.24(f)(4)(iv), the provider is required to submit a hard copy of the settlement summary, if applicable, which is a statement of certain worksheet totals, and a certification statement containing a signature by the provider's administrator or chief financial officer certifying the accuracy of the electronic file. The certification statement and the settlement summary both appear together on the ''Certification and Settlement Summary'' page of the Medicare cost report for all providers that are required to file a Medicare cost report. By signing the certification statement, the provider is certifying, among other things, to the accuracy of the electronic file, and also that it has read the statement that misrepresentation or falsification of information contained in the cost report may be punishable by criminal, civil or administrative action.

This certification statement signed by the provider's administrator or chief financial officer was incorporated into § 413.24(f)(4) of the regulations in a final rule with comment period (59 FR 26964 through 26965) issued in response to public comments received following the Uniform Electronic Cost Reporting System for Hospitals proposed rule (56 FR 41110). Currently, this certification statement is required to have an original signature. This original signature requirement is also set forth in Chapter 1 of the Provider Reimbursement Manual (CMS Pub. 15–2), which explains that a facsimile or stamped copy of the signature is unacceptable.

Due to the original signature requirement, the Certification and Settlement Summary page containing the original signature is required to be mailed by the provider to the contractor. As set forth in § 413.24(f)(4)(iv) and (5)(i) and (ii), an acceptable cost report submission must include the electronic cost report, along with a hard copy of the Certification and Settlement Summary page with an original signature, the Provider Cost Reimbursement Questionnaire, if applicable, and the supporting documentation required from teaching hospitals (the Intern and Resident Information System diskette).

2. Changes Relating to Electronic Signature on the Certification and Settlement Summary Page of the Medicare Cost Report

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20139 through 20142), in lieu of requiring the provider to sign the certification statement with an original signature on a hard copy of the Medicare cost report's Certification and Settlement Summary page, we proposed to revise § 413.24(f)(4)(iv) to allow providers to use an electronic signature. For Medicare cost reporting purposes, we proposed that this electronic signature be placed on the signature line of the certification statement and may be (1) any format of the original signature that contains the first and last name of the provider's administrator or chief financial officer (for example, photocopy or stamp) or (2) an electronic signature that must be the first and last name of the provider's administrator or chief financial officer entered in the provider's electronic program. An electronic signature for this purpose cannot be a symbol, numerical characters, or codes. We stated in the proposed rule that we believe allowing providers to utilize an electronic signature would afford providers greater flexibility in signing the certification statement and allow a faster and more efficient submission of the Medicare cost report.

To indicate the provider's election to sign the certification statement with an electronic signature, we proposed to add an electronic signature checkbox placed immediately after the certification statement and above the signature line on the Certification and Settlement Summary page of the Medicare cost report. We stated that the checkbox electing the electronic signature would read: ''I have read and agree with the above certification statement. I certify that I intend my electronic signature on this certification statement to be the legally binding equivalent of my original signature.'' We proposed that the checkbox must be checked to signify that the certification statement has been read and that an electronic signature will be placed on the signature line by the provider.

We proposed that only when the checkbox is checked would the signature line be accepted with an electronic signature. We stated in the proposed rule that completion of both the electronic signature checkbox and the electronic signature, placed on the signature line by the provider's administrator or chief financial officer under the certification statement, would together constitute an accepted electronic signature of the provider's administrator or chief financial officer on the certification statement. By signing the certification statement with an electronic signature on the Certification and Settlement Summary page, the signatory would be attesting that its electronic signature was executed with the intent to sign the certification statement, that the electronic signature is being submitted in lieu of an original signature, and additionally that the electronic signature has the same legal effect as an original signature. Because we proposed that it would be optional for providers to utilize an electronic signature on the certification statement, providers would continue to be able to sign the certification statement with an original signature on a hard copy of the Certification and Settlement Summary page.

We invited public comments on our proposals.

Comment: Many commenters supported the utilization of technology to allow for the electronic signature of the Certification and Settlement Summary page of the Medicare cost report and further stated that this has been long awaited in the industry. The commenters stated that allowing providers the option to electronically sign the Certification and Settlement Summary page will make the process easier, more efficient, and allow for fewer errors than the current paper process. Commenters also supported allowing facilities an option to continue using the current paper process to manually sign the Certification and Settlement Summary page.

Response: We appreciate the commenters' support.

Comment: One commenter suggested that CMS' proposal was to change the title of the signatory to the certification statement from the provider's administrator or ''officer'' to the provider's administrator or ''chief financial officer'' and disagreed with this alleged change, noting that many smaller providers do not have a chief financial officer.

Response: We disagree with this commenter's characterization of our proposal. Our proposal to allow providers the option to electronically sign the certification statement on the Certification and Settlement Summary page of the Medicare cost report, did not include a proposal to change the title of the person required to sign the certification statement. Section 413.24(f)(4)(iv) of the regulations requires that the certification statement be signed by the ''provider's administrator or chief financial officer.'' We did not propose to change the title of the person required to sign the certification statement. The requirements pertaining to the title of the person required to sign the certification statement remain the same.

Comment: One commenter suggested that CMS change the title of the person required to sign the certification statement on the Certification and Settlement Summary page of the Medicare cost report, citing that often the signor is someone other than the provider's administrator or chief financial officer.

Response: We consider this comment to be outside the scope of the policies we proposed in the proposed rule. We note that § 413.24(f)(4)(iv) of the regulations requires that the certification statement be signed by the ''provider's administrator or chief financial officer.''

After consideration of the public comments we received, for the reasons discussed above, we are finalizing our proposals discussed above without modification. As proposed, we are revising § 413.24(f)(4)(iv) to allow providers the option to use an electronic signature to sign the certification statement on the Certification and Settlement Summary page of the Medicare cost report. Under § 413.24(f)(4)(iv)(C)(1) as finalized in this rule, providers that are required to file an electronic cost report may elect to sign the certification statement with an electronic signature. As we proposed, this electronic signature must be placed on the signature line of the certification statement and may be (1) any format of the original signature that contains the first and last name of the provider's administrator or chief financial officer (for example, photocopy or stamp) or (2) an electronic signature that must be the first and last name of the provider's administrator or chief financial officer entered in the provider's electronic program. An electronic signature for this purpose cannot be a symbol, numerical characters, or codes. Furthermore, as we proposed, an electronic signature checkbox will be placed immediately after the certification statement and above the signature line on the Certification and Settlement Summary page of the Medicare cost report. The checkbox electing the electronic signature will read: ''I have read and agree with the above certification statement. I certify that I intend my electronic signature on this certification statement to be the legally binding equivalent of my original signature.'' The checkbox must be checked to signify that the certification statement has been read and that an electronic signature will be placed on the signature line by the provider. Completion of both the electronic signature checkbox and the electronic signature, placed on the signature line by the provider's administrator or chief financial officer under the certification statement, will together constitute an accepted electronic signature of the provider's administrator or chief financial officer on the certification statement. By signing the certification statement with an electronic signature on the Certification and Settlement Summary page, the signatory is attesting that its electronic signature was executed with the intent to sign the certification statement, that the electronic signature is being submitted in lieu of an original signature, and additionally that the electronic signature has the same legal effect as an original signature. Providers that are required to file an electronic cost report will still have the option under § 413.24(f)(4)(iv)(C)(2), as finalized in this rule, to sign the certification statement with an original signature and to submit a hard copy of the settlement summary, if applicable, and certification statement. In the proposed rule, we also proposed that these revisions would apply on a prospective only basis, to provider cost reporting periods that begin on or after October 1, 2017, the effective date of this final rule. However, after

consideration of the proposed effective date that would have delayed the period of time for the providers to electronically sign and submit the Certification and Settlement Summary page by almost one year and our desire to ease cost and burden upon providers, we have decided to allow providers the option to use an electronic signature to sign the certification statement on the Certification and Settlement Summary page of the Medicare cost report effective for cost reporting periods that end on or after December 31, 2017. This will allow providers to electronically sign and submit the Certification and Settlement Summary page much sooner, with their next cost reporting submission in 2018. Accordingly, these final revisions will apply, on a prospective only basis, to provider cost reporting periods ending on or after December 31, 2017.

3. Changes Relating to Electronic Submission of the Certification and Settlement Summary Page of the Medicare Cost Report

In section X.A.2. of the preamble of the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20140), we proposed to allow providers to use an electronic signature on the certification statement of the Certification and Settlement Summary page of the Medicare cost report. We further proposed that if the provider signs the certification statement with an electronic signature in the manner proposed in section X.A.2. of the preamble of the proposed rule and checks the electronic signature checkbox, the provider also may submit the Certification and Settlement Summary page electronically to the contractor at the same time and in the same manner in which the Medicare cost report is submitted. For example, if the provider submits the electronic cost report file via electronic mail to the contractor, the provider may also include the Certification and Settlement Summary page signed with an electronic signature.

Under our proposal, a provider could still choose to sign the certification statement with an original signature on a hard copy of the Certification and Settlement Summary page without checking the electronic signature box. However, if the provider chooses to do so, this page would have to be mailed to its contractor. We stated in the proposed rule that we believe this proposal to allow the electronic submission of the Certification and Settlement Summary page would reduce the need for and storage of paper documents. We stated that, under our proposal, providers would have the option to submit the entire cost report electronically, in lieu of the previous requirement to mail a hard copy of the Certification and Settlement Summary page of the Medicare cost report to the contractor. We stated that we believe this proposed option would improve the capability of providers to efficiently transmit the Medicare cost report and save providers an appreciable amount of time as well as the cost of separately mailing a hard copy of the Certification and Settlement Summary page of the Medicare cost report to the contractor.

We invited public comments on this proposal.

Comment: One commenter asked whether a provider's option to use an electronic signature on the certification statement of the Certification and Settlement Summary page of the Medicare cost report and submit this form electronically applied to outpatient facilities and to low or no utilization cost reports where the MAC is currently requiring a signed certification statement.

Response: As set forth in the preamble of the proposed rule, (82 FR 20141) and at § 413.24(f)(4)(iv)(C) (as finalized in this rule), the option to use an electronic signature on the certification statement of the Certification and Settlement Summary page and to submit this form electronically applies to providers that are required to file an electronic Medicare cost report. These providers are specified in § 413.24(f)(4)(ii). This includes providers with low or no utilization that submit a Certification with a Settlement Summary, if applicable.

Comment: One commenter asked whether the cost report file and the electronically signed certification statement on the Certification and Settlement Summary page would be filed together and sent to the contractor or sent separately but using the same process.

Response: This final rule allows the provider great flexibility to choose how it wishes to electronically sign the certification statement on the Certification and Settlement Summary page of the Medicare cost report and electronically submit this page. As set forth in section X.A.2. of the preamble of the proposed rule (82 FR 20140), if the provider chooses to sign the certification statement with an electronic signature, this signature must be placed on the signature line of the certification statement and may be (1) any format of the original signature that contains the first and last name of the provider's administrator or chief financial officer (for example, photocopy or stamp) or (2) an electronic signature that must be the first and last name of the provider's administrator or chief financial officer entered in the provider's electronic program. Regardless of which electronic signature method is selected by the provider, to indicate the provider's election to sign the certification statement with an electronic signature, the electronic signature checkbox placed immediately after the certification statement and above the signature line on the Certification and Settlement Summary page of the Medicare cost report must be checked to signify that the certification statement has been read and that an electronic signature will be placed on the signature line by the provider. As we stated earlier and in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20140), a provider may submit the Certification and Settlement Summary page electronically to the contractor at the same time and in the same manner in which the Medicare cost report is submitted. If the electronic signature is in the format specified ''(1)'' or ''(2)'' above (and in section X.A.2. of the preamble of the proposed rule), this electronic signature on the Certification and Settlement Summary page of the Medicare cost report can be submitted electronically with the electronic cost report to the provider's contractor. If the provider submits the Medicare cost report file to the contractor via email, the provider may elect to also send the electronically signed certification statement on the Certification and Settlement Summary page to the contractor via the same email or separately in a separate email. In addition, if the certification statement is signed with an electronic signature as in ''(1)'' or ''(2)'' above (and in section X.A.2. of the preamble of the proposed rule), the Certification and Settlement Summary page of the Medicare cost report can also be submitted on paper to the contractor via regular mailing and would still be considered to have an electronic signature. We will provide further instructions through manual provisions and provider educational materials.

After consideration of the public comments we received, for the reasons discussed above, we are finalizing our proposals without modification. As proposed, if the provider signs the certification statement with an electronic signature in the manner described in this final rule and checks the electronic signature checkbox, the provider also may submit the Certification and Settlement Summary page electronically to the contractor at the same time and in the same manner

in which the Medicare cost report is submitted. For example, if the provider submits the electronic cost report file via electronic mail to the contractor, the provider may also include the Certification and Settlement Summary page signed with an electronic signature. Thus, providers would have the option to submit the entire cost report electronically, in lieu of the previous requirement to mail a hard copy of the Certification and Settlement Summary page of the Medicare cost report to the contractor. We note that a provider could still choose to sign the certification statement with an original signature on the Certification and Settlement Summary page. However, if the provider chooses to do so, this page would have to be mailed to its contractor.

4. Clarifications Relating to the Items Required To Be Submitted by Providers With the Medicare Cost Report

a. Settlement Summary and Certification Statement

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20141), we clarified the portion of the language in § 413.24(f)(4)(iv) that describes the items a provider is required to submit along with the electronically filed cost report. We stated that § 413.24(f)(4)(iv) currently sets forth that a provider is required to submit a hard copy of a settlement summary, a statement of certain worksheet totals found within the electronic file, and a statement signed by its administrator or chief financial officer certifying the accuracy of the electronic file or the manually prepared cost report. These items are contained on the Certification and Settlement Summary page of the Medicare cost report. As we stated in the proposed rule, we believe that the structure of the sentence in the regulation text describing these items may give rise to the impression that these are three separate items: (1) A ''settlement summary''; (2) a ''statement of certain worksheet totals found within the electronic file''; and (3) a ''statement signed by its administrator or chief financial officer certifying the accuracy of the electronic file or the manually prepared cost report,'' also known as the certification statement. In the proposed rule, we clarified that ''a statement of certain worksheet totals found within the electronic file'' is not a separate item but rather is intended as a descriptor of the ''settlement summary.'' The settlement summary is actually the list of ''certain worksheet totals found within the electronic file.'' Therefore, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20141), we proposed to revise § 413.24(f)(4)(iv) to clarify this.

We did not receive any public comments on this proposal. Thus, for the reasons discussed above, we are finalizing, without modification, our proposed revisions to § 413.24(f)(4)(iv) (as further discussed in section X.A.5. of this final rule).

b. Removal of the Transition Period Language

Following the effective dates for which certain providers were required to submit cost reports in a standardized electronic format under § 413.24(f)(4)(ii), a transition period was implemented when certain providers were required to submit a hard copy of the completed cost report forms in addition to the electronic file. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20141), we proposed to remove the language in § 413.24(f)(4)(iv) which sets forth this expired transition period. Specifically, we proposed to remove the language that specifies that, during a transition period (first two cost-reporting periods on or after December 31, 2004 for hospices and end-stage renal disease facilities, and the first two cost-reporting periods on or after March 31, 2005 for organ procurement organizations, histocompatibility laboratories, rural health clinics, federally qualified health centers, and community mental health centers), providers must submit a hard copy of the completed cost report forms in addition to the electronic file. We stated that because the transition period has expired and these providers are no longer required to submit a hard copy of the completed cost report forms in addition to the electronic file, this language in § 413.24(f)(4)(iv) is no longer necessary. We did not receive any public comments on this proposal, and thus, for the reasons discussed above, we are finalizing without modification our proposal to remove this language (as further discussed below in section X.A.5. of the preamble of this final rule).

5. Revisions to 42 CFR 413.24(f)(4)(iv)

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20139 through 20142), to reflect our proposals discussed earlier, we proposed to revise § 413.24(f)(4)(iv) to specify that, effective for cost reporting periods beginning on or after October 1, 2017, providers that are required to file an electronic Medicare cost report may elect to electronically submit the settlement summary, if applicable, and the cost report's certification statement, found on the Certification and Settlement Summary page of the Medicare cost report, with an electronic signature of the provider's administrator or chief financial officer. We stated that a provider that elects to electronically sign and submit the Certification and Settlement Summary page would no longer be required to send this page in hard copy to its contractor with an original signature. We further proposed to revise § 413.24(f)(4)(iv) to specify that the provider must check the electronic signature checkbox that would be placed immediately after the certification statement and directly above the signature line of the certification statement. We proposed that this electronic signature checkbox would specify that the provider's administrator or chief financial officer has read and agrees with the certification statement, and certifies that he or she intends the electronic signature to be the legally binding equivalent of his or her original signature. We stated that the provider must check the electronic signature checkbox in order for the provider to sign the certification statement with an electronic signature and in order for the electronic signature to be accepted. We invited public comments on this proposal.

After consideration of the public comments we received (as summarized in sections X.A.2. and in X.A.3. of the preamble of this final rule), we are finalizing our proposed revisions to § 413.24(f)(4)(iv) as discussed above with the following modification. As discussed in section X.A.2. of the preamble of this final rule, after consideration of the proposed effective date that would have delayed the period of time for the providers to electronically sign and submit the Certification and Settlement Summary page by almost a year and our desire to ease cost and burden upon providers sooner, we have decided to allow providers the option to use an electronic signature to sign the certification statement on the Certification and Settlement Summary page of the Medicare cost report and to electronically submit this page effective for cost reporting periods ending on or after December 31, 2017. As such, effective for cost reporting periods ending on or after December 31, 2017, providers that are required to file an electronic Medicare cost report may elect to electronically submit the settlement summary, if applicable, and the cost report's certification statement, found on the Certification and Settlement Summary page of the Medicare cost report, with an electronic

signature of the provider's administrator or chief financial officer. A provider that elects to electronically sign and submit the Certification and Settlement Summary page is no longer required to send this page in hard copy to its contractor with an original signature. We are further revising § 413.24(f)(4)(iv), as proposed, to specify that the provider must check the electronic signature checkbox that would be placed immediately after the certification statement and directly above the signature line of the certification statement. This electronic signature checkbox specifies that the provider's administrator or chief financial officer has read and agrees with the certification statement, and certifies that he or she intends the electronic signature to be the legally binding equivalent of his or her original signature. The provider must check the electronic signature checkbox in order for the provider to sign the certification statement with an electronic signature and in order for the electronic signature to be accepted.

In addition, we proposed to revise the regulatory language under § 413.24(f)(4)(iv) to reflect our clarification that the phrase ''a statement of certain worksheet totals found within the electronic file'' describes the settlement summary and does not denote a separate item. Specifically, we proposed to revise § 413.24(f)(4)(iv) to state that a provider must submit a settlement summary, if applicable, which is a statement of certain worksheet totals found within the electronic file, and a certification statement signed by its administrator or chief financial officer certifying the accuracy of the electronic file or manually prepared cost report. We invited public comments on this proposal. We did not receive any public comments on our proposal. Therefore, for the reasons discussed above, we are finalizing, without modification, our proposal to revise the regulatory language under § 413.24(f)(4)(iv) to reflect our clarification that the phrase ''a statement of certain worksheet totals found within the electronic file'' describes the settlement summary and does not denote a separate item.

In addition, as indicated earlier, because the transition period during which certain providers were required to submit a hard copy of the completed cost report forms in addition to the electronic file has expired, we proposed to remove the transition period language in § 413.24(f)(4)(iv). We invited public comments on this proposal. We did not receive any public comments on this proposal, and therefore, for the reasons discussed above, we are finalizing, without modification, our proposal to remove the language in § 413.24(f)(4)(iv) that describes this expired transition period.

Finally, we proposed to revise the regulation text at § 413.24(f)(4)(iv) by adding the certification statement from the certification section of the Certification and Settlement Summary page of the Medicare cost report. This certification statement appeared in all caps in the proposed regulation text and stated as follows: ''Misrepresentation or falsification of any information contained in this cost report may be punishable by criminal, civil and administrative action, fine and/or imprisonment under Federal law. Furthermore if services identified in this report were provided or procured through the payment directly or indirectly of a kickback or were otherwise illegal, criminal, civil and administrative action, fines, and/or imprisonment may result.'' This language has appeared on the Certification and Settlement Summary page for many years. We stated in the proposed rule that because the certification section of the Medicare cost report refers to it as having been read by the provider, incorporation of it into the regulation text would provide completeness and clarification of the certification statement.

We invited public comments on this proposal. We did not receive any public comments on our proposal. Therefore, for the reasons discussed above, we are finalizing our proposal, without modification, to revise the regulation text at § 413.24(f)(4)(iv) by adding the certification statement from the certification section of the Certification and Settlement Summary page of the Medicare cost report. This certification statement appears in all caps and informs the provider that ''Misrepresentation or falsification of any information contained in this cost report may be punishable by criminal, civil and administrative action, fine and/or imprisonment under Federal law. Furthermore if services identified in this report were provided or procured through the payment directly or indirectly of a kickback or were otherwise illegal, criminal, civil and administrative action, fines, and/or imprisonment may result.''

B. Clarification of Limitations on the Valuation of Depreciable Assets Disposed of on or After December 1, 1997

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20142 through 20143), we proposed revisions to the Medicare provider reimbursement regulations to clarify our longstanding policy pertaining to allowable costs and the limits on the valuation of a depreciable asset that may be recognized in establishing an appropriate allowance for depreciation for assets disposed of on or after December 1, 1997. Questions have arisen with regard to whether this limitation on the valuation of depreciable assets depends on the manner in which a provider disposes of an asset. In the proposed rule, we clarified that the elimination of the gain or loss for depreciable assets applies to assets a provider disposes of by sale or scrapping on or after December 1, 1997, regardless of whether the asset is scrapped, sold as an individual asset of a Medicare participating provider, or sold incident to a provider's change of ownership.

Reasonable cost is defined at section 1861(v)(1)(A) of the Act and in the implementing regulations at 42 CFR part 413. Since the inception of the Medicare program, allowable costs under Medicare have included a provider's direct and indirect costs necessary for the provision of patient care, including the cost of using assets in patient care. Depreciation of these assets is an allowable cost under Medicare and the allowance is computed using the depreciable basis and estimated useful life of the assets (§ 413.134). Under Medicare's reasonable cost reimbursement system, the appropriate allowance for depreciation and for interest on capital indebtedness on buildings and equipment used in the provision of patient care is based in part on the historical cost of the asset (§ 413.134(a) and (b)). When an asset is disposed of, no further depreciation may be taken on it. Gains and losses on the disposition of depreciable assets may be includable, as applicable, either in computing allowable cost or in computing the adjustment to Medicare reimbursable cost, depending upon the manner of disposition of the asset, the date of the disposal, and the amount of the depreciation adjustment (§ 413.134 and Part 1, Chapter 1 of the Provider Reimbursement Manual (CMS Pub. 15–1)).

Prior to the enactment of the Balanced Budget Act (BBA) of 1997 (Pub. L. 105–33), when a Medicare certified provider's capital asset was disposed of through sale or scrapping, Medicare shared in any gain or loss from the transaction. In this regard, if a provider realized a gain or loss from the sale or scrapping of an asset, an adjustment to the provider's allowable costs was necessary so that Medicare paid its

share of the actual cost the provider incurred in using the asset for patient care. Generally, when a provider sold its depreciable assets at more than the net book value, Medicare shared in the gain. If the provider sold its depreciable assets at less than the net book value, Medicare shared in the loss. The amount of a gain was limited to the amount of depreciation previously included in Medicare allowable costs. The amount of a loss was limited to the undepreciated basis of the asset permitted under the program.

In the BBA of 1997, Congress eliminated Medicare's recognition of gains or losses on a provider's disposition of assets on or after December 1, 1997. Section 4404 of the BBA of 1997 amended section 1861(v)(1)(O)(i) of the Act to state that, in establishing an appropriate allowance for depreciation and for interest on capital indebtedness with respect to an asset of a provider of services which has undergone a change of ownership, such regulations shall provide, except as provided in clause (iii), that the valuation of the asset after such change of ownership shall be the historical cost of the asset, as recognized under the Medicare program, less depreciation allowed, to the owner of record as of August 5, 1997 (or, in the case of an asset not in existence as of August 5, 1997, the first owner of record of the asset after August 5, 1997).

In enacting section 4404 of the BBA of 1997, Congress was concerned with providers that may have been ''creating specious 'losses' '' on the disposition of assets ''in order to be eligible for additional Medicare payments'' (H. Rep. No. 105–149 (1997)). In addition, Congress cited the June 1997 OIG report, Medicare Losses on Hospital Sales (OEI–03–96–00170), which indicated that there were substantial Medicare losses due to depreciation adjustments for hospitals that underwent changes of ownership. In a January 1998 final rule with comment period (63 FR 1379), we conformed the regulations at § 413.134 to section 1861(v)(1)(O) of the Act, as amended by section 4404 of the BBA of 1997. In that rule, we stated that, under the provisions of section 4404 of the BBA of 1997, ''when a depreciable asset of a provider undergoes a change of ownership, the valuation of the asset, for purposes of establishing a Medicare allowance for depreciation and interest, will be the historical cost of the asset to the owner of record, less depreciation allowed. Thus, when a depreciable asset is sold, the value of the asset to the seller will be the historical cost (as recognized under Medicare) to the owner of record as of August 5, 1997, less depreciation allowed. In this case, there will be no adjustment for gain or loss on the sale. For the buyer, the value of the asset will also be the historical cost (as recognized under Medicare) to the owner of record as of August 5, 1997, less depreciation allowed. Accordingly, the new owner's allowance for depreciation and interest will be based on this value. Stated simply, the asset moves from the hands of the seller to the hands of the buyer at the asset's net book value defined in § 413.134(b)(9)'' (63 FR 1381).

Our policy referenced the asset of a provider undergoing a change of ownership, meaning the asset itself changing owners, regardless of whether the provider changes ownership. In conforming the regulations to the new statutory provision, we revised the regulations at § 413.134(f)(1) to specify that ''[d]epreciable assets may be disposed of through sale, scrapping, trade-in, exchange, demolition, abandonment, condemnation, fire, theft, or other casualty. If disposal of a depreciable asset, including the sale or scrapping of an asset before December 1, 1997, results in a gain or loss, an adjustment is necessary in the provider's allowable cost. (No gain or loss is recognized on either the sale or the scrapping of an asset that occurs on or after December 1, 1997.) The amount of a gain included in the determination of allowable cost is limited to the amount of depreciation previously included in Medicare allowable costs. The amount of a loss to be included is limited to the undepreciated basis of the asset permitted under the program. The treatment of the gain or loss depends upon the manner of disposition of the asset, as specified in paragraphs (f)(2) through (6) of [§ 413.134]. The gain or loss on the disposition of depreciable assets has no retroactive effect on a proprietary provider's equity capital for years prior to the year of disposition.''

In the January 1998 final rule with comment period, we added the parenthetical ''(No gain or loss is recognized on either the sale or the scrapping of an asset that occurs on or after December 1, 1997)'' to § 413.134(f)(1). This parenthetical was intended to implement section 4404 of the BBA of 1997 by disallowing the gain or loss when a provider sells or scraps an asset.

We believe that, under section 4404 of the BBA of 1997, Medicare's nonrecognition of a loss or gain with respect to an asset a provider disposes of by sale or scrapping applies, regardless of whether the sale of the asset occurs incident to a provider's change of ownership or whether the asset is otherwise sold or scrapped by a currently participating Medicare provider.

We note that following the enactment of the Deficit Reduction Act of 1984 (Pub. L. 98–369, section 2314), in which Congress amended section 1861(v)(1) of the Act by adding new subparagraph (O) concerning the valuation and determination of historical costs of assets after July 18, 1984, we stated that the new provisions applied ''not only to the sale or purchase of groups of assets, but also to the sale or purchase of individual assets'' (57 FR 43913). Similarly, we believe section 4404 of the BBA of 1997 applies to a provider's disposition of assets through sale or scrapping, including the sale or scrapping of individual provider assets and assets sold or scrapped incident to a provider's change of ownership. Accordingly, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20142 through 20143), we proposed to revise the regulation text at § 413.134(f)(1) to clarify our longstanding policy that Medicare does not recognize a provider's gain or loss on the sale or scrapping of an asset that occurs on or after December 1, 1997, regardless of whether the asset is sold incident to a provider's change of ownership or is otherwise sold or scrapped as an asset of a Medicare participating provider.

We did not receive any public comments on our proposal. We are finalizing our proposal to revise the Medicare provider reimbursement regulations at § 413.134(f)(1) to clarify our longstanding policy that Medicare does not recognize a provider's gain or loss on the sale or scrapping of an asset that occurs on or after December 1, 1997, regardless of whether the asset is sold incident to a provider's change of ownership or is otherwise sold or scrapped as an asset of a Medicare participating provider.

XI. Changes Relating to Survey and Certification Requirements

A. Revisions to the Application and Re-Application Procedures for National Accrediting Organizations (AOs), and Posting of Survey Reports and Acceptable Plans of Corrections (PoCs)

In an effort to increase transparency, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20143), we proposed to require AOs with CMS-approved accreditation programs to post final accreditation survey reports and PoCs on public facing Web site designated by the AO. All current AOs with CMS-approved accreditation programs have Web sites that inform the general public about their organization.

We stated in the proposed rule that establishing the standard for posting both accredited and non-accredited provider and supplier survey reports, which would include initial and recertification surveys, and PoCs, would expand transparency even further. Disclosure of survey findings protects both patient health and safety, in which public disclosure of findings currently only shows the subset of complaint activity. Expanding these requirements through the posting of all survey reports and PoCs would allow for a more comprehensive way to show a provider's or supplier's compliance with all health and safety requirements.

In the proposed rule, we proposed to revise § 488.5 of the regulations to incorporate this proposed requirement. We further proposed to add a new standard at § 488.5(a)(21) to require that each national AO applying or reapplying for CMS-approval of its Medicare provider or supplier accreditation program provide a statement acknowledging that it agreed to make all Medicare provider or supplier final accreditation survey reports (including statements of deficiency findings), as well as acceptable PoCs publicly available on its Web site within 90 days after such information is made available to those facilities for the most recent 3 years. This provision would include all triennial, full, follow-up, focused, and complaint surveys, whether they were performed onsite or offsite. We invited public comments on these proposals.

After consideration of the public comments received, we are not finalizing our proposed changes to 42 CFR 488.5. Section 1865(b) of the Act prohibits CMS from disclosing survey reports or compelling the AOs to disclose their reports themselves. The suggestion by CMS to have the AOs post their survey reports may appear as if CMS was attempting to circumvent the provision of section 1865(b) of the Act. Therefore, this provision is effectively being withdrawn.

B. Changes to Termination Public Notice Requirements for Certain Providers and Suppliers

1. Background

Under the provisions of sections 1866(b)(2) of the Act and implementing regulations at 42 CFR 489.53, the Secretary may terminate an agreement with a provider of services if it is determined that the provider is not in substantial compliance with applicable requirements governing provider agreements. For instance, CMS must determine that the provider:

- Is not complying substantially with the terms of the agreement, the provisions of title XVIII, or regulations promulgated thereunder;
- Has failed to supply information necessary to determine whether payments are or were due and the amounts of such payments;
- Refuses to permit examination of fiscal and other records (including medical records) necessary for the verification of information furnished as a basis for claiming payment under the Medicare program; or
- Refuses to permit photocopying of any records or other information necessary to determine or verify compliance with participation requirements.

Sections 1866(b)(1) and (2) of the Act require reasonable public notice, as prescribed in regulations, of both voluntary and involuntary terminations of Medicare and Medicaid participating providers and suppliers. Various existing regulations specify the requirements of public notice for voluntary and involuntary terminations prior to termination of a provider or supplier agreement. Specifically, for voluntary terminations, providers at 42 CFR 489.52(c)(2), RHCs at 42 CFR 405.2404(d), FQHCs at 42 CFR 405.2442, ASCs at 42 CFR 416.35(d), and OPOs at 42 CFR 486.312(e) are required to publish termination notices in the local public newspaper.

2. Basis for Changes

The existing regulations requiring termination notices to be published in local newspapers have become outdated over time as the public and beneficiaries increasingly turn to the Internet and other electronic forums for information. Currently, rural health centers (RHCs), federally qualified health centers (FQHCs), ambulatory surgical centers (ASCs), and organ procurement organizations (OPOs) are required to publish public notices of voluntary and involuntary termination of participation in the Medicare and Medicaid programs in one or more local newspapers. Providers and suppliers that voluntarily terminate their participation agreement must give notice to the public at least 15 days before the effective date of termination and the notice must be published in one or more local newspapers. The use of hard copy local newspaper through time has become less effective, as a large majority of the public uses alternate sources such as Web sites or other online news and resources.

According to national studies, approximately 23 percent of the general public continues to read print newspapers.[510] Many individuals have turned to digital platforms to read news rather than print news, which continues to decline on an annual basis, therefore, limiting the effectiveness of publishing termination notices in local newspapers. In light of the public's increased access to the Internet and other electronic forums for information and the decline of print newspaper readership, in this proposed rule, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20145 and 20146), we proposed changes in the existing regulations noted earlier regarding newspaper publication of termination notices to allow CMS Regional Offices and providers and suppliers more media platforms in which to publish termination notices, both voluntary and involuntary, with the intent of making these notices more visible and effective.

3. Changes to Regulations

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20145 and 20146), we proposed to remove the regulatory language specifying public notice of terminations for FQHCs, RHCs, ASCs, and OPOs to be exclusively in newspapers to allow for more flexibility for both the CMS Regional Offices and providers and suppliers. Specifically, we proposed changes to the regulations for RHCs at 42 CFR 405.2404(d), for FQHCs at 42 CFR 405.2442(a) and (b), for ASCs at 42 CFR 416.35(d), and for OPOs at 42 CFR 486.312(e) to remove the reference to publication in newspapers as the means for notifying the community of involuntary and voluntary terminations from participation in Medicare and Medicaid programs. This proposal for termination notices to the public for RHCs, FHQCs, ASCs, and OPOs would align with the termination notices CMS currently has set forth for all other providers and suppliers. For example, under 42 CFR 488.456(c) (enforcement procedures for long-term care facilities), CMS must notify the public of a termination of a nursing home's provider agreement, but the regulation does not specify through which public forum this notice is to be given. Similarly, 42 CFR 489.53(d)(5) also does not specify the method of public notification required for terminations. Through this proposed change, RHCs, FQHCs, ASCs, and OPOs would have the same requirement for the notice to the public as under 42 CFR 489.53(d)(5), where there is a termination by CMS in which public

[510] PewResearchCenter (2012) *Number of Americans Who Read Print Newspapers Continues Decline.* Available at: *http://www.pewresearch.org/daily-number/number-of-americans-who-read-print-newspapers-continues-decline/.*

notice is required but the method for these providers or suppliers for providing public notice is not specified, to allow for flexibility.

In addition, we proposed to revise 42 CFR 489.52(c)(2) to remove the requirement to publish notice in one or more local newspapers in circumstances of the termination of a provider agreement by a provider and instead to allow providers to inform the community via public notice, without specifying the method used for public notice. We stated in the proposed rule that we believe that these proposed changes will ensure that the community continues to be aware of terminations of Medicare and Medicaid participating providers and suppliers.

The method for delivering the required public notice is no longer being specified by removing the word ''newspaper'' from the regulations for RHCs, FQHCs, ASCs, and OPOs. Instead, we proposed to allow for flexibility for the CMS Regional Offices and the providers or suppliers to post public notices through a manner in which the maximum number of community individuals and beneficiaries would be informed. This may include, but is not limited to State Web site postings, facility Web sites, or local news and social media channels. It also would not preclude publication in local newspapers. Through the proposed rule, we will continue to fulfill the regulatory requirement to publically post involuntary termination notices. We are also operationally considering allowing voluntarily terminating providers and suppliers the same public notice platform used for involuntary notices in order to meet their regulatory public notice requirements. This could include media venues such as Web site postings and press releases through the use of CMS Regional press officers.

We invited public comments on our proposals. In addition, we sought suggestions from the public on sufficient mechanisms to provide public information, other than local newspapers, for posting Medicare and Medicaid participating provider and supplier termination notices.

Comment: Several commenters supported the proposal to eliminate the use of newspapers to provide public notice and agreed that the use of newspapers has become outdated. One commenter agreed with the proposal to allow CMS Regional Offices to use media platforms in which to publish termination notices, both voluntary and involuntary, in a more visible and effective manner.

Response: We thank the commenter for its support.

We are finalizing our proposal to remove the word ''newspaper'' from the regulations for RHCs, FQHCs, ASCs, and OPOs under the requirements for public notices for terminations of the provider agreement.

XII. MedPAC Recommendations

Under section 1886(e)(4)(B) of the Act, the Secretary must consider MedPAC's recommendations regarding hospital inpatient payments. Under section 1886(e)(5) of the Act, the Secretary must publish in the annual proposed and final IPPS rules the Secretary's recommendations regarding MedPAC's recommendations. We have reviewed MedPAC's March 2017 ''Report to the Congress: Medicare Payment Policy'' and have given the recommendations in the report consideration in conjunction with the policies set forth in this final rule. MedPAC recommendations for the IPPS for FY 2018 are addressed in Appendix B to this final rule.

For further information relating specifically to the MedPAC reports or to obtain a copy of the reports, contact MedPAC at (202) 653–7226, or visit MedPAC's Web site at: *http://www.medpac.gov*.

XIII. Other Required Information

A. Requests for Data From the Public

IPPS-related data are available on the Internet for public use. The data can be found on the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. We listed the IPPS-related data files that are available in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20146 through 20147).

Commenters interested in discussing any data files used in construction of this final rule should contact Michael Treitel at (410) 786–4552.

B. Collection of Information Requirements

1. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20147 through 20158), we solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

2. ICRs for Temporary Exception to the LTCH PPS Site Neutral Payment Rate for Certain Spinal Cord Specialty Hospitals

In section VIII.E. of the preamble of the proposed rule and this final rule, we discuss the proposed implementation of section 15009 of Public law 114–255, which provides for a temporary exception to the site neutral payment rate for certain spinal cord specialty hospitals under section 1886(m)(6)(F) of the Act. Under this provision, discharges occurring in cost reporting periods beginning during FY 2018 and FY 2019 for LTCHs that meet the specified statutory criteria are excepted from the site neutral payment rate (that is, all discharges from such LTCHs during this period would be paid at the LTCH PPS standard Federal payment rate). In order for an LTCH to qualify for this temporary exception, the LTCH must, among other things, meet the ''significant out-of-state admissions criterion'' at section 1886(m)(6)(F)(iii) of the Act. To meet the significant out-of-state admissions criterion, an LTCH must have discharged inpatients (including both individuals entitled to, or enrolled for, Medicare Part A benefits and individuals not so entitled or enrolled) during FY 2014 who had been admitted from at least 20 of the 50 States, determined by the States of residency of such inpatients and based on such data submitted by the hospital to the Secretary as the Secretary may require. The statute further provides authority for the Secretary to implement the significant out-of-state admissions criterion at section 1886(m)(6)(F)(iii) of the Act by program instruction or otherwise, and exempts the policy initiatives from any information collection requirements under the Paperwork Reduction Act. As such, the burden associated with the data

submitted by the hospital to meet the significant out-of-State admissions criteria is not subject to the PRA. However, our estimate of the burden associated with this data submission is discussed in section I.J. of Appendix A of this final rule.

We did not receive any public comments on this information collection.

3. ICRs for the Hospital Inpatient Quality Reporting (IQR) Program

a. Background

OMB has currently approved 3,681,023 hours of burden and approximately $121 million under OMB control number 0938–1022, accounting for burden experienced by 3,300 IPPS hospitals and 1,100 non-IPPS hospitals for the FY 2019 payment determination. In section IX.A. of the preambles of the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20031 through 20075) and this final rule, we discuss the policies that we expect to affect our burden estimates. We refer readers to section I.A.2.h. of the preamble of this final rule, where we summarize our finalized policies. The details about our finalized policies that impact information collection requirements for IPPS-hospitals are described below.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20149) and prior rules (81 FR 57260) and (80 FR 49763), we have estimated that reporting eCQMs for the Hospital IQR Program could be accomplished by staff with a median hourly wage of $16.42 per hour.[511] We note that since the publication of the FY 2018 IPPS/LTCH PPS proposed rule, more recent wage data have become available, and we are updating the wage rate used in these calculations in this FY 2018 IPPS/LTCH PPS final rule. The most recent data from the Bureau of Labor Statistics reflects a median hourly wage of $18.29 per hour for a Medical Records and Health Information Technician professional.[512] We calculated the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, consistent with previous years (81 FR 57260). This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer-to-employer and because methods of estimating these costs vary widely from study-to-study. Nonetheless, we believe that doubling the hourly wage rate ($18.29 × 2 = $36.58) to estimate total cost is a reasonably accurate estimation method. Accordingly, we calculate cost burden to hospitals using a wage plus benefits estimate of $36.58 per hour throughout the discussion below for the Hospital IQR Program.

b. Burden Estimates for the Modifications to the eCQM Reporting Requirements for the CY 2017 Reporting Period/FY 2019 Payment Determination and CY 2018 Reporting Period/FY 2020 Payment Determination

In the FY 2017 IPPS/LTCH PPS final rule, we finalized policies to require hospitals to submit a full year (four quarters) of data (81 FR 57159) for at least eight of the available eCQMs in the Hospital IQR Program measure set (81 FR 57157) for both the FY 2019 and FY 2020 payment determinations. In section IX.A.8. of the preamble of this final rule, we are finalizing modified, reduced eCQM reporting requirements. For both the CY 2017 reporting period/FY 2019 payment determination and the CY 2018 reporting period/FY 2020 payment determination, hospitals will be required to report four eCQMs and to submit one, self-selected calendar quarter of data.

As in previous years, we believe the total burden associated with eCQM reporting will be similar to that previously outlined in the Medicare EHR Incentive Program Stage 2 final rule (77 FR 54126 through 54133). Under that program, the burden estimate for a hospital to report one eCQM is 10 minutes per record per quarter. We believe this estimate is accurate and appropriate to apply to the Hospital IQR Program because we align the eCQM reporting requirements between both programs. Therefore, using the estimate of 10 minutes per record per quarter, we anticipate our finalized policies to require: (1) Reporting on at least four of the available eCQMs; and (2) submission of one, self-selected quarter of eCQM data, will result in a burden reduction of 4.67 hours (280 minutes) per hospital for each of the FY 2019 and FY 2020 payment determinations. This estimate was calculated by considering the burden difference between the updated eCQM reporting requirements finalized in section IX.A.8. of the preamble of this final rule for each of the FY 2019 and FY 2020 payment determinations, which are the same (10 minutes per record × 4 eCQMs × 1 quarter = 40 minutes for 1 quarter of reporting), and the eCQM reporting requirements previously finalized in the FY 2017 IPPS/LTCH PPS final rule for each of the CY 2017 and CY 2018 reporting periods (81 FR 57157 through 57159) (10 minutes per record × 8 eCQMs × 4 quarters = 320 minutes for 4 quarters of reporting). Through these calculations (40 minutes − 320 minutes), we arrived at a reduction of 280 minutes per hospital per year, or 4.67 hours per hospital per year, for each of the FY 2019 and FY 2020 payment determinations.

In total, for each of the FY 2019 and FY 2020 payment determinations, we expect our finalized proposal to require hospitals to report one, self-selected calendar quarter of data for 4 eCQMs (as compared to our previously finalized requirements to report four quarters of data for 8 eCQMs) to represent an annual burden reduction of 15,400 hours across all 3,300 IPPS hospitals participating in the Hospital IQR Program (−280 minutes per hospital/60 minutes per hour × 3,300 hospitals = −15,400 hours). Using the updated wage estimate described above, we expect this to represent a cost reduction of $563,332 ($36.58 hourly wage × 15,400 annual hours reduction) across all 3,300 IPPS hospitals participating in the Hospital IQR Program for each of the FY 2019 and FY 2020 payment determinations. In summary, we estimate a revised total burden of 2,200 hours (40 minutes per hospital/60 minutes per hour × 3,300 hospitals) and $80,476 (2,200 hours across 3,300 hospitals × $36.58 per hour) across all hospitals associated with this finalized policy.

c. Burden Estimate for the Modifications to eCQM Certification Requirements for the FY 2019 and FY 2020 Payment Determinations

In section IX.10.d. of the preamble of this final rule, we discuss changes we are finalizing to the Hospital IQR Program eCQM submission requirements to align them with the Medicare EHR Incentive Program for eligible hospitals and CAHs. Specifically, for both the CY 2017 reporting period/FY 2019 payment determination and the CY 2018 reporting period/FY 2020 payment determination, we are finalizing that: (1) A hospital using EHR technology certified to the 2014 Edition, 2015 Edition, or a combination of both, but such EHR technology is not certified to all available eCQMs, will be required to have its EHR technology certified to all eCQMs that are available to report; and (2) EHR technology that is certified to all available eCQMs will not need to be recertified each time it is updated to a more recent version of the eCQM specifications. Further, we are finalizing that: (1) For the CY 2017 reporting period, hospitals will be required to use

[511] Occupational Outlook Handbook. Available at: *http://www.bls.gov/oes/2012/may/oes292071.htm.*

[512] Occupational Employment and Wages, May 2016. Available at: *https://www.bls.gov/oes/current/oes292071.htm.*

the most recent version of the CQM electronic specifications (namely, the Spring 2016 version of the eCQM specifications and any applicable addenda); and (2) for the CY 2018 reporting period, hospitals be required to use the most recent version of the CQM electronic specifications (namely, the Spring 2017 version of the eCQM specifications and any applicable addenda). Because the use of certified EHR technology is already required for the Medicare EHR Incentive Program, we believe that harmonizing these finalized policies will create no additional burden for hospitals under the Hospital IQR Program. We refer readers to OMB control number 0938–1158 for a discussion of the burden associated with the requirements for the Medicare EHR Incentive Program.

d. Burden Estimates for the Modifications to the Existing Data Validation Processes

(1) Calculations for Modifications to the Validation of eCQM Data for the FY 2020 and FY 2021 Payment Determinations and Subsequent Years

In section IX.A.11. of the preamble of this final rule, we discuss our finalized policies for the eCQM data validation process for the Hospital IQR Program data beginning with validation for the FY 2020 payment determination. First, we are finalizing our proposal to require hospitals selected for eCQM data validation to submit 8 cases per quarter for eCQM validation for the FY 2020 payment determination and subsequent years. As applied with our finalized modified, reduced policy to require one, self-selected calendar quarter of data for each of the CY 2017 and CY 2018 eCQM reporting periods, hospitals will be required to submit 8 records (eight cases per quarter over one quarter) for each of the FY 2020 and FY 2021 payment determinations. Second, we are finalizing our proposal to add additional exclusion criteria to our hospital and case selection process for eCQM data validation for the FY 2020 payment determination and subsequent years. Third, we are finalizing our proposal to continue our previously finalized medical record submission requirements (81 FR 57181), for the FY 2021 payment determination and subsequent years. We believe these additional exclusions and maintaining previously finalized medical record submission requirements will have no effect on burden for hospitals, because, while they influence which hospitals and cases will be selected, they will not change the number of hospitals that must participate in eCQM validation, the number of records that will be collected for validation, or the validation reporting requirements for the hospitals selected. We discuss the burden associated with the finalized eCQM data validation process in more detail below.

In previous years (79 FR 50347), we estimated a burden of 16 hours (960 minutes) for the submission of 12 records, which will equal 1 hour and 20 minutes (or 80 minutes) per record (960 minutes / 12 records) for validation of eCQM data. Applying the time per individual submission of 1 hour and 20 minutes (or 80 minutes) per record for the 8 records we are requiring hospitals selected for eCQM data validation to submit for each of the FY 2020 and FY 2021 payment determinations, we estimate a total burden of approximately 10.67 hours (80 minutes × 8 records/60 minutes per hour) for each hospital selected for participation in eCQM data validation for the FY 2020 and FY 2021 payment determinations. We estimate that the total burden will be approximately 2,133 hours across the 200 hospitals selected for eCQM validation (10.67 hours per hospital × 200 hospitals = 2,133 hours). As compared to our total burden estimate of 8,533 hours previously estimated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57261), this represents a burden reduction of approximately 6,400 hours across up to 200 hospitals selected for eCQM validation (2,133 hours estimated in this final rule—8,533 hours estimated in the FY 2017 IPPS/LTCH PPS final rule = −6,400 hours). Using the estimated hourly labor cost of $36.58, we estimate an annual cost reduction of $234,112 (6,400 hours × $36.58 per hour) across the 200 hospitals selected for eCQM validation due to our finalized policy to decrease the number of records collected for validation from 32 records to 8 records for each of the FY 2020 and FY 2021 payment determinations. In summary, we estimate a revised total burden of 2,133 hours (10.67 hours × 200 hospitals) and $78,025 (2,133 hours across 200 hospitals × $36.58 per hour) associated with this finalized policy.

(2) Calculations for Modifications to the eCQM Data Validation Exclusions for the FY 2020 Payment Determination and Subsequent Years

In section IX.A.11.b. of the preamble of this final rule, we are finalizing our an additional eCQM data validation exclusion criterion. Specifically, hospitals that do not have at least five discharges for at least one reported eCQM (among the 4 required eCQMs finalized for each of the CY 2017 and CY 2018 eCQM reporting periods) included in their QRDA I file submissions will be excluded from the random sample of up to 200 hospitals selected for eCQM validation for the FY 2020 payment determination and subsequent years. For the FY 2020 payment determination and subsequent years, hospitals meeting this newly finalized exclusion criterion discussed above and/or either of the two additional exclusion criteria previously finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57178) will be excluded from the random sample of up to 200 hospitals selected for eCQM data validation. Lastly, we are finalizing our proposal that the three exclusion criteria will be applied before the random selection of 200 hospitals for eCQM validation, such that hospitals meeting any one of these exclusions will not be eligible for selection.

In section IX.A.11.b. of the preamble of this final rule, we are finalizing our proposal to exclude the following cases from validation for those hospitals selected to participate in eCQM data validation: (1) Episodes of care that are longer than 120 days; and (2) cases with a zero denominator for each measure, for the FY 2020 payment determination and subsequent years. We do not believe that these finalized policies will affect the burden experienced by hospitals because, while they influence which hospitals and cases will be selected, they will not change the number of hospitals that must participate in eCQM validation, the number of records that will be collected for validation, or the validation reporting requirements for the hospitals selected.

e. Burden Estimate for Voluntary Reporting on the Hybrid Hospital-Wide 30-Day Readmission Measure for the CY 2018 Reporting Period

In section IX.A.7. of the preamble of this final rule, we are finalizing our proposal to begin voluntary reporting on the Hybrid Hospital-Wide 30-Day Readmission (HWR) measure for CY 2018 reporting period. This measure uses both claims-based data as well as a set of 13 core clinical data elements from patient electronic health records (EHRs) and 6 linking variables. We do not expect any additional burden to hospitals to report the claims-based portion of this measure because these data are already reported to the Medicare program for payment purposes.

As described in section IX.A.7.b. of the preamble of this final rule, we are finalizing our proposal that hospitals may voluntarily submit the 13 core clinical data elements and the six data

elements required for linking with claims data for this measure using the same submission process required for eCQM reporting, specifically, that these data be reported using QRDA I files submitted to the CMS data receiving system. Accordingly, we expect the burden associated with voluntary reporting of this measure to be similar to our estimates for eCQM reporting (that is 10 minutes per measure, per quarter). Consistent with estimates for previous voluntary reporting of quality measures, such as the eCQM reporting pilot, we anticipate that approximately 100 hospitals will voluntarily report the Hybrid HWR measure. Therefore, using the estimate of 10 minutes per measure per quarter, we estimate that our proposal will result in a burden increase of 0.67 hours (40 minutes) per participating hospital for the one year (4 quarters) during which this voluntary measure will take place (10 minutes per record × 1 measure × 4 quarters / 60 minutes per hour = 0.67 hours). In total, for the one year duration of voluntary reporting the Hybrid HWR measure, we estimate an annual burden increase of 67 hours across up to 100 hospitals voluntarily participating (40 minutes per hospital / 60 minutes per hour × 100 hospitals = 67 hours). Using the updated wage estimate described above, we estimate this to represent a cost increase of $2,451 ($36.58 hourly wage × 67 annual hours) across up to 100 hospitals voluntarily participating in reporting for the Hybrid HWR measure. We note that the claims-based version of the Hospital-Wide All-Cause Unplanned Readmission measure is currently a part of the Hospital IQR Program measure set, as adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53530).

f. Burden Estimate for the Refinement of the HCAHPS Survey Measure for the FY 2020 Payment Determination and Subsequent Years

In section IX.A.6.a. of the preamble of this final rule, we are finalizing our proposal to update the HCAHPS survey measure (OMB control number 0938–0981) by replacing the current set of three Pain Management questions (HCAHPS Q12, Q13, and Q14) with new questions referred to collectively as the ''Communication About Pain'' composite measure beginning with the FY 2020 payment determination. There is no additional information collection burden associated with the refinement of these questions because we are rewording the existing questions and not changing the total number of questions.

g. Burden Estimate for the Refinement of the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Ischemic Stroke Measure for the FY 2023 Payment Determination and Subsequent Years

In section IX.A.6.b. of the preamble of this final rule, we are finalizing our proposal to refine the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Ischemic Stroke measure to include the use of NIH stroke scale claims data for risk adjustment beginning with the FY 2023 payment determination. Because this refinement will result only in the inclusion of additional claims-based data that are already reported to the Medicare program for payment purposes, we believe no additional burden on hospitals will result from the update to the stroke mortality measure.

h. Burden Estimate for the Changes to the Hospital IQR Program Extraordinary Circumstances Exceptions (ECE) Policy for the FY 2020 Payment Determination and Subsequent Years

In section IX.A.15.b. of the preamble of this final rule we discuss our alignment of the naming of this exception policy and update to 42 CFR 412.140 to reflect our current ECE policies. We also are clarifying the timing of CMS' response to ECE requests. Because we are not seeking any new or additional information in our ECE finalized proposals, we believe the updates will have no effect on burden for hospitals.

i. Summary of Burden Estimates for the Hospital IQR Program

In summary, under OMB control number 0938–1022, we estimate: (1) A burden reduction of 15,400 hours (−15,400 hours due to the finalized modifications to the CY 2017 reporting period/FY 2019 payment determination eCQM reporting requirements) and a total cost reduction of $563,332 (−15,400 hours × $36.58 per hour) for the FY 2019 payment determination; (2) a burden reduction of 21,733 hours (−15,400 hours due to the finalized modifications to the CY 2018 eCQM reporting requirements for the CY 2018 reporting period/FY 2020 payment determination −6,400 hours due to the finalized modifications to the eCQM data validation process for the FY 2020 payment determination + 67 hours for the voluntary reporting of the Hybrid HWR measure) and a total cost reduction of $794,993 (−21,733 hours × $36.58 per hour) for the FY 2020 payment determination; and (3) a burden reduction of 6,400 hours (−6,400 hours due to the finalized modifications to eCQM validation process for the FY 2021 payment determination) and a total cost reduction of $234,112 (−6,400 hours × $36.58 per hour) for the FY 2021 payment determination. We therefore estimate a total burden reduction of 43,533 hours and $1,592,437 across all hospitals as a result of the finalized proposals in this final rule. These are the burden estimate updates for which we are requesting OMB approval under OMB number 0938–1022.

HOSPITAL IQR PROGRAM CY 2017 REPORTING PERIOD/FY 2019 PAYMENT DETERMINATION BURDEN ESTIMATES

Activity	Annual recordkeeping and reporting requirements under OMB control number 0938–1022 for CY 2017 reporting period/FY 2019 payment determination							
	Estimated time per record (minutes)	Number reporting quarters per year	Number of IPPS hospitals reporting	Average number records per hospital per quarter	Annual burden (hours) per hospital	Newly finalized annual burden (hours) across IPPS hospitals	Previously finalized annual burden (hours) across IPPS hospitals	Net difference in annual burden hours
Reporting on 4 eCQMs for 1 Quarter.	40 (10 minutes × 4 measures).	1	3,300	1	0.67	2,200	17,600	−15,400
	Total Change in Burden Hours: −15,400 Total Cost Estimate: Updated Hourly Wage ($36.58) × Change in Burden Hours (−15,400) = −$563,332							

HOSPITAL IQR PROGRAM CY 2018 REPORTING PERIOD/FY 2020 PAYMENT DETERMINATION BURDEN ESTIMATES

Activity	Annual recordkeeping and reporting requirements under OMB control number 0938–1022 for CY 2018 reporting period/FY 2020 payment determination							
	Estimated time per record (minutes)	Number reporting quarters per year	Number of IPPS hospitals reporting	Average number records per hospital per quarter	Annual burden (hours) per hospital	Newly finalized annual burden (hours) across IPPS hospitals	Previously finalized annual burden (hours) across IPPS hospitals	Net difference in annual burden hours
Reporting on 4 eCQMs for 1 Quarter.	40 (10 minutes × 4 measures).	1	3,300	1	0.67	2,200	17,600	−15,400
FY 2020 eCQM Data Validation.	80	1	200	8	10.67	2,133	8,533	−6,400
Hybrid Hospital-Wide 30-Day Readmission Measure Voluntary Reporting.	10	4	100	1	0.67	67	0	67
	Total Change in Burden Hours: −21,733 Total Cost Estimate: Updated Hourly Wage ($36.58) × Change in Burden Hours (−21,733) = −$794,993							

HOSPITAL IQR PROGRAM CY 2019 REPORTING PERIOD/FY 2021 PAYMENT DETERMINATION BURDEN ESTIMATES

Activity	Annual recordkeeping and reporting requirements under OMB control number 0938–1022 for CY 2019 reporting period/FY 2021 payment determination							
	Estimated time per record (minutes)	Number reporting quarters per year	Number of IPPS hospitals reporting	Average number records per hospital per quarter	Annual burden (hours) per hospital	Newly finalized annual burden (hours) across IPPS hospitals	Previously finalized annual burden (hours) across IPPS hospitals	Net difference in annual burden hours
FY 2021 eCQM Data Validation.	80	1	200	8	10.67	2,133	8,533	−6,400
	Total Change in Burden Hours: −6,400 Total Cost Estimate: Updated Hourly Wage ($36.58) × Change in Burden Hours (−6,400) = −$234,112							

We received the following public comment regarding our burden estimates.

Comment: One commenter objected to the notion that reporting eCQMs for the Hospital IQR Program measures could be accomplished by staff with a mean hourly wage of $16.42 per hour. The commenter encouraged CMS to reevaluate this calculation and utilize the salary surveys by professional organizations like the Health Information Management System Society (HIMSS).

Response: As we noted in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20149), we acknowledge that more recent wage data have become available from the Bureau of Labor and Statistics (BLS),[513] and we have updated the Hospital IQR Program wage estimate above using these updated data in this final rule. We believe the BLS is the most appropriate source of these data, because the BLS collects a far greater volume of employment and wage data through its surveys than other sources such as the HIMSS Compensation Survey.[514] In addition, the HIMSS Compensation Survey is a proprietary tool intended to assist health information technology professionals compare salaries and compensation packages, whereas the BLS is intended to provide a large-scale survey of national employment statistics. HIMSS does not suggest what level employee would likely be doing this work; we note that while the HIMSS Compensation Survey 2015 provides overall salary data, it does not explicitly state, or provide granular enough employee groupings to be able to determine which level of employee would likely be doing this work. We utilized data from the BLS since we could ascertain a specific wage rate for the associated position of a person doing this work. We will continue to evaluate the appropriateness of using the BLS wage rate in future years.

4. ICRs for PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

As discussed in sections IX.B. of the preambles of the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20075 through 20086) and this final rule, section 1866(k)(1) of the Act requires, for purposes of FY 2014 and each subsequent fiscal year, that a hospital described in section 1886(d)(1)(B)(v) of the Act (a PPS-exempt cancer hospital, or a PCH) submit data in accordance with section 1866(k)(2) of the Act with respect to such fiscal year. There is no financial impact to PCH Medicare reimbursement if a PCH does not participate.

We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50957 through 50959), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50347 through 50348), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49764), and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57182), as well as to OMB Control Number 0938–1175, for a detailed discussion of the burden related to the program requirements that we have previously adopted. Below we discuss only changes in burden that will result from the policies we are finalizing in this final rule.

a. Estimated Hourly Labor Cost

Previously, we used $66 as our hourly labor cost in calculating the burden associated with chart-abstraction activities in the PCHQR Program. However, our experience working with our data analysis contractors and those

[513] Occupational Employment and Wages, May 2016. Available at: *https://www.bls.gov/oes/current/oes292071.htm.*

[514] 2015 HIMSS Salary Calculator & Compensation Survey. Available at: *http://www.himss.org/compensationSurvey.*

performing chart abstraction indicates that this work is performed by a different labor category than we previously thought. In addition, our previous labor costs are different from those used in other quality reporting and value-based purchasing programs, and we do not believe there is a justification for these different values given the similarity in quality measures and required staff. Therefore, to align the estimated hourly labor costs (hourly wage plus fringe and overhead, as discussed below) used to calculate burden in the PCHQR Program with those used in other CMS quality reporting programs, including the Hospital IQR Program, we are finalizing our proposal to revise our hourly labor cost estimate to $36.58 ($32.84 [515] with a modification) which incorporates hourly wage plus fringe benefits and overhead costs.

This labor cost is based on the May 2016 BLS wage for a Medical Records and Health Information Technician. The BLS is ''the principal Federal agency responsible for measuring labor market activity, working conditions, and price changes in the economy.'' [516] The BLS describes Medical Records and Health Information Technicians as those responsible for organizing and managing health information data; therefore, we believe it is reasonable to assume that these individuals will be tasked with abstracting clinical data for submission for the PCHQR Program. According to the BLS, the median pay for Medical Records and Health Information Technicians which we used in the proposed rule was $16.42 per hour, before inclusion of overhead and fringe benefits. However, we have learned that the BLS has updated the median pay for Medical Records and Health Information Technicians to $18.29 per hour, before inclusion of overhead and fringe benefits. We used this updated estimate for this final rule.

Obtaining data on overhead costs is challenging because overhead costs vary across PCHs, and cost elements assigned as ''indirect'' or ''overhead'' costs, as opposed to direct costs or employee wages, are subject to interpretation at the facility level. Therefore, we are finalizing our proposal to calculate the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, as is currently done in other CMS quality reporting programs.[517] This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the updated hourly wage rate ($18.29 × 2 = $36.58) to estimate total cost is a reasonably accurate estimation method. Accordingly, we are finalizing, with a modification to update the hourly labor cost, our proposal to use an hourly labor cost estimate of $36.58 ($18.29 base salary + $18.29 fringe and overhead) for calculation of burden forthwith. We again note that because more recent wage data has become available, we are updating the wage rate used in these calculations in this FY 2018 IPPS/LTCH PPS final rule.

We did not receive any public comments on this proposal.

b. Estimated Burden of PCHQR Program Finalized Proposals for the FY 2020 Program Year

In section IX.B.4. of the preamble of this final rule, we are finalizing our proposals to adopt four claims-based measures beginning with the FY 2020 program: (1) Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (NQF #0210); (2) Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life (NQF #0213); (3) Proportion of Patients Who Died from Cancer Not Admitted to Hospice (NQF #0215); and (4) Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days (NQF #0216).

In conjunction with these finalized policies, in section IX.B.3.b. of the preamble of this final rule, we are finalizing the removal of three existing chart-abstracted measures beginning with the FY 2020 program—(1) Adjuvant Chemotherapy is Considered or Administered Within 4 Months (120 Days) of Diagnosis to Patients Under the Age of 80 with AJCC III (Lymph Node Positive) Colon Cancer (PCH–01/NQF #0223); (2) Combination Chemotherapy is Considered or Administered Within 4 Months (120 Days) of Diagnosis for Women Under 70 with AJCC T1c, or Stage II or III Hormone Receptor Negative Breast Cancer (PCH–02/NQF #0559); and (3) Adjuvant Hormonal Therapy (PCH–03/NQF #0220)). Therefore, the PCHQR Program measure set will consist of 18 measures for the FY 2020 program.

Our finalized policy to remove the three chart-abstracted measures will reduce the burden associated with quality data reporting on PCHs. We relied on the estimates finalized in the FY 2013 IPPS/LTCH PPS final rule to estimate the reduction in burden because the measures we proposed to remove were adopted in the FY 2013 IPPS/LTCH PPS final rule, and the burden estimates for these chart-abstracted measures have not been amended since their introduction. The burden associated with these reporting requirements is currently under OMB Control Number 0938–1175. Therefore, based on the FY 2013 IPPS/LTCH PPS final rule (77 FR 53667) finalized estimates of the burden of collecting measure information, submitting measure information, and training personnel, we estimate the reduction in burden for collecting measure information, submitting measure information, and training personnel provided by the removal of the three measures to be approximately 3,776 hours per year for each PCH, or an average reduction in burden of 315 hours per month per PCH. Therefore, we estimate a reduction in hourly burden of chart abstraction and data submission of approximately 41,537 hours per year across the 11 PCHs.[518]

We do not anticipate any increase in burden on the PCHs corresponding to our finalized policy to adopt four claims-based measures into the PCHQR Program beginning with the FY 2020 program year. The four measures are claims-based and therefore do not require facilities to report any additional data. Because these measures do not require facilities to submit any additional data, we do not believe that there is any increase in burden associated with this proposal.

In summary, as a result of our finalized policies, we estimate a reduction of 41,537 hours of burden per year associated with the proposals above for all 11 PCHs beginning with the FY 2020 program. Coupled with our updated estimated salary costs, we estimate that these proposed changes will result in a reduction in annual labor costs of $1,519,427 (41,537.1 hours × $36.58 hourly labor cost) across the 11 PCHs beginning with the FY 2020 PCHQR Program. The burden associated with these reporting requirements is currently under OMB Control Number

[515] *https://www.bls.gov/oes/2012/may/oes292071.htm.*

[516] *http://www.bls.gov/bls/infohome.htm.*

[517] See, for example, FY 2016 IPPS/LTCH PPS final rule (80 FR 49764 FN 153).

[518] In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53667), we originally calculated the burden for reporting the three chart-abstracted cancer measures and two NHSN CDC measures (CLABSI and CAUTI) at approximately 6,293.5 hours annually for each PCH, or 69,228.5 burden hours annually for all 11 PCHs. To calculate the reduction in burden achieved by removing three of these five measures, we multiplied the annual burden by 11 (the number of PCHs), divided by 5 (the total number of measures making up the burden estimate), and multiplied the result by 3 (the total number of measures being removed).

0938–1175. The information collection will be revised and submitted to OMB.

5. ICRs for the Hospital Value-Based Purchasing (VBP) Program

In section V.J. of the preambles of the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19968 through 19986) and this final rule, we discuss proposed and newly finalized requirements for the Hospital VBP Program. Specifically, in this final rule, with respect to quality measures, we are finalizing our proposals to: (1) Remove the current Patient Safety for Selected Indicators (PSI 90) measure beginning with the FY 2019 program year; (2) adopt the Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Pneumonia (PN Payment) measure beginning with the FY 2022 program year; and (3) adopt the Patient Safety and Adverse Events (Composite) (NQF #0531) (modified PSI 90) beginning with the FY 2023 program year.

As required under section 1886(o)(2)(A) of the Act, Hospital VBP Program measures, including the finalized additional and updated measures, are used in the Hospital IQR Program. Therefore, their inclusion in the Hospital VBP Program does not result in any additional burden because the Hospital VBP Program uses data that are required for and collected under the Hospital IQR Program. Therefore, the burden associated with these reporting requirements is currently approved under OMB Control Number 0938–1022.

6. ICRs for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

As discussed in section IX.C.7.a. of the preamble of this final rule, we are finalizing our proposals to replace the current pressure ulcer measure beginning with the FY 2020 LTCH QRP and adopt two new measures also beginning with the FY 2020 LTCH QRP.

LTCH QRP Quality Measures Newly Finalized in This FY 2018 IPPS/LTCH PPS Final Rule Beginning With the FY 2020 LTCH QRP

Measure title
Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury.
Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay.
Ventilator Liberation Rate.

The LTCH QRP measure set also currently includes claims-based measures that are calculated based on data that LTCHs are already required to report to the Medicare program for payment purposes. In this final rule, we are finalizing our proposal to remove the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512) from the LTCH QRP measure set, beginning with the FY 2019 LTCH QRP. However, because LTCHs will still be required to report data on this measure for payment purposes, we believe that the removal of this measure will not affect the burden estimate for the LTCH QRP.

The LTCH CARE Data Set Version 3.00 was implemented April 1, 2016 and is approved under OMB control number 0938–1163. The LTCH CARE Data Set Version 3.00 is available on the LTCH QRP Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-CARE-Data-Set-and-LTCH-QRP-Manual.html*. For a discussion of burden related to LTCH CARE Data Set Version 3.00, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57339 through 57341).

The LTCH CARE Data Set Version 4.00 will be effective July 1, 2018, as discussed in section IX.C.11.d. of the preamble of the proposed rule. The associated burden for the Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP quality measure was finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57219 through 57223).

In this final rule, we are finalizing our proposals to adopt three measures: Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury; and two new measures related to ventilator weaning, Compliance with SBT by Day 2 of the LTCH Stay and Ventilator Liberation Rate.

Adoption of the proposed pressure ulcer measure, Change in Skin Integrity Post-Acute Care: Pressure Ulcer Injury, to replace the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), will result in the removal of some data elements related to pressure ulcer assessment that we believe are duplicative or no longer necessary. As a result, the estimated burden and cost for LTCHs to report the measure we are finalizing in this final rule will be reduced from the burden and cost to report the current measure. Specifically, we believe that there will be a 3-minute reduction in clinical staff time to report data. We estimate 146,592 discharges from 426 LTCHs annually. This equates to a decrease of 7,330 hours in burden for all LTCHs (0.05 hours × 146,592 discharges). Given 3 minutes of RN time at $69.40 per hour completing an average of 344 sets of LTCH CARE Data Set assessments per provider per year, we estimated the total cost will be reduced by $1,194.07 per LTCH annually, or $508,674 for all LTCHs annually. This decrease in burden will be accounted for in the information collection under OMB control number (0938–1163).

We estimate the additional data elements for the newly finalized Compliance with SBT by Day 2 of the LTCH Stay quality measure will take 1.5 minutes of clinical staff time to report data on admission. We believe that the additional LTCH CARE Data Set items we are finalizing will be completed by registered nurses and respiratory therapists (RT). Individual LTCHs determine the staffing resources necessary. We estimate 146,592 discharges from 426 LTCHs annually. This equates to an increase of 3,665 hours in burden for all LTCHs (0.025 hours × 146,592 discharges). Given 0.75 minutes of RN time at $69.40 per hour and 0.75 minutes of RT time at $58.30 per hour completing an average of 344 sets of LTCH CARE Data Set assessments per provider per year, we estimated the total cost will be increased by $549.29 per LTCH annually, or $233,997 for all LTCHs annually. This increase in burden will be accounted for in the information collection under OMB control number (0938–1163).

We estimate the additional elements for the newly finalized Ventilator Liberation Rate quality measure will take 2.7 minutes of clinical staff time to report data on admission and 0.3 minutes of clinical staff time to report data on discharge, for a total of 3 minutes. We believe that the additional LTCH CARE Data Set items we are finalizing will be completed by registered nurses and respiratory therapists. Individual LTCHs determine the staffing resources necessary. We estimate 146,592 discharges from 426 LTCHs annually. This equates to an increase of 7,330 hours in burden for all LTCHs (0.05 hours × 146,592 discharges). Given 2.85 minutes of RN time at $69.40 per hour and 0.15 minutes of respiratory therapist (RT) time at $58.30 per hour completing an average of 344 sets of LTCH CARE Data Set assessments per provider per year, we estimated the total cost will be increased by $1,184.52 per LTCH annually, or $504,606 for all LTCHs annually. This increase in burden will be accounted for in the information collection under OMB control number (0938–1163).

We are finalizing our proposal to remove the program interruption items from the LTCH CARE Data Set. Specifically, we are finalizing our proposal to remove the following items: (1) A2500, Program Interruption(s); (2) A2510, Number of Program Interruptions During This Stay in This Facility; and (3) A2525, Program Interruption Dates, because we do not currently utilize this information nor do we have plans to utilize this information for the LTCH QRP. As a result, the estimated burden and cost for LTCHs will be reduced. Specifically, we believe that there will be a 3.6 minute reduction in clinical staff time to report data. We estimate 146,592 discharges from 426 LTCHs annually. This equates to a decrease of 8,796 hours in burden for all LTCHs (0.06 hours × 146,592 discharges). Given 3.6 minutes of RN time at $69.40 per hour completing an average of 344 sets of LTCH CARE Data Set assessments per provider per year, we estimated the total cost will be reduced by $1,432.89 per LTCH annually, or $610,409 for all LTCHs annually. This decrease in burden will be accounted for in the information collection under OMB control number (0938–1163).

Also, in section IX.C.10. of the preamble of this final rule, we are finalizing standardized patient assessment data proposals with respect to the Functional Status and Medical Condition and Comorbidity categories. All of the data elements are already included on the LTCH CARE Data Set, and therefore our finalized proposal to characterize those data elements as standardized patient assessment data will not result in an additional reporting burden for LTCHs.

We are not finalizing our proposals to adopt 25 new standardized patient assessment data elements with respect to LTCH admissions and 17 new standardized patient assessment data elements with respect to LTCH discharges. In the FY 2018 IPPS/LTCH PPS proposed rule (81 FR 20225 through 20226), we discussed that our burden estimates for these proposals were estimated at an additional $4,080.30 per LTCH annually, or $1,738,206 for all LTCHs annually. Because we are not finalizing the proposals, this results in a burden reduction from what was proposed.

In summary, the 4.5-minute increase in burden for the two finalized ventilator weaning quality measures is offset by the 3 minute reduction in burden for the finalized pressure ulcer quality measure and the 3.6 minute reduction in burden for the program interruption items. This results in a net reduction in burden of 2.1 minutes. Overall, this results in a net decrease in cost associated with the finalized changes to the LTCH QRP, which we estimate to be reduced by $893.14 per LTCH annually, or $380,480 for all LTCHs annually.

The finalized LTCH CARE Data Set Version 4.00 is available on the LTCH QRP Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-CARE-Data-Set-and-LTCH-QRP-Manual.html.*

Under section 1899B(m) of the Act, the Paperwork Reduction Act does not apply to the specific changes to the collections of information described in this final rule. While the reporting of data on quality measures is an information collection, we believe that the burden associated with modifications to the LTCH CARE Data Set discussed in this final rule fall under the PRA exceptions provided in 1899B(m) of the Act because they are required to achieve the standardization of patient assessment data. Section 1899B(m) of the Act provides that the PRA does not apply to section 1899B and the sections referenced in section 1899B(a)(2)(B) of the Act that require modification to achieve the standardization of patient assessment data. We are, however, setting out the burden as a courtesy to advise interested parties of the proposed actions' time and costs and we also refer readers to section I.M. of Appendix A of the preamble of this final rule. The requirement and burden will be submitted to OMB for review and approval when the modifications to the LTCH CARE Data Set are not used to achieve standardization and are not exempt from the requirements under section 1899B(m) of the Act.

For a discussion of the revised burden calculations related to LTCH CARE Data Set Version 4.00, and our discussion and response to public comments we received on these information collection requirements, we refer readers to section I.M. of Appendix A of the preamble of this final rule.

7. ICRs for the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program

We refer readers to the FY 2015 IPF PPS final rule (79 FR 45978 through 45980), the FY 2016 IPF PPS final rule (80 FR 46720 through 46721), and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57265 through 57266) for a detailed discussion of the burden for the program requirements that we have previously adopted. Additional information on the full burden of existing requirements can also be found in the information collection approved under OMB Control number 0938–1171. In section IX.D. of the preambles of the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20120 through 20130) and this final rule, we discuss and finalize provisions that affect the FY 2019 payment determination (through procedural requirements that occur in FY 2018). We are not finalizing the adoption of the Medication Continuation following Inpatient Psychiatric Discharge measure for the FY 2020 payment determination and subsequent years. ICRs associated with finalized proposals for each period are discussed in more detail below.

a. Burden Associated With Finalized Procedural Proposals for the FY 2019 Payment Determination and Subsequent Years

In this final rule, we are finalizing: (1) Proposed updates to the Extraordinary Circumstances Exception (ECE) process (affecting submission of ECE requests in FY 2018, which will impact payment determination year FY 2019 and subsequent years); (2) proposals to adopt measure removal factors, including criteria for determining when a measure is ''topped-out,'' and measure retention factors (which will take effect immediately following the finalization of this rule for updates to be proposed through future rulemaking); and (3) changes associated with procedural deadlines (which affect the FY 2019 payment determination and subsequent years).

First, for the ECE proposals, we are specifically finalizing our proposals to: (1) Specify that ECE forms may be signed by either the CEO or the designated personnel as listed in the contact information section of the form; (2) change the ECE request form submission deadline to within 90 days of the date that the extraordinary circumstance occurred; and (3) state that we will strive to complete our review of ECE requests within 90 days of receipt. These changes to the ECE process will not change data submission requirements for facilities requesting ECEs, but update procedural requirements related to ECE requests instead. Therefore, we do not expect any changes to burden associated with these proposals.

Second, the finalized proposal to adopt measures removal and retention factors does not affect the data submission requirements. These factors are intended to improve transparency of our measure review and evaluation process.

Third, for the procedural deadlines, we are finalizing our proposals to: (1) Change the submission deadline such that facilities have a 45-day submission period beginning at least 30 days following the end of the data collection period for a measure; (2) change the submission timeframes for both NOPs and withdrawals to the end of the data submission period before each respective payment determination year; and (3) provide exact dates that define the end of the data submission period/NOP/withdrawal submission deadline through subregulatory means. These finalized proposals do not affect the data that a facility must submit; instead, these proposals affect the specification of timeframes.

Because none of the policies that we are finalizing for FY 2018 and subsequent years affects the data that IPFs are required to submit, we do not believe there will be any change in burden as compared to the burden finalized in prior rulemakings, which is described in more detail in the FY 2015 IPF PPS final rule (79 FR 45978 through 45980), the FY 2016 IPF PPS final rule (80 FR 46720 through 46721), and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57265 through 57266) and in the information collection previously approved under OMB Control number 0938–1171.

b. Burden Associated With the FY 2020 Payment Determination and Subsequent Years

For FY 2020 and subsequent years, we are not finalizing our proposal to adopt one measure, Medication Continuation following Inpatient Psychiatric Discharge.

8. ICRs for the Electronic Health Record (EHR) Incentive Programs and Meaningful Use

In section IX.E. of the preambles of the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20130 through 20133) and this final rule, we discuss proposed and newly finalized policies for eligible hospitals and CAHs reporting CQMs electronically under the Medicare and Medicaid EHR Incentive Programs in 2017 and 2018. As outlined in this final rule, we are finalizing modifications to our proposals and making the following modifications to the CY 2017 final CQM policies: (1) Revise the CY 2017 reporting period for eligible hospitals and CAHs reporting CQMs electronically to require the submission of one self-selected quarter of data; and (2) revise the number of CQMs eligible hospitals and CAHs are required to report electronically for CY 2017 to 4 (self-selected) available CQMs.

In addition, we are finalizing modifications to our proposals that adopt the following CQM reporting requirements for CY 2018: (1) For eligible hospitals and CAHs reporting CQMs electronically that demonstrate meaningful use for the first time in 2018 or that have demonstrated meaningful use in any year prior to 2018, the reporting period will be one, self-selected quarter of data from CY 2018 with a submission period (Medicare EHR Incentive Program only) consisting of the 2 months following the close of the calendar year, ending on February 28, 2019; (2) eligible hospitals and CAHs reporting CQMs electronically are required to report at least 4 (self-selected) of the available CQMs; (3) eligible hospitals and CAHs that report CQMs by attestation under the Medicare EHR Incentive Program because electronic reporting is not feasible, and eligible hospitals and CAHs that report CQMs by attestation under their State's Medicaid EHR Incentive Program, will be required to report on all 16 available CQMs; and (4) eligible hospitals and CAHs reporting CQMs by attestation under the Medicare EHR Incentive Program will have a submission period that will be the 2 months following the close of the CY 2018 CQM reporting period, ending February 28, 2019.

Because the finalized reporting requirements for data collection regarding the reporting of CQMs electronically under the Medicare and Medicaid EHR Incentive Programs will align with the reporting requirements under the Hospital IQR Program, we do not believe that there is any additional burden for the collection of such information. We did not propose modifications for the CQMs reporting requirements by attestation in this section. Therefore, no change in burden associated with attestation of CQMs will result from this section.

In section IX.F. of the preamble of this final rule, we discuss newly finalized policies regarding clinical quality measurement for EPs participating in the Medicaid EHR Incentive Program. We note that there may be costs incurred by States associated with systems development as a result of the newly finalized policies. State attestation systems will likely require minor updates, which may be eligible for support through enhanced Federal funding, subject to CMS prior approval, if outlined in an updated Implementation Advance Planning Document (IAPD). We anticipate that EPs may also face minor burden and incremental capital cost for updating clinical quality measures and reporting capabilities in the EHR. We intend to reduce EP burden and simplify the program through these newly finalized policies, which are intended to better align CQM reporting periods and CQM reporting for the Medicaid EHR Incentive Program with policies under MIPS. Overall, we believe the newly finalized CQM alignment at the State attestation system and EP levels will both reduce burden associated with reporting on multiple CMS programs and enhance state and CMS operational efficiency.

In section IX.G.1. of the preamble of the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20135 through 20136) and IX.G.2. of the preamble of this final rule, we discuss our proposed and newly finalized policy which changes the EHR reporting period in 2018 from the full CY 2018 to any continuous 90-day period within CY 2018 for all new and returning EPs, eligible hospitals and CAHs attesting to meaningful use in the Medicare and Medicaid EHR Incentive Programs. We do not believe that modifying the EHR reporting period for attestation will cause an increase in burden as the reporting requirements for a 90-day EHR reporting period are virtually the same as for a full calendar year EHR reporting period and the same objectives and measures will be used for attestation for a full calendar year EHR reporting period or a 90-day EHR reporting period.

In section IX.G.2. of the preamble of the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20136 through 20138) and IX.G.3. of the preamble of this final rule, as required by the 21st Century Cures Act (Pub. L. 114–255), we discuss and finalize our proposal for an exemption from the payment adjustments under sections 1848(a)(7)(A), 1886(b)(3)(B)(ix)(I), and 1814(l)(4) of the Act for EPs, eligible hospitals and CAHs, respectively, that demonstrate through an application process that compliance with the requirement for being a meaningful EHR user is not possible because their certified EHR technology has been decertified under ONC's Health IT Certification Program. The application process involves participants completing an application form for an exception. While the form is standardized, we believe it is exempt from the PRA. The form is structured as an attestation. Therefore, we believe it is exempt under 5 CFR 1320.3(h)(1) of the implementing regulations of the PRA. The form is an attestation that imposes no burden beyond what is required to provide identifying information and to attest to the applicable information.

In section IX.G.3. of the preamble of the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20138 through 20139) and

IX.G.4. of the preamble of this final rule, as required by the 21st Century Cures Act, we discuss and finalize our proposal to exempt ambulatory surgical center-based EPs from the 2017 and 2018 payment adjustments under section 1848(a)(7)(A) of the Act if they furnish substantially all of their covered professional services in an ambulatory surgical center. We do not believe this requirement will cause an increase in burden as CMS will identify the EPs who might meet this requirement. We did not receive any public comments regarding this information collection. For the expected effects relating to the above proposals, we refer readers to section I.O. of Appendix A of this final rule.

9. ICRs Relating to Electronic Signature and Electronic Submission of the Certification and Settlement Summary Page of Medicare Cost Reports

In section X.A. of the preambles of the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20139 through 20142) and this final rule, we discuss and finalize our proposal to allow providers to use an electronic signature on the certification statement of the Certification and Settlement Summary page of the Medicare cost report and submit it electronically. The Certification and Settlement Summary page, which contains the required provider signature line, currently exists in the Medicare cost report and is mailed to the contractor from the provider. We are finalizing our proposal to allow providers the option to sign and submit this page electronically. The signature from the provider's administrator or chief financial officer is an existing data collection requirement. There will be no new data collection from providers resulting from our new policy. The policy, which allows providers to sign this page electronically, is not a substantive change to the existing data collection instrument and would have a minimal impact on providers to complete. As discussed in section I.P. of Appendix A of this final rule, we estimate that this finalized proposal will collectively save these providers approximately $362,000 in postage costs.

10. ICRs Relating to Changes in Public Notices of Terminations

In section XI.B. of the preambles of the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20145 through 20146) and this final rule, we discuss and finalize our proposal to no longer require the posting of voluntary and involuntary termination public notice in newspapers for RHCs, FQHCs, ASCs, and OPOs. These providers and suppliers will be permitted to use other methods of notification in light of the expanded use of information technology. In this final rule, we also are finalizing our proposal to change the regulations regarding termination of provider agreements by CMS (that is, involuntary termination) or providers or suppliers to remove the provision for public notice through ''newspapers'' to allow flexibility in the method of public notice.

We believe none of the provisions would have a financial burden as we are only eliminating the specification which requires newspaper hard print to be the notice source. We refer readers to the economic impact provisions of section I.Q. of Appendix A of this final rule for additional information.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping, Rural areas, X-rays.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 486

Grant programs—health, Health facilities, Medicare, Reporting and recordkeeping requirements, X-ray.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 495

Administrative practice and procedure, Electronic health records, Health facilities, Health professions, Health maintenance organizations (HMO), Medicaid, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble of this final rule, the Centers for Medicare and Medicaid Services is amending 42 CFR Chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 is revised to read as follows:

Authority: Secs. 205(a), 1102, 1142, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1320b–12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

■ 2. Section 405.2404 is amended by revising paragraph (d) introductory text to read as follows:

§ 405.2404 Termination of rural health clinic agreements.

* * * * *

(d) *Notice to the public.* Prompt notice of the date and effect of termination must be given to the public by either of the following:

* * * * *

■ 3. Section 405.2442 is amended by revising paragraph (a) introductory text and paragraph (b) to read as follows:

§ 405.2442 Notice to the public.

(a) When the FQHC voluntarily terminates the agreement and an effective date is set for the termination, the FQHC must notify the public in the area serviced by the FQHC prior to a prospective effective date or on the actual day that business ceases, if no prospective date of termination has been set. The notice must include—

* * * * *

(b) When CMS terminates the agreement, CMS will notify the public in the area serviced by the FQHC.

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 4. The authority citation for part 412 is revised to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh); sec. 124 of Pub. L. 106–113 (113 Stat. 1501A–332); sec. 1206 of Pub. L. 113–67; sec. 112 of Pub. L. 113–93; sec. 231 of Pub. L. 114–113; and secs. 15004, 15006, 15007, 15008, 15009, and 15010 of Pub. L. 114–255.

■ 5. Section 412.22 is amended by revising paragraph (e) introductory text and paragraph (e)(1)(v) introductory text and adding paragraph (i) to read as follows:

§ 412.22 Excluded hospitals and hospital units: General rules.

* * * * *

(e) *Hospitals-within-hospitals.* A hospital-within-a-hospital is a hospital that occupies space in a building also used by another hospital, or in one or more separate buildings located on the same campus as buildings used by another hospital. Prior to October 1, 2017, except as provided in paragraphs (e)(1)(vi) and (f) of this section, a hospital-within-a-hospital must meet the following criteria in order to be excluded from the prospective payment systems specified in § 412.1(a)(1). On or after October 1, 2017, except as provided in paragraphs (e)(1)(vi) and (f) of this section, a hospital-within-hospital that is excluded from the prospective payment systems specified in § 412.1(a)(1) that occupies space in a building also used by a hospital which is not excluded from the prospective payment systems specified in § 412.1(a)(1), or in one or more separate buildings located on the same campus as buildings used by a hospital not excluded from the prospective payment systems specified in § 412.1(a)(1) must meet the following criteria in order to be excluded from the prospective payment systems specified in § 412.1(a)(1).

(1) * * *

(v) *Performance of basic hospital functions.* Prior to October 1, 2017, the hospital meets one of the following criteria:

* * * * *

(i)(1) *Requirements for extended neoplastic disease care hospitals.* For cost reporting periods beginning on or after January 1, 2015, an extended neoplastic disease care hospital is a hospital that was first excluded from the prospective payment system under this section in 1986 which has an average inpatient length of stay for all patients, including both Medicare and non-Medicare inpatients, of greater than 20 days and demonstrates that at least 80 percent of its annual Medicare inpatient discharges in the 12-month cost reporting period ending in fiscal year 1997 have a principal diagnosis that reflects a finding of neoplastic disease as defined in paragraph (f)(1)(iv) of this section.

(2) *Payment to extended neoplastic disease care hospitals.* Payment for inpatient operating costs for hospitals classified under paragraph (i)(1) of this section is made as set forth in § 412.526(c)(3). Payment for capital costs for hospitals classified under paragraph (i)(1) of this section is made as set forth in § 412.526(c)(4).

■ 6. Section 412.23 is amended by revising paragraphs (e)(2)(ii), (e)(3)(vi), and (e)(7)(iii) to read as follows:

§ 412.23 Excluded hospitals: Classifications.

* * * * *

(e) * * *

(2) * * *

(ii) For cost reporting periods beginning on or after August 5, 1997 and on or before December 31, 2014, a hospital that was first excluded from the prospective payment system under this section in 1986 meets the length-of-stay criterion if it has an average inpatient length of stay for all patients, including both Medicare and non-Medicare inpatients, of greater than 20 days and demonstrates that at least 80 percent of its annual Medicare inpatient discharges in the 12-month cost reporting period ending in fiscal year 1997 have a principal diagnosis that reflects a finding of neoplastic disease as defined in paragraph (f)(1)(iv) of this section.

(3) * * *

(vi) For cost reporting periods beginning on or after October 1, 2015, the Medicare inpatient days and discharges that are paid at the site neutral payment rate specified at § 412.522(c)(1) or paid under a Medicare Advantage plan (Medicare Part C) will not be included in the calculation of the Medicare inpatient average length of stay specified under paragraph (e)(2)(i) of this section.

* * * * *

(7) * * *

(iii) April 1, 2014 through September 30, 2017—The number of Medicare-certified beds in an existing long-term care hospital or an existing long-term care hospital satellite facility must not be increased beyond the number of Medicare-certified beds prior to April 1, 2014, unless one of the exceptions specified in paragraph (e)(6)(ii) of this section is met.

* * * * *

■ 7. Section 412.64 is amended by—

■ a. Revising paragraph (d)(1)(vii);

■ b. Adding paragraph (d)(4)(iii);

■ c. Revising paragraph (h)(4) introductory text and paragraph (h)(4)(vi) introductory text; and

■ c. Revising paragraph (i)(3)(iii).

The revisions and addition read as follows:

§ 412.64 Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years.

* * * * *

(d) * * *

(1) * * *

(vii) For fiscal years 2017 and 2018, the percentage increase in the market basket index (as defined in § 413.40(a)(3) of this chapter) for prospective payment hospitals, subject to the provisions of paragraphs (d)(2) and (3) of this section, less a multifactor productivity adjustment (as determined by CMS) and less 0.75 percentage point.

* * * * *

(4) * * *

(iii) *Exception for decertified EHR technology.* Beginning with the fiscal year 2019 payment adjustment year, the Secretary shall exempt an eligible hospital that is not a qualifying eligible hospital from the application of the reduction under paragraph (d)(3) of this section if the Secretary determines that compliance with the requirement for being a meaningful EHR user is not possible because the certified EHR technology used by the eligible hospital has been decertified under ONC's Health IT Certification Program. To be considered for an exception, an eligible hospital must submit an application, in the manner specified by CMS, demonstrating that the certified EHR technology was decertified during the 12-month period preceding the applicable EHR reporting period for the payment adjustment year, or during the applicable EHR reporting period for the payment adjustment year, and that the eligible hospital made a good faith effort to obtain another certified EHR technology for that EHR reporting period. (See § 495.4 of this chapter for definitions of payment adjustment year, EHR reporting period, and meaningful EHR user.) Applications requesting this exception must be submitted by July 1 of the year before the applicable payment adjustment year, or a later date specified by CMS. This exception is subject to annual renewal, but in no case may an eligible hospital be granted an exception under paragraph (d)(4) of this section for more than 5 years.

* * * * *

(h) * * *

(4) For discharges on or after October 1, 2004 and before October 1, 2018, CMS establishes a minimum wage index for each all-urban State, as defined in paragraph (h)(5) of this section. This minimum wage index value is computed using the following methodology:

* * * * *

(vi) For discharges on or after October 1, 2012 and before October 1, 2018, the minimum wage index value for the State is the higher of the value determined under paragraph (h)(4)(iv) of this section or the value computed using the following alternative methodology:

* * * * *

(i) * * *

(3) * * *

(iii) Any wage index adjustment made under this paragraph (i) is effective for a period of 3 fiscal years, except that hospitals in a qualifying county may elect to waive the application of the wage index adjustment. A hospital may waive the application of the wage index adjustment by notifying CMS in writing within 45 days of the date of public display of the annual notice of proposed rulemaking for the hospital inpatient prospective payment system at the Office of the Federal Register.

* * * * *

■ 8. Section 412.87 is amended by revising paragraph (b)(2) to read as follows:

§ 412.87 Additional payment for new medical services and technologies: General provisions.

* * * * *

(b) * * *

(2) A medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code (as defined in section 1886(d)(5)(K)(iii) of the Social Security Act) assigned to the new service or technology (depending on when a new code is assigned and data on the new service or technology become available for DRG recalibration). After CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical service or technology, the medical service or technology will no longer be considered ''new'' under the criterion of this section.

* * * * *

■ 9. Section 412.90 is amended by revising paragraph (j) to read as follows:

§ 412.90 General rules.

* * * * *

(j) *Medicare-dependent, small rural hospitals.* For cost reporting periods beginning on or after April 1, 1990, and before October 1, 1994, and for discharges occurring on or after October 1, 1997 and before October 1, 2017, CMS adjusts the prospective payment rates for inpatient operating costs determined under subparts D and E of this part if a hospital is classified as a Medicare-dependent, small rural hospital.

* * * * *

■ 10. Section 412.92 is amended by revising paragraph (e)(3) introductory text to read as follows:

§ 412.92 Special Treatment: Sole community hospitals.

* * * * *

(e) * * *

(3) Effective for cost reporting periods beginning before October 1, 2017, the intermediary determines a lump sum adjustment amount not to exceed the difference between the hospital's Medicare inpatient operating costs and the hospital's total DRG revenue for inpatient operating costs based on DRG-adjusted prospective payment rates for inpatient operating costs (including outlier payments for inpatient operating costs determined under subpart F of this part and additional payments made for inpatient operating costs for hospitals that serve a disproportionate share of low-income patients as determined under § 412.106 and for indirect medical education costs as determined under § 412.105). Effective for cost reporting periods beginning on or after October 1, 2017, the MAC determines a lump sum adjustment amount equal to the difference between the hospital's fixed Medicare inpatient operating costs and the hospital's total MS–DRG revenue based on MS–DRG-adjusted prospective payment rates for inpatient operating costs (including outlier payments for inpatient operating costs determined under subpart F of this part and additional payments made for inpatient operating costs for hospitals that serve a disproportionate share of low-income patients as determined under § 412.106 and for indirect medical education costs as determined under § 412.105) multiplied by the ratio of the hospital's fixed inpatient operating costs to its total inpatient operating costs.

* * * * *

■ 11. Section 412.101 is amended by revising paragraph (b)(2) introductory text and adding paragraph (e) to read as follows:

§ 412.101 Special treatment: Inpatient hospital payment adjustment for low-volume hospitals.

* * * * *

(b) * * *

(2) In order to qualify for this adjustment, a hospital must meet the following criteria, subject to the provisions of paragraph (e) of this section:

* * * * *

(e) *Special treatment regarding hospitals operated by the Indian Health Service (IHS) or a Tribe.* For discharges occurring in FY 2018 and subsequent fiscal years—

(1) A hospital operated by the IHS or a Tribe will be considered to meet the applicable mileage criterion specified under paragraph (b)(2) of this section if it is located more than the specified number of road miles from the nearest subsection (d) hospital operated by the IHS or a Tribe.

(2) A hospital, other than a hospital operated by the IHS or a Tribe, will be considered to meet the applicable mileage criterion specified under paragraph (b)(2) of this section if it is located more than the specified number of road miles from the nearest subsection (d) hospital other than a subsection (d) hospital operated by the IHS or a Tribe.

■ 12. Section 412.106 is amended by adding paragraph (g)(1)(iii)(C)(*4*) to read as follows:

§ 412.106 Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * * *

(g) * * *

(1) * * *

(iii) * * *

(C) * * *

(4) For fiscal year 2018, CMS will base its estimates of the amount of hospital uncompensated care on utilization data for Medicaid and Medicare SSI patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (b)(4) of this section, using data on Medicaid utilization from 2012 and 2013 cost reports from the most recent HCRIS database extract and 2012 cost report data submitted to CMS by IHS or Tribal hospitals and the most recent available 2 years of data on Medicare SSI utilization (or, for Puerto Rico hospitals, a proxy for Medicare SSI utilization data), and for hospitals other than Puerto Rico hospitals, IHS or Tribal hospitals, and all-inclusive rate providers, data on uncompensated care costs, defined as charity care costs plus non-Medicare bad debt costs from 2014 cost reports from the most recent HCRIS database extract.

* * * * *

■ 13. Section 412.108 is amended by revising paragraph (d)(3) introductory text to read as follows:

§ 412.108 Special treatment: Medicare-dependent, small rural hospitals.

* * * * *

(d) * * *

(3) The intermediary determines a lump sum adjustment amount in accordance with the methodology set forth in § 412.92(e)(3).

* * * * *

■ 14. Section 412.140 is amended by revising paragraphs (c)(2) and (d)(2) to read as follows:

§ 412.140 Participation, data submission, and validation requirements under the Hospital Inpatient Quality Reporting (IQR) Program.

* * * * *

(c) * * *

(2) *Extraordinary circumstances exceptions.* CMS may grant an exception with respect to quality data reporting requirements in the event of extraordinary circumstances beyond the control of the hospital. CMS may grant an exception as follows:

(i) For circumstances not relating to the reporting of electronic clinical quality measure data, a hospital participating in the Hospital IQR Program that wishes to request an exception with respect to quality data reporting requirements must submit its request to CMS within 90 days of the date that the extraordinary circumstances occurred. For circumstances relating to the reporting of electronic clinical quality measures, a hospital participating in the Hospital IQR Program that wishes to request an exception must submit its request to CMS by April 1 following the end of the reporting calendar year in which the extraordinary circumstances occurred. Specific requirements for submission of a request for an exception are available on QualityNet.org.

(ii) CMS may grant an exception to one or more hospitals that have not requested an exception if: CMS determines that a systemic problem with CMS data collection systems directly affected the ability of the hospital to submit data; or if CMS determines that an extraordinary circumstance has affected an entire region or locale.

(d) * * *

(2)(i) A hospital meets the chart-abstracted validation requirement with respect to a fiscal year if it achieves a 75-percent score, as determined by CMS.

(ii) A hospital meets the eCQM validation requirement with respect to a fiscal year if it submits at least 75 percent of sampled eCQM measure medical records in a timely and complete manner, as determined by CMS.

* * * * *

■ 15. Section 412.211 is amended by revising paragraph (f)(3)(iii) to read as follows:

§ 412.211 Puerto Rico rates for Federal fiscal year 2004 and subsequent fiscal years.

* * * * *

(f) * * *

(3) * * *

(iii) Any wage index adjustment made under this paragraph (f) is effective for a period of 3 fiscal years, except that hospitals in a qualifying county may elect to waive the application of the wage index adjustment. A hospital may waive the application of the wage index adjustment by notifying CMS in writing within 45 days of the date of public display of the annual notice of proposed rulemaking for the hospital inpatient prospective payment system at the Office of the **FEDERAL REGISTER.**

* * * * *

■ 16. Section 412.230 is amended by revising paragraphs (a)(3) introductory text, (a)(3)(i) and (ii), and (d)(3) to read as follows:

§ 412.230 Criteria for an individual hospital seeking redesignation to another rural area or an urban area.

(a) * * *

(3) *Special rules for sole community hospitals and rural referral centers.* To be redesignated under the special rules in this paragraph, a hospital must be approved as a sole community hospital or a rural referral center as of the date of the MGCRB's review.

(i) A hospital that is approved as a rural referral center or a sole community hospital, or both, does not have to demonstrate a close proximity to the area to which it seeks redesignation.

(ii) If a hospital that is approved as a rural referral center or a sole community hospital, or both, qualifies for urban redesignation, it is redesignated to the urban area that is closest to the hospital or to the hospital's geographic home area. If the hospital is closer to another rural area than to any urban area, it may seek redesignation to either the closest rural area or the closest urban area.

* * * * *

(d) * * *

(3) *Rural referral center exceptions.* (i) If a hospital was ever approved as a rural referral center, it does not have to demonstrate that it meets the average hourly wage criterion set forth in paragraph (d)(1)(iii) of this section.

(ii) If a hospital was ever approved as a rural referral center, it is required to meet only the criterion that applies to rural hospitals under paragraph (d)(1)(iv) of this section, regardless of its actual location in an urban or rural area.

* * * * *

■ 17. Section 412.273 is amended by revising paragraphs (c)(1)(ii) and (c)(2) to read as follows:

§ 412.273 Withdrawing an application, terminating an approved 3-year reclassification, or cancelling a previous withdrawal or termination.

* * * * *

(c) * * *

(1) * * *

(ii) After the MGCRB issues a decision, provided that the request for withdrawal is received by the MCGRB within 45 days of the date that CMS' annual notice of proposed rulemaking is issued in the **Federal Register** concerning changes to the inpatient hospital prospective payment system and proposed payment rates for the fiscal year for which the application has been filed.

(2) A request for termination must be received by the MGCRB within 45 days of the date that CMS' annual notice of proposed rulemaking is issued in the **Federal Register** concerning changes to the inpatient hospital prospective payment system and proposed payment rates for the fiscal year for which the termination is to apply.

* * * * *

■ 18. Section 412.500 is amended by adding paragraphs (a)(7) and (8) to read as follows:

§ 412.500 Basis and scope of subpart.

(a) * * *

(7) Section 411 of Public Law 114–10 which revises the annual update to the LTCH PPS standard Federal payment rate in FY 2018.

(8) Public Law 114–255 which at—

(i) Section 15004 amended the moratorium on increasing beds in existing LTCHs and LTCH satellite facilities and amended high cost outlier payment requirements;

(ii) Section 15006 amended moratoria on certain payment policies;

(iii) Section 15007 amended the average length of stay requirements;

(iv) Section 15009 temporally excepted certain spinal cord specialty hospitals from the site neutral payment rate; and

(v) Section 15010 temporally excepted certain wound care discharges from certain LTCHs from the site neutral payment rate.

* * * * *

■ 19. Section 412.522 is amended by adding paragraphs (b)(3) and (4) to read as follows:

§ 412.522 Application of site neutral payment rate.

* * * * *

(b) * * *

(3) *Temporary exception for certain severe wound discharges.*—(i) *Definitions.* For purposes of this paragraph (b)(3) the following definitions are applicable:

Severe wound means a wound which is a stage 3 wound, stage 4 wound, unstageable wound, non-healing

surgical wound, fistula, as identified by the applicable code on the claim from the long-term care hospital.

Wound means an injury, usually involving division of tissue or rupture of the integument or mucous membrane with exposure to the external environment.

(ii) *Discharges for severe wounds.* A discharge that occurs in a cost reporting period beginning during fiscal year 2018 for a patient who was treated for a severe wound that meets all of the following criteria is excluded from the site neutral payment rate specified under this section:

(A) The severe wound meets the definition specified in paragraph (b)(3)(i) of this section.

(B) The discharge is from a long-term care hospital that is described in § 412.23(e)(2)(i) and meets the criteria of § 412.22(f); and

(C) The discharge is classified under MS–LTC–DRG 539, 540, 602, or 603.

(4) *Temporary exception for certain spinal cord specialty hospitals.* For discharges in cost reporting periods beginning in fiscal years 2018 and 2019, the site neutral payment rate specified under this section does not apply if such discharge is from a long-term care hospital that meets each of the following requirements:

(i) The hospital was a not-for-profit long-term care hospital on June 1, 2014, as determined by cost report data;

(ii) Of the discharges in calendar year 2013 from the long-term care hospital for which payment was made under subpart O, at least 50 percent were classified under MS–LTC–DRGs 28, 29, 52, 57, 551, 573, and 963; and

(iii) The long-term care hospital discharged inpatients (including both individuals entitled to, or enrolled for, benefits under Medicare Part A and individuals not so entitled or enrolled) during fiscal year 2014 who had been admitted from at least 20 of the 50 States determined by the States of residency of such inpatients.

* * * * *

■ 20. Section 412.523 is amended by—

■ a. Adding paragraph (c)(3)(xiv);

■ b. Revising paragraph (d)(1); and

■ c. Adding paragraph (d)(5).

The additions and revision read as follows:

§ 412.523 Methodology for calculating the Federal prospective payment rates.

* * * * *

(c) * * *

(3) * * *

(xiv) *For long-term care hospital prospective payment system fiscal year beginning October 1, 2017, and ending September 30, 2018.* The LTCH PPS standard Federal payment rate for the long-term care hospital prospective payment system beginning October 1, 2017, and ending September 30, 2018, is the standard Federal payment rate for the previous long-term care hospital prospective payment system fiscal year updated by 1.0 percent and further adjusted, as appropriate, as described in paragraph (d) of this section.

* * * * *

(d) * * *

(1) *Outlier payments.* CMS adjusts the LTCH PPS standard Federal payment rate by a reduction factor of 8 percent, the estimated proportion of outlier payments under § 412.525(a) payable for discharges described in § 412.522(a)(2) (notwithstanding the provisions of § 412.525(a)(2)(ii) for FY 2018 and subsequent years.

* * * * *

(5) *Adjustment for changes to the short-stay outlier policy.* The standard Federal rate determined under paragraph (c)(3) of this section is permanently adjusted by a one-time factor so that estimated aggregate payments to LTCH PPS standard Federal rate cases in FY 2018 are projected to equal estimated aggregate payments that would have been paid for such cases without regard to the change in the short-stay outlier policy for FY 2018 under § 412.529(c)(4).

* * * * *

■ 21. Section 412.525 is amended by revising paragraph (a)(2) to read as follows:

§ 412.525 Adjustments to the Federal prospective payment.

(a) * * *

(2)(i) The fixed loss-amount for discharges from a long-term care hospital described under § 412.522(a)(2) is determined for the long-term care hospital prospective payment system payment year, using the LTC–DRG relative weights that are in effect at the start of the applicable long-term care hospital prospective payment system payment year.

(ii) For FY 2018 and subsequent years, the fixed-loss amount for long-term care hospital discharges described under § 412.522(a)(2) is determined such that the estimated proportion of outlier payments under paragraph (a) of this section payable for such discharges is projected to be equal to 99.6875 of 8 percent.

* * * * *

■ 22. Section 412.529 is amended by—

■ a. Revising paragraph (c)(3) introductory text;

■ b. Adding paragraph (c)(4); and

■ c. Revising paragraph (f) introductory text.

The revisions and addition read as follows:

§ 412.529 Special payment provision for short-stay outliers.

* * * * *

(c) * * *

(3) *Discharges occurring on or after July 1, 2007 and before December 29, 2007 and discharges occurring on or after December 29, 2012 and on or before September 30, 2017.* For discharges from long-term care hospitals described under § 412.23(e)(2)(i) occurring on or after July 1, 2007, and on or before December 29, 2007 and discharges occurring on or after December 29, 2012, and on or before September 30, 2017, the LTCH prospective payment system adjusted payment amount for a short-stay outlier case is adjusted by either of the following:

* * * * *

(4) *Discharges occurring on or after October 1, 2017.* For discharges occurring on or after October 1, 2017, short-stay outlier payments are determined according to paragraph (c)(2)(iv) of this section.

* * * * *

(f) *Reconciliation of short-stay payments.* Payments for discharges occurring before October 1, 2017 are reconciled in accordance with one of the following:

* * * * *

■ 23. Section 412.538 is amended by revising paragraph (a)(1) to read as follows:

§ 412.538 Limitation on long-term care hospital admissions from referring hospitals.

(a) * * *

(1) The provisions of this section apply to all long-term care hospitals excluded from the hospital inpatient prospective payment system under § 412.23(e), except as specified in paragraph (a)(2) of this section, effective for discharges occurring on or after October 1, 2018.

* * * * *

■ 24. Section 412.560 is amended by revising the section heading, paragraph (a), the paragraph (b) heading, paragraphs (b)(1), (c) introductory text, (c)(1), (c)(3)(vii), (c)(4)(ii), (d)(1), and (d)(2)(vii), and adding paragraph (f) to read as follows:

§ 412.560 Requirements under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP).

(a) *Participation in the LTCH QRP.* A long-term-care hospital must begin

submitting data on measures specified under sections 1886(m)(5)(D), 1899B(c)(1), and 1899B(d)(1) of the Act, and standardized patient assessment data required under section 1899B(b)(1) of the Act, under the LTCH QRP by no later than the first day of the calendar quarter subsequent to 30 days after the date on its CMS Certification Number (CCN) notification letter.

(b) *Data submission requirements and payment impact.* (1) Except as provided in paragraph (c) of this section, a long-term care hospital must submit to CMS data on measures specified under sections 1886(m)(5)(D), 1899B(c)(1) and 1899B(d)(1) of the Act, and standardized patient assessment data required under section 1899B(b)(1) of the Act. Such data must be submitted in a form and manner, and at a time, specified by CMS.

* * * * *

(c) *Exception and extension request requirements.* Upon request by a long-term care hospital, CMS may grant an exception or extension with respect to the measures data and standardized patient assessment data reporting requirements, for one or more quarters, in the event of certain extraordinary circumstances beyond the control of the long-term care hospital, subject to the following:

(1) A long-term care hospital that wishes to request an exception or extension with respect to measures data and standardized patient assessment data reporting requirements must submit its request to CMS within 90 days of the date that the extraordinary circumstances occurred.

* * * * *

(3) * * *

(vii) The date on which the long-term care hospital will be able to again submit measures data and standardized patient assessment data under the LTCH QRP and a justification for the proposed date.

(4) * * *

(ii) A systemic problem with one of CMS' data collection systems directly affected the ability of the long-term care hospital to submit measures data and standardized patient assessment data.

* * * * *

(d) * * *

(1) *Written notification of noncompliance decision.* CMS will send a long-term care hospital written notification of a decision of noncompliance with the measures data and standardized patient assessment data reporting requirements for a particular fiscal year. CMS also will use the Quality Improvement and Evaluation system (QIES) Assessment Submission and Processing (ASAP) System to provide notification of noncompliance to the long-term care hospital.

(2) * * *

(vii) Accompanying documentation that demonstrates compliance of the long-term care hospital with the LTCH QRP requirements. This documentation must be submitted electronically at the same time as the reconsideration request as an attachment to the email.

* * * * *

(f) *Data completion thresholds.* (1) Long-term care hospitals must meet or exceed two separate data completeness thresholds: One threshold set at 80 percent for completion of measures data and standardized patient assessment data collected using the LTCH CARE Data Set submitted through the QIES ASAP System; and a second threshold set at 100 percent for measures data collected and submitted using the CDC NHSN.

(2) The thresholds in paragraph (f)(1) of this section apply to all data that must be submitted under paragraph (b) of this section.

(3) A long-term care hospital must meet or exceed both thresholds in paragraph (f)(1) of this section to avoid receiving a 2 percentage point reduction to its annual payment update for a given fiscal year, beginning with the FY 2019 LTCH QRP.

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

■ 25. The authority for part 413 is revised to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883 and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Public Law 106–113, 113 Stat. 1501A–332; sec. 3201 of Public Law 112–96, 126 Stat. 156; sec. 632 of Public Law 112–240, 126 Stat. 2354; sec. 217 of Public Law 113–93, 129 Stat. 1040; and sec. 204 of Public Law 113–295, 128 Stat. 4010; and sec. 808 of Public Law 114–27, 129 Stat. 362.

■ 26. Section 413.24 is amended by revising paragraph (f)(4)(iv) to read as follows:

§ 413.24 Adequate cost data and cost finding.

* * * * *

(f) * * *

(4) * * *

(iv)(A) Effective as specified in paragraphs (f)(4)(iv)(A)(*1*) through (*4*) and except as provided in paragraph (f)(4)(iv)(C) of this section, a provider must submit a hard copy of a settlement summary, if applicable, which is a statement of certain worksheet totals found within the electronic file, and the certification statement described in paragraph (f)(4)(iv)(B) of this section signed by its administrator or chief financial officer certifying the accuracy of the electronic file or the manually prepared cost report.

(*1*) For hospitals, effective for cost reporting periods ending on or after September 30, 1994;

(*2*) For skilled nursing facilities and home health agencies, effective for cost reporting periods ending on or after February 1, 1997;

(*3*) For hospices and end-stage renal disease facilities, effective for cost reporting periods ending on or after December 31, 2004; and

(*4*) For organ procurement organizations, histocompatibility laboratories, rural health clinics, Federally qualified health centers, and community mental health centers, effective for cost reporting periods ending on or after March 31, 2005.

(B) The following certification statement must immediately precede the dated original signature, or electronic signature as set forth in paragraph (f)(4)(iv)(C)(*1*) of this section, of the provider's administrator or chief financial officer:

MISREPRESENTATION OR FALSIFICATION OF ANY INFORMATION CONTAINED IN THIS COST REPORT MAY BE PUNISHABLE BY CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINE AND/OR IMPRISONMENT UNDER FEDERAL LAW. FURTHERMORE, IF SERVICES IDENTIFIED IN THIS REPORT WERE PROVIDED OR PROCURED THROUGH THE PAYMENT DIRECTLY OR INDIRECTLY OF A KICKBACK OR WERE OTHERWISE ILLEGAL, CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINES AND/OR IMPRISONMENT MAY RESULT.

I hereby certify that I have read the above certification statement and that I have examined the accompanying electronically filed or manually submitted cost report and the Balance Sheet and Statement of Revenue and Expenses prepared by _____ (Provider Name(s) and Number(s)) for the cost reporting period beginning _____a and ending _____a and that to the best of my knowledge and belief, this report and statement are true, correct, complete and prepared from the books

and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

(C) Effective for cost reporting periods ending on or after December 31, 2017—(*1*) A provider that is required to file an electronic cost report may elect to electronically submit the settlement summary, if applicable, and the certification statement with an electronic signature of the provider's administrator or chief financial officer. The following checkbox for electronic signature and submission will immediately follow the certification statement as set forth in paragraph (f)(4)(iv)(B) of this section and must be checked if electronic signature and submission is elected.

☐ I have read and agree with the above certification statement. I certify that I intend my electronic signature on this certification statement to be the legally binding equivalent of my original signature.

(*2*) A provider that is required to file an electronic cost report but does not elect to electronically submit the certification statement with an electronic signature, must submit a hard copy of the settlement summary, if applicable, and a certification statement with an original signature of the provider's administrator or chief financial officer as set forth in paragraphs (f)(4)(iv)(A) and (B) of this section.

* * * * *

■ 27. Section 413.65 is amended by revising paragraph (m) introductory text to read as follows:

§ 413.65 Requirements for a determination that a facility or an organization has provider-based status.

* * * * *

(m) *Status of Indian Health Service and Tribal facilities and organizations.* Facilities and organizations operated by the Indian Health Services and Tribes will be considered to be departments of hospitals operated by the Indian Health Service or Tribes if they furnish only services that are billed, using the CCN of the main provider and with the consent of the main provider, as if they had been furnished by a department of a hospital operated by the Indian Health Service or a Tribe and they are:

* * * * *

■ 28. Section 413.70 is amended by—

■ a. Redesignating paragraph (a)(6)(iii) as paragraph (a)(6)(iv);

■ b. Adding a new paragraph (a)(6)(iii) ; and

■ c. Revising newly redesignated paragraph (a)(6)(iv).

The addition and revisionto read as follows:

§ 413.70 Payment for services of a CAH.

(a) * * *

(6) * * *

(iii) *Exception for decertified EHR technology.* Beginning with the fiscal year 2018 payment adjustment year, the Secretary shall exempt a CAH that is not a qualifying CAH from the application of the payment adjustment under paragraph (a)(6)(i) of this section if the Secretary determines that compliance with the requirement for being a meaningful EHR user is not possible because the certified EHR technology used by the CAH has been decertified under ONC's Health IT Certification Program. In order to be considered for an exception, a CAH must submit an application, in the manner specified by CMS, demonstrating that the certified EHR technology was decertified during the 12-month period preceding the applicable EHR reporting period for the payment adjustment year, or during the applicable EHR reporting period for the payment adjustment year, and that the CAH made a good faith effort to obtain another certified EHR technology for that EHR reporting period. Applications requesting this exception must be submitted by November 30 after the end of the applicable payment adjustment year, or a later date specified by CMS.

(iv) Exceptions granted under paragraphs (a)(6)(ii) and (iii) of this section are subject to annual renewal, but in no case may a CAH be granted such an exception for more than 5 years.

* * * * *

■ 29. Section 413.134 is amended by revising paragraph (f)(1) to read as follows:

§ 413.134 Depreciation: Allowance for deprecation based on asset costs.

* * * * *

(f) * * *

(1) *General.* Depreciable assets may be disposed of through sale, scrapping, trade-in, exchange, demolition, abandonment, condemnation, fire, theft, or other casualty.

(i) *Disposal of an asset before December 1, 1997.* If disposal of a depreciable asset, including the sale or scrapping of an asset before December 1, 1997, results in a gain or loss, an adjustment is necessary in the provider's allowable cost.

(A) The amount of a gain included in the determination of allowable cost is limited to the amount of depreciation previously included in Medicare allowable costs.

(B) The amount of a loss to be included is limited to the undepreciated basis of the asset permitted under the program.

(C) The treatment of the gain or loss depends upon the manner of disposition of the asset, as specified in paragraphs (f)(2) through (6) of this section.

(D) The gain or loss on the disposition of depreciable assets has no retroactive effect on a proprietary provider's equity capital for years prior to the year of disposition.

(ii) *Disposal of an asset on or after December 1, 1997.* No gain or loss is recognized on either the sale or scrapping of an asset that occurs on or after December 1, 1997, regardless of whether the asset is sold incident to a provider's change of ownership, or otherwise sold or scrapped as an asset of a Medicare participating provider. Gains or losses on dispositions other than sales or scrapping are recognized to the same extent as prior to December 1, 1997.

* * * * *

PART 416—AMBULATORY SURGICAL SERVICES

■ 30. The authority citation for part 416 is revised to read as follows:

Authority: Secs. 1102, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1320b–8, and 1395hh) and section 371 of the Public Health Service Act (42 U.S.C. 273).

■ 31. Section 416.35 is amended by revising paragraph (d) introductory text to read as follows:

§ 416.35 Termination of agreement.

* * * * *

(d) *Notice to the public.* Prompt notice of the date and effect of termination is given to the public by—

* * * * *

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

■ 32. The authority citation for part 486 continues to read as follows:

Authority: Secs. 1102, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1320b–8, and 1395hh) and section 371 of the Public Health Service Act (42 U.S.C. 273).

■ 33. Section 486.312 is amended by revising paragraph (e) to read as follows:

§ 486.312 De-certification.

* * * * *

(e) *Public notice.* Once CMS approves the date for a voluntary termination, the OPO must provide prompt public notice

in the service area of the date of de-certification and such other information as CMS may require. In the case of involuntary termination or nonrenewal of an agreement, CMS also provides notice to the public in the service area of the date of de-certification. No payment under titles XVIII or XIX of the Act will be made with respect to organ procurement costs attributable to the OPO on or after the effective date of de-certification.

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 34. The authority citation for part 488 is revised to read as follows:

Authority: Secs. 1102, 1128l, 1864, 1865, 1871, and 1875 of the Social Security Act, unless otherwise noted (42 U.S.C. 1302, 1320a–7, 1395aa, 1395bb, 1395hh, and 1395ll).

■ 35. Section 488.5 is amended by adding paragraph (a)(21) to read as follows:

§ 488.5 Application and re-application procedures for national accrediting organizations.

(a) * * *

(21) A statement acknowledging that the organization agrees to make all Medicare cited deficiencies, both standard and condition level, immediate jeopardy situations, and dates of correction, for final accreditation survey reports publicly available on the organization's Web site within 90 days after the survey report is made available to those facilities for the most recent 3 years, on an ongoing basis in a manner specified by CMS. This acknowledgement includes all initial, triennial, full, follow-up, focused, and complaint surveys.

* * * * *

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 36. The authority citation for part 489 continues to read as follows:

Authority: Secs. 1102 1819, 1820(E), 1861, 1864(M), 1866, 1869, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395i–3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395(hh)).

■ 37. Section 489.52 is amended by revising paragraph (c)(2) introductory text to read as follows:

§ 489.52 Termination by the provider.

* * * * *

(c) * * *

(2) The notice must—

* * * * *

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 38. The authority citation for part 495 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 39. Section 495.4 is amended by—

■ a. Adding in alphabetical order a definition of ''Ambulatory surgical center-based EP'';

■ b. In the definition of ''EHR reporting period,'' revising paragraph (1)(ii) introductory text, adding paragraph (1)(ii)(D), revising paragraph (1)(iii) introductory text, revising paragraph (2)(ii) introductory text, adding paragraph (2)(ii)(D) and revising paragraph (2)(iii) introductory text; and

■ c. In the definition of ''EHR reporting period for a payment adjustment year'', revising paragraph (2)(ii) introductory text, adding paragraph (2)(ii)(D), revising paragraph (2)(iii) introductory text, revising paragraph (3)(ii) introductory text, adding paragraph (3)(ii)(D), and revising paragraph (3)(iii) introductory text.

The additions and revisions read as follows:

§ 495.4 Definitions.

* * * * *

Ambulatory surgical center-based EP means an EP who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the codes used in the HIPAA standard transaction as an ASC setting in the calendar year that is 2 years before the payment adjustment year.

* * * * *

EHR reporting period. * * *

(1) * * *

(ii) The following are applicable for 2015, 2016, 2017, and 2018:

* * * * *

(D) For the CY 2018 payment year under the Medicaid EHR Incentive Program:

(*1*) For the EP first demonstrating he or she is a meaningful EHR user, any continuous 90-day period within CY 2018.

(*2*) For the EP who has successfully demonstrated he or she is a meaningful EHR user in any prior year, any continuous 90-day period within CY 2018.

(iii) The following are applicable beginning with the CY 2019 payment year under the Medicaid EHR Incentive Program:

* * * * *

(2) * * *

(ii) The following are applicable for 2015, 2016, 2017, and 2018:

* * * * *

(D) For the FY 2018 payment year under the Medicaid EHR Incentive Program:

(*1*) For the eligible hospital or CAH first demonstrating it is a meaningful EHR user, any continuous 90-day period within CY 2018.

(*2*) For the eligible hospital or CAH that has successfully demonstrated it is a meaningful EHR user in any prior year, any continuous 90-day period within CY 2018.

(iii) The following are applicable beginning with the FY 2019 payment year under the Medicaid EHR Incentive Program:

* * * * *

EHR reporting period for a payment adjustment year. * * *

(2) * * *

(ii) The following are applicable for 2015, 2016, 2017, and 2018:

* * * * *

(D) In 2018 as follows:

(*1*) If an eligible hospital has not successfully demonstrated it is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 90-day period within CY 2018 and applies for the FY 2019 and 2020 payment adjustment years. For the FY 2019 payment adjustment year, the EHR reporting period must end before and the eligible hospital must successfully register for and attest to meaningful use no later than October 1, 2018.

(*2*) If in a prior year an eligible hospital has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is any continuous 90-day period within CY 2018 and applies for the FY 2020 payment adjustment year.

(iii) The following are applicable beginning in 2019:

* * * * *

(3) * * *

(ii) The following are applicable for 2015, 2016, 2017, and 2018:

* * * * *

(D) In 2018 as follows:

(*1*) If a CAH has not successfully demonstrated it is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 90-day period within CY 2018 and applies for the FY 2018 payment adjustment year.

(*2*) If in a prior year a CAH has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is any continuous 90-day period within CY 2018 and applies for the FY 2018 payment adjustment year.

(iii) The following are applicable beginning in 2019:

* * * * *

■ 40. Section 495.22 is amended by—
■ a. Revising the section heading;
■ b. Revising paragraph (a);
■ c. Revising the paragraph (b) heading and the paragraph (b)(1) heading;
■ d. Revising the paragraph (c) heading and paragraph (c)(1);
■ e. Revising the paragraph (e) heading and paragraphs (e)(8)(i)(A)(*2*)(*ii*), (e)(8)(ii)(A)(*2*)(*ii*), and (e)(9)(ii)(A)(*3*); and
■ f. Revising the paragraph (f) heading.

The revisions read as follows:

§ 495.22 Meaningful use objectives and measures for EPs, eligible hospitals, and CAHs for 2015 through 2018.

(a) *General rules.* (1) Subject to the provisions of paragraph (a)(2) of this section, the criteria specified in this section are applicable for EPs, eligible hospitals, and CAHs for 2015 through 2018.

(2) For 2017 and 2018, EPs, eligible hospitals, and CAHs that have successfully demonstrated meaningful use in a prior year have the option to use the criteria specified for 2019 in § 495.24 instead of the criteria specified for 2017 and 2018 under paragraphs (e) and (f) of this section.

(b) *Criteria for EPs for 2015 through 2018*—(1) *General rule regarding criteria for meaningful use for 2015 through 2018 for EPs.* * * *

(c) *Criteria for eligible hospitals and CAHs for 2015 through 2018.*—(1) *General rule regarding criteria for meaningful use for 2015 through 2018 for eligible hospitals and CAHs.* Except as specified in paragraph (c)(2) of this section, eligible hospitals and CAHs attesting to CMS must meet all objectives and associated measures of the meaningful use criteria specified under paragraph (e) of this section to meet the definition of a meaningful EHR user in 2015 and 2016 and must meet all objectives and associated measures of the meaningful use criteria specified under paragraph (f) of this section to meet the definition of a meaningful EHR user in 2017 and 2018. Except as specified in paragraph (c)(2) of this section, eligible hospitals and CAHs attesting to a State for the Medicaid EHR Incentive Program must meet all objectives and associated measures of the meaningful use criteria specified under paragraph (e) of this section to meet the definition of a meaningful EHR user in 2015 through 2018.

* * * * *

(e) *Meaningful use objectives and measures for EPs for 2015 through 2018, for eligible hospitals and CAHs attesting to CMS for 2015 and 2016, and for eligible hospitals and CAHs attesting to a State for the Medicaid EHR Incentive Program for 2015 through 2018.* * * *

(8) * * *
(i) * * *
(A) * * *
(*2*) * * *

(*ii*) In 2017 and 2018, more than 5 percent of unique patients seen by the EP during the EHR reporting period (or their authorized representatives) views, downloads or transmits their health information to a third party during the EHR reporting period.

* * * * *

(ii) * * *
(A) * * *
(*2*) * * *

(*ii*) In 2017 and 2018, more than 5 percent of unique patients (or patient-authorized representatives) discharged from the inpatient or emergency department (POS 21 or POS 23) of an eligible hospital or CAH during the EHR reporting period view, download or transmit to a third party their health information during the EHR reporting period.

* * * * *

(9) * * *
(ii) * * *
(A) * * *

(*3*) In 2017 and 2018, for more than 5 percent of unique patients seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative) during the EHR reporting period.

* * * * *

(f) *Meaningful use objectives and measures for eligible hospitals and CAHs attesting to CMS for 2017 and 2018*—* * *

* * * * *

■ 41. Section 495.24 is amended by—
■ a. Revising the section heading;
■ b. Revising the introductory text;
■ c. Revising the paragraph (c) heading and
■ d. Revising the paragraph (d) heading and paragraphs (d)(6)(i)(B)(*2*)(*i*) and (*ii*), (d)(6)(ii)(B)(*1*)(*iv*), and (d)(6)(ii)(B)(*2*)(*i*) and (*ii*).

The revisions read as follows:

§ 495.24 Stage 3 meaningful use objectives and measures for EPs, eligible hospitals and CAHs for 2019 and subsequent years.

The criteria specified in paragraphs (c) and (d) of this section are optional for 2017 and 2018 for EPs, eligible hospitals, and CAHs that have successfully demonstrated meaningful use in a prior year. The criteria specified in paragraph (c) of this section are applicable for eligible hospitals and CAHs attesting to CMS for 2019. The criteria specified in paragraph (d) of this section are applicable for all EPs for 2019 and subsequent years, and for eligible hospitals and CAHs attesting to a State for the Medicaid EHR Incentive Program for 2019.

* * * * *

(c) *Stage 3 objectives and measures for eligible hospitals and CAHs attesting to CMS for 2019*—* * *

(d) *Stage 3 objectives and measures for all EPs for 2019 and subsequent years, and for eligible hospitals and CAHs attesting to a State for the Medicaid EHR Incentive Program for 2019*—* * *

(6) * * *
(i) * * *
(B) * * *
(*2*) * * *

(*i*) For an EHR reporting period in 2017 and 2018, for more than 5 percent of all unique patients seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or their authorized representatives), or in response to a secure message sent by the patient; or

(*ii*) For an EHR reporting period other than 2017 and 2018, for more than 25 percent of all unique patients seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or their authorized representatives), or in response to a secure message sent by the patient.

* * * * *

(ii) * * *
(B) * * *
(*1*) * * *

(*iv*) For an EHR reporting period in 2017 and 2018, an eligible hospital or CAH may meet a threshold of 5 percent instead of 10 percent for the measure at paragraph (d)(6)(ii)(B)(*1*) of this section.

(*2*) * * *

(*i*) For an EHR reporting period in 2017 and 2018, for more than 5 percent of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or their authorized representatives), or in response to a secure message sent by the patient (or their authorized representatives).

(*ii*) For an EHR reporting period other than 2017 and 2018, for more than 25

percent of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or their authorized representatives), or in response to a secure message sent by the patient (or their authorized representatives).

* * * * *

■ 42. Section 495.40 is amended by—

■ a. Amending paragraph (a)(2)(i)(F) by adding ''and CY 2018'' after ''For CY 2017'';

■ b. Revising paragraph (a)(2)(i)(G); and

■ c. Revising paragraphs (b)(2)(i)(F) introductory text and (b)(2)(i)(G) introductory text.

The revisions read as follows:

§ 495.40 Demonstration of meaningful use criteria.

(a) * * *

(2) * * *

(i) * * *

(G) For CY 2019 and subsequent years, satisfied the required objectives and associated measures under § 495.24(d) for meaningful use.

* * * * *

(b) * * *

(2) * * *

(i) * * *

(F) For CY 2017 and CY 2018:

* * * * *

(G) For CY 2019:

* * * * *

■ 43. Section 495.102 is amended by redesignating paragraph (d)(5) as paragraph (d)(6) and adding new paragraphs (d)(5) and (7) to read as follows:

§ 495.102 Incentive payments to EPs.

* * * * *

(d) * * *

(5) *Exception for decertified EHR technology.* The Secretary shall exempt an EP from the application of the payment adjustment for CY 2018 under paragraph (d)(1) of this section if the Secretary determines that compliance with the requirement for being a meaningful EHR user is not possible because the certified EHR technology used by the EP has been decertified under ONC's Health IT Certification Program. To be considered for an exception, an EP must submit, in the manner specified by CMS, an application demonstrating that the certified EHR technology was decertified during the 12-month period preceding the applicable EHR reporting period for the CY 2018 payment adjustment year, or during the applicable EHR reporting period for the CY 2018 payment adjustment year, and that the EP made a good faith effort to obtain another certified EHR technology for that EHR reporting period. Applications requesting this exception must be submitted no later than October 1, 2017, or a later date specified by CMS.

* * * * *

(7) *Payment adjustments not applicable to ambulatory surgical center-based EPs.* For the CY 2017 and CY 2018 payment adjustment years, no payment adjustment under paragraphs (d)(1) through (3) of this section may be made in the case of an ambulatory surgical center-based eligible professional, as defined in § 495.4.

Dated: July 26, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: July 27, 2017.

Thomas E. Price,

Secretary, Department of Health and Human Services.

Note: The following Addendum and Appendixes will not appear in the Code of Federal Regulations.

Addendum—Schedule of Standardized Amounts, Update Factors, Rate-of-Increase Percentages Effective with Cost Reporting Periods Beginning on or after October 1, 2017, and Payment Rates for LTCHs Effective for Discharges Occurring on or after October 1, 2017

I. Summary and Background

In this Addendum, we are setting forth a description of the methods and data we used to determine the prospective payment rates for Medicare hospital inpatient operating costs and Medicare hospital inpatient capital-related costs for FY 2018 for acute care hospitals. We also are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS for FY 2018. We note that, because certain hospitals excluded from the IPPS are paid on a reasonable cost basis subject to a rate-of-increase ceiling (and not by the IPPS), these hospitals are not affected by the figures for the standardized amounts, offsets, and budget neutrality factors. Therefore, in this final rule, we are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS that will be effective for cost reporting periods beginning on or after October 1, 2017.

In addition, we are setting forth a description of the methods and data we used to determine the standard Federal payment rate that will be applicable to Medicare LTCHs for FY 2018.

In general, except for SCHs, for FY 2018, each hospital's payment per discharge under the IPPS is based on 100 percent of the Federal national rate, also known as the national adjusted standardized amount. This amount reflects the national average hospital cost per case from a base year, updated for inflation. We note that, under section 205 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted on April 16, 2015), the MDH program is set to expire at the end of FY 2017. SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal national rate (including, as discussed in section V.G. of the preamble of this final rule, uncompensated care payments under section 1886(r)(2) of the Act); the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge. As noted, under current law, the MDH program is set to expire at the end of FY 2017.

As discussed in section V.B. of the preamble of this final rule, in accordance with section 1886(d)(9)(E) of the Act as amended by section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113), for FY 2018, subsection (d) Puerto Rico hospitals will continue to be paid based on 100 percent of the national standardized amount. Because Puerto Rico hospitals are paid 100 percent of the national standardized amount and are subject to the same national standardized amount as subsection (d) hospitals that receive the full update, our discussion below does not include references to the Puerto Rico standardized amount or the Puerto Rico-specific wage index.

As discussed in section II. of this Addendum, we are making changes in the determination of the prospective payment rates for Medicare inpatient operating costs for acute care hospitals for FY 2018. In section III. of this Addendum, we discuss our policy changes for determining the prospective payment rates for Medicare inpatient capital-related costs for FY 2018. In section IV. of this Addendum, we are setting forth the rate-of-increase percentage for determining the rate-of-increase limits for certain hospitals excluded from the IPPS for FY 2018. In section V. of this Addendum, we discuss policy changes for determining the standard Federal rate for LTCHs paid under the LTCH PPS for FY 2018. The tables to which we refer in the preamble of this final rule are listed in section VI. of this Addendum and are available via the Internet on the CMS Web site.

II. Changes to Prospective Payment Rates for Hospital Inpatient Operating Costs for Acute Care Hospitals for FY 2018

The basic methodology for determining prospective payment rates for hospital inpatient operating costs for acute care hospitals for FY 2005 and subsequent fiscal years is set forth under § 412.64. The basic methodology for determining the prospective payment rates for hospital inpatient operating costs for hospitals located in Puerto Rico for FY 2005 and subsequent fiscal years is set forth under §§ 412.211 and 412.212. Below we discuss the factors we used for determining the prospective payment rates for FY 2018.

In summary, the standardized amounts set forth in Tables 1A, 1B, and 1C that are listed and published in section VI. of this Addendum (and available via the Internet on the CMS Web site) reflect—

• Equalization of the standardized amounts for urban and other areas at the level computed for large urban hospitals during FY 2004 and onward, as provided for under section 1886(d)(3)(A)(iv)(II) of the Act.

• The labor-related share that is applied to the standardized amounts to give the hospital the highest payment, as provided for under sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act. For FY 2018, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the national standardized amount. We refer readers to section V.B. of the preamble of this final rule for a complete discussion on the FY 2018 inpatient hospital update. Below is a table with these four options:

FY 2018	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Market Basket Rate-of-Increase	2.7	2.7	2.7	2.7
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.675	−0.675
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−2.025	0.0	−2.025
MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.6	−0.6	−0.6	−0.6
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.75	−0.75	−0.75	−0.75
Applicable Percentage Increase Applied to Standardized Amount	1.35	−0.675	0.675	−1.35

We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for ''subsection (d)'' hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico.

In addition, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016, and also to apply the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act to Puerto Rico hospitals that are not meaningful EHR users, effective FY 2022. Accordingly, because the provisions of section 1886(b)(3)(B)(ix) of the Act are not applicable to hospitals located in Puerto Rico until FY 2022, the adjustments under this provision are not applicable for FY 2018.

• An adjustment to the standardized amount to ensure budget neutrality for DRG recalibration and reclassification, as provided for under section 1886(d)(4)(C)(iii) of the Act.

• An adjustment to ensure the wage index and labor-related share changes are budget neutral, as provided for under section 1886(d)(3)(E)(i) of the Act (as discussed in the FY 2006 IPPS final rule (70 FR 47395) and the FY 2010 IPPS final rule (74 FR 44005). We note that section 1886(d)(3)(E)(i) of the Act requires that when we compute such budget neutrality, we assume that the provisions of section 1886(d)(3)(E)(ii) of the Act (requiring a 62-percent labor-related share in certain circumstances) had not been enacted.

• An adjustment to ensure the effects of geographic reclassification are budget neutral, as provided for under section 1886(d)(8)(D) of the Act, by removing the FY 2017 budget neutrality factor and applying a revised factor.

• Removal of the adjustment in FY 2017 to offset the cost of the 3-year hold harmless transitional wage index provisions provided by CMS as a result of the implementation of the new OMB labor market area delineations (beginning with FY 2015).

• A single positive adjustment of 0.4588 in FY 2018 as required under section 15005 of the 21st Century Cures Act (Pub. L. 114–255), which amended section 7(b)(1)(B) of the TMA, as amended by section 631 of the ATRA and section 414 of the MACRA, to reduce the adjustment for FY 2018 from 0.5 percentage point to 0.4588 percentage point.

• An adjustment to remove the FY 2017 outlier offset and apply an offset for FY 2018, as provided for in section 1886(d)(3)(B) of the Act.

• As discussed in section V.M. of the preamble of this final rule, a factor of (1/1.006) in the calculation of the FY 2018 standardized amount. Specifically, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57058 through 57060), using our authority under section 1886(d)(5)(I)(i) of the Act, we finalized a policy to include a permanent factor of (1/0.998) and a temporary one-time factor of (1.006) in the calculation of the FY 2017 standardized amount and to include a factor of (1/1.006) in the calculation of the FY 2018 standardized amount to remove the temporary one-time factor of 1.006 applied in FY 2017 to address the effects of the 0.2 percent reduction to the rate for the 2-midnight policy in effect for FY 2014, FY 2015, and FY 2016. Therefore, in this final rule, for FY 2018, we are removing the temporary one-time prospective increase to the FY 2017 standardized amount of 0.6 percent or a factor of 1.006.

For FY 2018, consistent with current law, we are applying the rural floor budget neutrality adjustment to hospital wage indexes. Also, consistent with section 3141 of the Affordable Care Act, instead of applying a State-level rural floor budget neutrality adjustment to the wage index, we are applying a uniform, national budget neutrality adjustment to the FY 2018 wage index for the rural floor. We note that, in section III.H.2.b. of the preamble to this final rule, we are extending the imputed floor policy (both the original methodology and alternative methodology) for FY 2018. Therefore, for FY 2018, in this final rule, we are continuing to include the imputed floor (calculated under the original methodology and alternative methodology) in calculating the uniform, national rural floor budget neutrality adjustment, which is reflected in the FY 2018 wage index.

In prior fiscal years, CMS made an adjustment to ensure the effects of the Rural Community Hospital Demonstration Program required under section 410A of Public Law 108–173, as amended by sections 3123 and 10313 of Public Law 111–148, which extended the demonstration program for an additional 5 years, were budget neutral as required under section 410A(c)(2) of Public Law 108–173. As discussed in section V.L.3. of the preamble to this final rule, section 15003 of Public Law 114–255 amended section 410A of Public Law 108–173 to provide for a 10-year extension of the demonstration (in place of the 5-year extension required by the Affordable Care Act) beginning on the date immediately following the last day of the initial 5-year period under section 410A(a)(5) of Public Law 108–173. Therefore, section 15003 of Public Law 114–255 requires an additional 5-year extension of the demonstration. Regarding the costs of the demonstration specifically for FY 2018, as described in section V.L.3. of the preamble to this final rule, we proposed in the FY 2018 IPS/LTCH PPS proposed rule (82 FR 19994) that if the selection of additional hospitals pursuant to section 410A(g)(6) of Public Law 108–173 (as added by section 15003 of Pub. L. 114–255) was announced by June 2017, we would include in the FY 2018 IPPS/LTCH PPS final rule an estimate of the costs of the demonstration for FY 2018 and the resulting budget neutrality offset amount for the newly selected hospitals (Cohort 3 hospitals) and for the previously participating hospitals

(Cohorts 1 and 2 hospitals). We stated that if the final selection of the additional hospitals is not announced by June 2017, we would not be able to include an estimate of the costs of the demonstration for any participating hospitals or an estimated budget neutrality adjustment for FY 2018 in the FY 2018 IPPS/LTCH PPS final rule. As of June 2017, we did not announce the final selection of the additional hospitals. Therefore, for this final rule, we are not able to include an estimate of the costs of the demonstration for any participating hospitals or an estimated budget neutrality adjustment for FY 2018. We refer readers to section V.L.3. of the preamble of this final rule for complete details on the Rural Community Hospital Demonstration Program and our methodology for calculating budget neutrality for this demonstration.

A. Calculation of the Adjusted Standardized Amount

1. Standardization of Base-Year Costs or Target Amounts

In general, the national standardized amount is based on per discharge averages of adjusted hospital costs from a base period (section 1886(d)(2)(A) of the Act), updated and otherwise adjusted in accordance with the provisions of section 1886(d) of the Act. The September 1, 1983 interim final rule (48 FR 39763) contained a detailed explanation of how base-year cost data (from cost reporting periods ending during FY 1981) were established for urban and rural hospitals in the initial development of standardized amounts for the IPPS.

Sections 1886(d)(2)(B) and 1886(d)(2)(C) of the Act require us to update base-year per discharge costs for FY 1984 and then standardize the cost data in order to remove the effects of certain sources of cost variations among hospitals. These effects include case-mix, differences in area wage levels, cost-of-living adjustments for Alaska and Hawaii, IME costs, and costs to hospitals serving a disproportionate share of low-income patients.

For FY 2018, we are rebasing and revising the national labor-related and nonlabor-related shares (based on the 2014-based hospital market basket discussed in section IV. of the preamble of this final rule). Specifically, under section 1886(d)(3)(E) of the Act, the Secretary estimates, from time to time, the proportion of payments that are labor-related and adjusts the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates. We refer to the proportion of hospitals' costs that are attributable to wages and wage-related costs as the ''labor-related share.'' For FY 2018, as discussed in section IV.B.3. of the preamble of this final rule, we are applying a labor-related share of 68.3 percent for the national standardized amounts for all IPPS hospitals (including hospitals in Puerto Rico) that have a wage index value that is greater than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, we are applying the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals (including hospitals in Puerto Rico) whose wage index values are less than or equal to 1.0000.

The standardized amounts for operating costs appear in Tables 1A, 1B, and 1C that are listed and published in section VI. of the Addendum to this final rule and are available via the Internet on the CMS Web site.

2. Computing the National Average Standardized Amount

Section 1886(d)(3)(A)(iv)(II) of the Act requires that, beginning with FY 2004 and thereafter, an equal standardized amount be computed for all hospitals at the level computed for large urban hospitals during FY 2003, updated by the applicable percentage update. Accordingly, we calculated the FY 2018 national average standardized amount irrespective of whether a hospital is located in an urban or rural location.

3. Updating the National Average Standardized Amount

Section 1886(b)(3)(B) of the Act specifies the applicable percentage increase used to update the standardized amount for payment for inpatient hospital operating costs. We note that, in compliance with section 404 of the MMA, in this final rule, we used the rebased and revised 2014-based IPPS operating and capital market baskets for FY 2018. As discussed in section V.B. of the preamble of this final rule, in accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we reduced the FY 2018 applicable percentage increase (which is based on IGI's second quarter 2017 forecast of the 2014-based IPPS market basket) by the MFP adjustment (the 10-year moving average of MFP for the period ending FY 2018) of 0.6 percentage point, which is also calculated based on IGI's second quarter 2017 forecast.

In addition, in accordance with section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we further updated the standardized amount for FY 2018 by the estimated market basket percentage increase less 0.75 percentage point for hospitals in all areas. Sections 1886(b)(3)(B)(xi) and (xii) of the Act, as added and amended by sections 3401(a) and 10319(a) of the Affordable Care Act, further state that these adjustments may result in the applicable percentage increase being less than zero. The percentage increase in the market basket reflects the average change in the price of goods and services required as inputs to provide hospital inpatient services.

Based on IGI's 2017 second quarter forecast of the hospital market basket increase (as discussed in Appendix B of this final rule), the forecast of the hospital market basket increase for FY 2018 for this final rule is 2.7 percent. As discussed earlier, for FY 2018, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act, there are four possible applicable percentage increases that can be applied to the standardized amount. We refer readers to section V.B. of the preamble of this final rule for a complete discussion on the FY 2018 inpatient hospital update to the standardized amount. We also refer readers to the table above for the four possible applicable percentage increases that will be applied to update the national standardized amount. The standardized amounts shown in Tables 1A through 1C that are published in section VI. of this Addendum and that are available via the Internet on the CMS Web site reflect these differential amounts.

Although the update factors for FY 2018 are set by law, we are required by section 1886(e)(4) of the Act to recommend, taking into account MedPAC's recommendations, appropriate update factors for FY 2018 for both IPPS hospitals and hospitals and hospital units excluded from the IPPS. Section 1886(e)(5)(A) of the Act requires that we publish our recommendations in the **Federal Register** for public comment. Our recommendation on the update factors is set forth in Appendix B of this final rule.

4. Methodology for Calculation of the Average Standardized Amount

The methodology we used to calculate the FY 2018 standardized amount is as follows:

- To ensure we are only including hospitals paid under the IPPS in the calculation of the standardized amount, we apply the following inclusion and exclusion criteria: Include hospitals whose last four digits fall between 0001 and 0879 (section 2779A1 of Chapter 2 of the State Operations Manual on the CMS Web site at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf*); exclude CAHs at the time of this final rule; exclude hospitals in Maryland (because these hospitals are paid under an all payer model under section 1115A of the Act); and remove PPS-excluded cancer hospitals that have a ''V'' in the fifth position of their provider number or a ''E'' or ''F'' in the sixth position.
- As in the past, we adjusted the FY 2018 standardized amount to remove the effects of the FY 2017 geographic reclassifications and outlier payments before applying the FY 2018 updates. We then applied budget neutrality offsets for outliers and geographic reclassifications to the standardized amount based on FY 2018 payment policies.
- We do not remove the prior year's budget neutrality adjustments for reclassification and recalibration of the DRG relative weights and for updated wage data because, in accordance with sections 1886(d)(4)(C)(iii) and 1886(d)(3)(E) of the Act, estimated aggregate payments after updates in the DRG relative weights and wage index should equal estimated aggregate payments prior to the changes. If we removed the prior year's adjustment, we would not satisfy these conditions.

Budget neutrality is determined by comparing aggregate IPPS payments before and after making changes that are required to be budget neutral (for example, changes to MS–DRG classifications, recalibration of the MS–DRG relative weights, updates to the wage index, and different geographic reclassifications). We include outlier payments in the simulations because they may be affected by changes in these parameters.

- Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50433), because IME Medicare Advantage payments

are made to IPPS hospitals under section 1886(d) of the Act, we believe these payments must be part of these budget neutrality calculations. However, we note that it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation or the outlier offset to the standardized amount because the statute requires that outlier payments be not less than 5 percent nor more than 6 percent of total ''operating DRG payments,'' which does not include IME and DSH payments. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.

• Consistent with the methodology in the FY 2012 IPPS/LTCH PPS final rule, in order to ensure that we capture only fee-for-service claims, we are only including claims with a ''Claim Type'' of 60 (which is a field on the MedPAR file that indicates a claim is an FFS claim).

• Consistent with our methodology established in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57277), in order to further ensure that we capture only FFS claims, we are excluding claims with a ''GHOPAID'' indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).

• Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50423), we examine the MedPAR file and remove pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of ''3'' for blood clotting with a revenue code of ''0636'' from the covered charge field for the budget neutrality adjustments. We also remove organ acquisition charges from the covered charge field for the budget neutrality adjustments because organ acquisition is a pass-through payment not paid under the IPPS.

• The Bundled Payments for Care Improvement (BPCI) initiative, developed under the authority of section 3021 of the Affordable Care Act (codified at section 1115A of the Act), is comprised of four broadly defined models of care, which link payments for multiple services beneficiaries receive during an episode of care. Under the BPCI initiative, organizations enter into payment arrangements that include financial and performance accountability for episodes of care. On January 31, 2013, CMS announced the first set of health care organizations selected to participate in the BPCI initiative. Additional organizations were selected in 2014. For additional information on the BPCI initiative, we refer readers to the CMS Center for Medicare and Medicaid Innovation's Web site at: *http://innovation.cms.gov/initiatives/Bundled-Payments/index.html*.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53341 through 53343), for FY 2013 and subsequent fiscal years, we finalized a methodology to treat hospitals that participate in the BPCI initiative the same as prior fiscal years for the IPPS payment modeling and ratesetting process (which includes recalibration of the MS–DRG relative weights, ratesetting, calculation of the budget neutrality factors, and the impact analysis) without regard to a hospital's participation within these bundled payment models (that is, as if they are not participating in those models under the BPCI initiative). For FY 2018, as we proposed, we are continuing to include all applicable data from subsection (d) hospitals participating in BPCI Models 1, 2, and 4 in our IPPS payment modeling and ratesetting calculations.

• Consistent with our methodology established in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688), we believe that it is appropriate to include adjustments for the Hospital Readmissions Reduction Program and the Hospital VBP Program (established under the Affordable Care Act) within our budget neutrality calculations.

Both the hospital readmissions payment adjustment (reduction) and the hospital VBP payment adjustment (redistribution) are applied on a claim-by-claim basis by adjusting, as applicable, the base-operating DRG payment amount for individual subsection (d) hospitals, which affects the overall sum of aggregate payments on each side of the comparison within the budget neutrality calculations.

In order to properly determine aggregate payments on each side of the comparison, as we have done for the last 4 fiscal years, for FY 2018 and subsequent years, we are continuing to apply the hospital readmissions payment adjustment and the hospital VBP payment adjustment on each side of the comparison, consistent with the methodology that we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688). That is, we applied the readmissions payment adjustment factor and the hospital VBP payment adjustment factor on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

For the proposed rule, for the purpose of calculating the FY 2018 readmissions payment adjustment factors, we used excess readmission ratios and aggregate payments for excess readmissions based on admissions from the prior fiscal year's applicable period because, at that time, hospitals not yet had the opportunity to review and correct the data before the data were made public under the policy we adopted regarding the reporting of hospital-specific readmission rates, consistent with section 1886(q)(6) of the Act. For FY 2018, in this final rule, we calculated the readmissions payment adjustment factors using excess readmission ratios and aggregate payments for excess readmissions based on admissions from the finalized applicable period for FY 2018 as hospitals have had the opportunity to review and correct these data under our policy regarding the reporting of hospital-specific readmission rates consistent with section 1886(q)(6) of the Act. We discuss our final policy regarding the reporting of hospital-specific readmission rates for FY 2018 in section V.I.5. of the preamble of this final rule. (For additional information on our general policy for the reporting of hospital-specific readmission rates, consistent with section 1886(q)(6) of the Act, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53399 through 53400).)

In addition, for FY 2018, in this final rule, for the purpose of modeling aggregate payments when determining all budget neutrality factors, we used proxy hospital VBP payment adjustment factors for FY 2018 that are based on data from a historical period because hospitals have not yet had an opportunity to review and submit corrections for their data from the FY 2018 performance period. (For additional information on our policy regarding the review and correction of hospital-specific measure rates under the Hospital VBP Program, consistent with section 1886(o)(10)(A)(ii) of the Act, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53578 through 53581), the CY 2012 OPPS/ASC final rule with comment period (76 FR 74544 through 74547), and the Hospital Inpatient VBP final rule (76 FR 26534 through 26536).)

• The Affordable Care Act also established section 1886(r) of the Act, which modifies the methodology for computing the Medicare DSH payment adjustment beginning in FY 2014. Beginning in FY 2014, IPPS hospitals receiving Medicare DSH payment adjustments receive an empirically justified Medicare DSH payment equal to 25 percent of the amount that would previously have been received under the statutory formula set forth under section 1886(d)(5)(F) of the Act governing the Medicare DSH payment adjustment. In accordance with section 1886(r)(2) of the Act, the remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals under age 65 who are uninsured and an additional statutory adjustment, will be available to make additional payments to Medicare DSH hospitals based on their share of the total amount of uncompensated care reported by Medicare DSH hospitals for a given time period. In order to properly determine aggregate payments on each side of the comparison for budget neutrality, prior to FY 2014, we included estimated Medicare DSH payments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

To do this for FY 2018 (as we did for the last 4 fiscal years), we included estimated empirically justified Medicare DSH payments that will be paid in accordance with section 1886(r)(1) of the Act and estimates of the additional uncompensated care payments made to hospitals receiving Medicare DSH payment adjustments as described by section 1886(r)(2) of the Act. That is, we considered estimated empirically justified Medicare DSH payments at 25 percent of what would otherwise have been paid, and also the estimated additional uncompensated care payments for hospitals receiving Medicare DSH payment adjustments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

• When calculating total payments for budget neutrality, to determine total

payments for SCHs, we model total hospital-specific rate payments and total Federal rate payments and then include whichever one of the total payments is greater. As discussed in section V.G. of the preamble to this final rule and below, we are continuing the FY 2014 finalized methodology under which we take into consideration uncompensated care payments in the comparison of payments under the Federal rate and the hospital-specific rate for SCHs. Therefore, we included estimated uncompensated care payments in this comparison.

• We are including an adjustment to the standardized amount for those hospitals that are not meaningful EHR users in our modeling of aggregate payments for budget neutrality for FY 2018. Similar to FY 2017, we included this adjustment based on data on the prior year's performance. Payments for hospitals will be estimated based on the applicable standardized amount in Tables 1A and 1B for discharges occurring in FY 2018.

a. Recalibration of MS–DRG Relative Weights

Section 1886(d)(4)(C)(iii) of the Act specifies that, beginning in FY 1991, the annual DRG reclassification and recalibration of the relative weights must be made in a manner that ensures that aggregate payments to hospitals are not affected. As discussed in section II.G. of the preamble of this final rule, we normalized the recalibrated MS–DRG relative weights by an adjustment factor so that the average case relative weight after recalibration is equal to the average case relative weight prior to recalibration. However, equating the average case relative weight after recalibration to the average case relative weight before recalibration does not necessarily achieve budget neutrality with respect to aggregate payments to hospitals because payments to hospitals are affected by factors other than average case relative weight. Therefore, as we have done in past years, we are making a budget neutrality adjustment to ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is met.

For FY 2018, to comply with the requirement that MS–DRG reclassification and recalibration of the relative weights be budget neutral for the standardized amount and the hospital-specific rates, we used FY 2016 discharge data to simulate payments and compared the following:

• Aggregate payments using the FY 2017 labor-related share percentages, the FY 2017 relative weights, and the FY 2017 pre-reclassified wage data, and applied the FY 2018 hospital readmissions payment adjustments and estimated FY 2018 hospital VBP payment adjustments; and

• Aggregate payments using the FY 2017 labor-related share percentages, the FY 2018 relative weights, and the FY 2017 pre-reclassified wage data, and applied the same FY 2018 hospital readmissions payment adjustments and estimated FY 2018 hospital VBP payment adjustments applied above. (As discussed in section II.G. of the preamble of this final rule, in response to public comments, we are adopting a temporary measure for FY 2018 for MS–DRGs where the relative weight would have declined by more than 20 percent. Specifically, for these MS DRGs, the FY 2018 relative weight is set at 80 percent of the FY 2017 final relative weight, and it is these FY 2018 relative weights that are used to determine the MS–DRG reclassification and recalibration budget neutrality factor in this final rule.)

Based on this comparison, we computed a budget neutrality adjustment factor equal to 0.997432 and applied this factor to the standardized amount. As discussed in section IV. of this Addendum, we also applied the MS–DRG reclassification and recalibration budget neutrality factor of 0.997432 to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2017.

b. Updated Wage Index—Budget Neutrality Adjustment

Section 1886(d)(3)(E)(i) of the Act requires us to update the hospital wage index on an annual basis beginning October 1, 1993. This provision also requires us to make any updates or adjustments to the wage index in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. Section 1886(d)(3)(E)(i) of the Act requires that we implement the wage index adjustment in a budget neutral manner. However, section 1886(d)(3)(E)(ii) of the Act sets the labor-related share at 62 percent for hospitals with a wage index less than or equal to 1.0000, and section 1886(d)(3)(E)(i) of the Act provides that the Secretary shall calculate the budget neutrality adjustment for the adjustments or updates made under that provision as if section 1886(d)(3)(E)(ii) of the Act had not been enacted. In other words, this section of the statute requires that we implement the updates to the wage index in a budget neutral manner, but that our budget neutrality adjustment should not take into account the requirement that we set the labor-related share for hospitals with wage indexes less than or equal to 1.0000 at the more advantageous level of 62 percent. Therefore, for purposes of this budget neutrality adjustment, section 1886(d)(3)(E)(i) of the Act prohibits us from taking into account the fact that hospitals with a wage index less than or equal to 1.0000 are paid using a labor-related share of 62 percent. Consistent with current policy, for FY 2018, we adjusted 100 percent of the wage index factor for occupational mix. We describe the occupational mix adjustment in section III.E. of the preamble of this final rule.

To compute a budget neutrality adjustment factor for wage index and labor-related share percentage changes, we used FY 2016 discharge data to simulate payments and compared the following:

• Aggregate payments using the FY 2018 relative weights and the FY 2017 pre-reclassified wage indexes, applied the FY 2017 labor-related share of 69.6 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the FY 2018 hospital readmissions payment adjustment and the estimated FY 2018 hospital VBP payment adjustment; and

• Aggregate payments using the FY 2018 relative weights and the FY 2018 pre-reclassified wage indexes, applied the labor-related share for FY 2018 of 68.3 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the same FY 2018 hospital readmissions payment adjustments and estimated FY 2018 hospital VBP payment adjustments applied above.

In addition, we applied the MS–DRG reclassification and recalibration budget neutrality adjustment factor (derived in the first step) to the payment rates that were used to simulate payments for this comparison of aggregate payments from FY 2017 to FY 2018. By applying this methodology, we determined a budget neutrality adjustment factor of 1.001148 for changes to the wage index.

c. Reclassified Hospitals—Budget Neutrality Adjustment

Section 1886(d)(8)(B) of the Act provides that certain rural hospitals are deemed urban. In addition, section 1886(d)(10) of the Act provides for the reclassification of hospitals based on determinations by the MGCRB. Under section 1886(d)(10) of the Act, a hospital may be reclassified for purposes of the wage index.

Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amount to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. We note that the wage index adjustments provided for under section 1886(d)(13) of the Act are not budget neutral. Section 1886(d)(13)(H) of the Act provides that any increase in a wage index under section 1886(d)(13) shall not be taken into account in applying any budget neutrality adjustment with respect to such index under section 1886(d)(8)(D) of the Act. To calculate the budget neutrality adjustment factor for FY 2018, we used FY 2016 discharge data to simulate payments and compared the following:

• Aggregate payments using the FY 2018 labor-related share percentages, the FY 2018 relative weights, and the FY 2018 wage data prior to any reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act, and applied the FY 2018 hospital readmissions payment adjustments and the estimated FY 2018 hospital VBP payment adjustments; and

• Aggregate payments using the FY 2018 labor-related share percentages, the FY 2018 relative weights, and the FY 2018 wage data after such reclassifications, and applied the same FY 2018 hospital readmissions payment adjustments and the estimated FY 2018 hospital VBP payment adjustments applied above.

We note that the reclassifications applied under the second simulation and comparison are those listed in Table 2 associated with this final rule, which is available via the Internet on the CMS Web site. This table reflects reclassification crosswalks for FY 2018, and apply the policies explained in section III. of the preamble to this final rule. Based on these simulations, we calculated a budget neutrality adjustment factor of 0.988008 to ensure that the effects of these provisions are budget neutral, consistent with the statute. The FY 2018 budget neutrality adjustment factor was applied to

the standardized amount after removing the effects of the FY 2017 budget neutrality adjustment factor. We note that the FY 2018 budget neutrality adjustment reflects FY 2018 wage index reclassifications approved by the MGCRB or the Administrator at the time of development of this final rule.

d. Rural Floor Budget Neutrality Adjustment

Under § 412.64(e)(4), we make an adjustment to the wage index to ensure that aggregate payments after implementation of the rural floor under section 4410 of the BBA (Pub. L. 105–33) and the imputed floor under § 412.64(h)(4) are equal to the aggregate prospective payments that would have been made in the absence of such provisions. Consistent with section 3141 of the Affordable Care Act and as discussed in section III.H. of the preamble of this final rule and codified at § 412.64(e)(4)(ii), the budget neutrality adjustment for the rural floor and imputed floor is a national adjustment to the wage index.

As noted above and as discussed in section III.H.2. of the preamble of this final rule, we are extending the imputed floor policy (both the original policy and alternative methodology) for FY 2018. Therefore, in order to ensure that aggregate payments to hospitals are not affected, similar to prior years, for FY 2018 we follow our policy of including the imputed floor (calculated under the original and alternative methodologies) in the national rural floor budget neutrality adjustment to the wage index.

Similar to our calculation in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50369 through 50370), for FY 2018, we calculated a national rural Puerto Rico wage index. Because there are no rural Puerto Rico hospitals with established wage data, our calculation of the FY 2018 rural Puerto Rico wage index is based on the policy adopted in the FY 2008 IPPS final rule with comment period (72 FR 47323). That is, we use the unweighted average of the wage indexes from all CBSAs (urban areas) that are contiguous (share a border with) to the rural counties to compute the rural floor (72 FR 47323; 76 FR 51594). Under the OMB labor market area delineations, except for Arecibo, Puerto Rico (CBSA 11640), all other Puerto Rico urban areas are contiguous to a rural area. Therefore, based on our existing policy, the FY 2018 rural Puerto Rico wage index is calculated based on the average of the FY 2018 wage indexes for the following urban areas: Aguadilla-Isabela, PR (CBSA 10380); Guayama, PR (CBSA 25020); Mayaguez, PR (CBSA 32420); Ponce, PR (CBSA 38660); San German, PR (CBSA 41900); and San Juan-Carolina-Caguas, PR (CBSA 41980).

To calculate the national rural floor and imputed floor budget neutrality adjustment factor, we used FY 2016 discharge data to simulate payments and the post-reclassified national wage indexes and compared the following:

- National simulated payments without the national rural floor and imputed floor; and
- National simulated payments with the national rural floor and imputed floor.

Based on this comparison, we determined a national rural floor and imputed floor budget neutrality adjustment factor of 0.993348. The national adjustment was applied to the national wage indexes to produce a national rural floor and imputed floor budget neutral wage index.

e. Adjustment for FY 2018 Required Under Section 414 of Public Law 114–10 (MACRA) and Section 15005 of Public Law 114–255

As stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56785), once the recoupment required under section 631 of the ATRA was complete, we had anticipated making a single positive adjustment in FY 2018 to offset the reductions required to recoup the $11 billion under section 631 of the ATRA. However, section 414 of the MACRA (which was enacted on April 16, 2015) replaced the single positive adjustment we intended to make in FY 2018 with a 0.5 percent positive adjustment for each of FYs 2018 through 2023. In the FY 2017 rulemaking, we indicated that we would address the adjustments for FY 2018 and later fiscal years in future rulemaking. As noted previously, section 15005 of the 21st Century Cures Act (Public Law 114–255), which was enacted December 13, 2016, amended section 7(b)(1)(B) of the TMA, as amended by section 631 of the ATRA and section 414 of the MACRA, to reduce the adjustment for FY 2018 from 0.5 percentage points to 0.4588 percentage points. Therefore, for FY 2018, we are implementing the required +0.4588 percent adjustment to the standardized amount. This is a permanent adjustment to payment rates. In the FY 2018 IPPS/LTCH PPS proposed rule, we noted, that while we are not proposing future adjustments required under section 414 of the MACRA and section 15005 of Public Law 114–255 at this time, we expect to propose positive 0.5 percent adjustments to the standardized amounts for FYs 2019 through 2023.

f. Outlier Payments

Section 1886(d)(5)(A) of the Act provides for payments in addition to the basic prospective payments for ''outlier'' cases involving extraordinarily high costs. To qualify for outlier payments, a case must have costs greater than the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, uncompensated care payments, any new technology add-on payments, and the ''outlier threshold'' or ''fixed-loss'' amount (a dollar amount by which the costs of a case must exceed payments in order to qualify for an outlier payment). We refer to the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, uncompensated care payments, any new technology add-on payments, and the outlier threshold as the outlier ''fixed-loss cost threshold.'' To determine whether the costs of a case exceed the fixed-loss cost threshold, a hospital's CCR is applied to the total covered charges for the case to convert the charges to estimated costs. Payments for eligible cases are then made based on a marginal cost factor, which is a percentage of the estimated costs above the fixed-loss cost threshold. The marginal cost factor for FY 2018 is 80 percent, or 90 percent for burn MS–DRGs 927, 928, 929, 933, 934 and 935. We have used a marginal cost factor of 90 percent since FY 1989 (54 FR 36479 through 36480) for designated burn DRGs as well as a marginal cost factor of 80 percent for all other DRGs since FY 1995 (59 FR 45367).

In accordance with section 1886(d)(5)(A)(iv) of the Act, outlier payments for any year are projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments (which does not include IME and DSH payments) plus outlier payments. When setting the outlier threshold, we compute the 5.1 percent target by dividing the total operating outlier payments by the total operating DRG payments plus outlier payments. We do not include any other payments such as IME and DSH within the outlier target amount. Therefore, it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation. Section 1886(d)(3)(B) of the Act requires the Secretary to reduce the average standardized amount by a factor to account for the estimated proportion of total DRG payments made to outlier cases. More information on outlier payments may be found on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/outlier.htm*.

(1) FY 2018 Outlier Fixed-Loss Cost Threshold

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50977 through 50983), in response to public comments on the FY 2013 IPPS/LTCH PPS proposed rule, we made changes to our methodology for projecting the outlier fixed-loss cost threshold for FY 2014. We refer readers to the FY 2014 IPPS/LTCH PPS final rule for detailed discussion of the changes.

As we have done in the past, to calculate the FY 2018 outlier threshold, we simulated payments by applying FY 2018 payment rates and policies using cases from the FY 2016 MedPAR file. Therefore, in order to determine the FY 2018 outlier threshold, we inflated the charges on the MedPAR claims by 2 years, from FY 2016 to FY 2018. As discussed in the FY 2015 IPPS/LTCH PPS final rule, we believe a methodology that is based on 1-year of charge data will provide a more stable measure to project the average charge per case because our prior methodology used a 6-month measure, which inherently uses fewer claims than a 1-year measure and makes it more susceptible to fluctuations in the average charge per case as a result of any significant charge increases or decreases by hospitals. As finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57282), we used the following methodology to calculate the charge inflation factor for FY 2018:

- To produce the most stable measure of charge inflation, we applied the following inclusion and exclusion criteria of hospitals claims in our measure of charge inflation: Include hospitals whose last four digits fall between 0001 and 0899 (section 2779A1 of Chapter 2 of the State Operations Manual on the CMS Web site at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf*); include CAHs that were IPPS hospitals for the time period of the MedPAR data being used to calculate the charge inflation factor;

include hospitals in Maryland; and remove PPS-excluded cancer hospitals who have a ''V'' in the fifth position of their provider number or a ''E'' or ''F'' in the sixth position.

• We excluded Medicare Advantage IME claims for the reasons described in section I.A.4. of this Addendum. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.

• In order to ensure that we capture only FFS claims, we included claims with a ''Claim Type'' of 60 (which is a field on the MedPAR file that indicates a claim is an FFS claim).

• In order to further ensure that we capture only FFS claims, we excluded claims with a ''GHOPAID'' indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).

• We examined the MedPAR file and removed pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of ''3'' for blood clotting with a revenue code of ''0636'' from the covered charge field. We also removed organ acquisition charges from the covered charge field because organ acquisition is a pass-through payment not paid under the IPPS.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49779 through 49780), we stated that commenters were concerned that they were unable to replicate the calculation of the charge inflation factor that CMS used in the proposed rule. In response to those comments, we stated that we continue to believe that it is optimal to use the most recent period of charge data available to measure charge inflation. In response to those comments, similar to FY 2016 and 2017, for FY 2018 we grouped claims data by quarter in the table below in order that the public would be able to replicate the claims summary for the claims with discharge dates through September 30, 2016, that are available under the current LDS structure. In order to provide even more information in response to the commenters' request, similar to FY 2016 and FY 2017, for FY 2018 we have made available on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* (click on the link on the left titled ''FY 2018 IPPS Proposed Rule Home Page''' and then click the link ''FY 2018Proposed Rule Data Files''') a more detailed summary table by provider with the monthly charges that were used to compute the charge inflation factor. In the proposed rule, we stated that we would continue to work with our systems teams and privacy office to explore expanding the information available in the current LDS, perhaps through the provision of a supplemental data file for future rulemaking.

Quarter	Covered charges (January 1, 2015, through December 31, 2015)	Cases January 1, 2015, through December 31, 2015)	Covered Charges (January 1, 2016, through December 31, 2016)	Cases (January 1, 2016, through December 31, 2016)
1	$134,654,491,108	2,550,009	$140,324,387,852	2,503,723
2	128,043,608,047	2,432,111	134,274,423,481	2,401,159
3	125,070,725,661	2,352,162	129,395,535,792	2,318,480
4	130,224,314,081	2,386,486	104,063,409,952	1,850,535
Total	517,93,138,897	9,720,768	508,057,757,077	9,073,897

Under this methodology, to compute the 1-year average annualized rate-of-change in charges per case for FY 2018, we compared the average covered charge per case of $53,287 ($517,993,138,897/9,720,768) from the second quarter of FY 2015 through the first quarter of FY 2016 (January 1, 2015, through December 31, 2015) to the average covered charge per case of $55,991 ($508,057,757,077/9,073,897) from the second quarter of FY 2016 through the first quarter of FY 2017 (January 1, 2016, through December 31, 2016). This rate-of-change was 5.1 percent (1.05074) or 10.4 percent (1.104055) over 2 years. The billed charges are obtained from the claim from the MedPAR file and inflated by the inflation factor specified above.

Comment: Several commenters were concerned with what they stated was a lack of transparency with respect to the charge inflation component of the fixed-loss threshold calculation. One commenter requested that CMS not implement the increase in the outlier threshold from FY 2017 to FY 2018 until the agency provides data that can be independently validated to demonstrate the need for an increase in the outlier threshold.

Another commenter stated that it was unable to match the figures in the table from the proposed rule with publicly available data sources and that CMS did not disclose the source of the data. The commenter further stated that CMS has not made the necessary data available, or any guidance that describes whether and how CMS edited such data to arrive at the total of quarterly charges and charges per case used to measure charge inflation. Consequently, the commenter stated that the table provided in the proposed rule was not useful in assessing the accuracy of the charge inflation figure that CMS used in the proposed rule to calculate the outlier threshold. The commenter noted that CMS provided a detailed summary table by provider with the monthly charges that were used to compute the charge inflation factor. The commenters appreciated the additional data, but still believed that CMS has not provided enough specific information and data to allow the underlying numbers used in CMS' calculation of the charge inflation factor to be replicated and/or tested for accuracy. The commenter concluded that, in the absence of more specific data and information about how the data were edited by CMS to arrive at the totals used in the charge inflation calculation, CMS has not provided adequate notice to allow for meaningful comment.

Response: We responded to a similar comment in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50375), FY 2016 IPPS/LTCH PPS final rule (80 FR 49779 through 49780) and FY 2017 IPPS/LTCH PPS final rule (81 FR 57283) and refer readers to those final rules for our complete response. As previously noted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50375), we did not have sufficient time to restructure the files (such as ensuring that personal identification information is compliant with privacy regulations) prior to the publication of the proposed and this final rule. As we stated in last year's final rule, while the charge data may not be immediately available after the issuance of this final rule, we believe the data and supporting files we have provided will provide the commenters with additional information that can be verified once the charge data are available. We have produced the actual figures we used and disclosed our formula. We intend to post the actual charge data as soon as possible so that the public can verify the raw data with the figures we used in the calculation. As stated earlier and in the proposed rule, the charge data used to calculate the charge inflation factor are sourced from our MedPAR database.

In addition, as stated in last year's final rule, for this final rule we continue to believe that it is optimal to use the most recent period of charge data available to measure charge inflation. Similar to last year, the commenters did not propose to use charge data from a different period to compute the charge inflation factor. If we computed the charge inflation factor using the latest data available to the public at the time of issuance of this final rule, we would need to compare charge data from FY 2015 (October 2014—September 2015) to FY 2016 (October 2015—September 2016), data which would be at least 10 months old compared to the charge data we currently use that are 4 months old.

Comment: One commenter requested that CMS add the claims data used to compute the charge inflation factor to the list of limited data set (LDS) files that can be ordered through the usual LDS data request process.

Response: As we stated in response to a similar comment in last year's final rule,

there are limitations on how expeditiously we can add the charge data to the LDS. After consulting with our systems teams and privacy office, we do not anticipate being able to provide the charge data we currently use to calculate the charge inflation factor within the commenter's requested timeframe. We prefer using the latest data available at the time of the proposed and final rules to compute the charge inflation factor because we believe it leads to greater accuracy in the calculation of the fixed-loss cost outlier threshold. As noted earlier and in last year's final rule, we believe that using older data may not provide the same accuracy as the current data we use. We invite commenters to inform us if they believe their need to have complete access to the data we use in our methodology outweighs the greater accuracy provided by the use of more up-to-date data. As noted above, the data we currently use will eventually be publicly available for replication but not in the timeframe the commenter has requested. To summarize, we are confronted with a dilemma—either we use older data that commenters can access earlier, or we use the most up-to-date data which will be more accurate, but will not be available to the public until after publication of the proposed and final rules. For this final rule, we continue to believe the latter approach, using the best available data to produce a more accurate charge inflation factor, is preferable. However, for the FY 2019 IPPS/LTCH PPS proposed rule, we are considering using data that commenters can access earlier. As we have done in the past, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20173), we proposed to establish the FY 2018 outlier threshold using hospital CCRs from the December 2016 update to the Provider-Specific File (PSF)—the most recent available data at the time of the development of the proposed rule. We proposed to apply the following edits to providers' CCRs in the PSF. We believe these edits are appropriate in order to accurately model the outlier threshold. We first search for Indian Health Service providers and those providers assigned the statewide average CCR from the current fiscal year. We then replace these CCRs with the statewide average CCR for the upcoming fiscal year. We also assign the statewide average CCR (for the upcoming fiscal year) to those providers that have no value in the CCR field in the PSF or whose CCRs exceed the ceilings described later in this section (3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals). We do not apply the adjustment factors described below to hospitals assigned the statewide average CCR.

For FY 2018, we proposed to continue to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained below). We proposed that, if more recent data became available, we would use that data to calculate the final FY 2018 outlier threshold.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we adopted a new methodology to adjust the CCRs. Specifically, we finalized a policy to compare the national average case-weighted operating and capital CCR from the most recent update of the PSF to the national average case-weighted operating and capital CCR from the same period of the prior year.

Therefore, as we have done since FY 2014, we proposed to adjust the CCRs from the December 2016 update of the PSF by comparing the percentage change in the national average case-weighted operating CCR and capital CCR from the December 2015 update of the PSF to the national average case-weighted operating CCR and capital CCR from the December 2016 update of the PSF. We note that, in the proposed rule, we used total transfer-adjusted cases from FY 2016 to determine the national average case-weighted CCRs for both sides of the comparison. As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we believe that it is appropriate to use the same case count on both sides of the comparison because this will produce the true percentage change in the average case-weighted operating and capital CCR from one year to the next without any effect from a change in case count on different sides of the comparison.

Using the proposed methodology above, for the proposed rule, we calculated a December 2015 operating national average case-weighted CCR of 0.274139 and a December 2016 operating national average case-weighted CCR of 0.26579. We then calculated the percentage change between the two national operating case-weighted CCRs by subtracting the December 2015 operating national average case-weighted CCR from the December 2016 operating national average case-weighted CCR and then dividing the result by the December 2015 national operating average case-weighted CCR. This resulted in a proposed national operating CCR adjustment factor of 0.979187.

We used the same methodology proposed above to adjust the capital CCRs. Specifically, for the proposed rule, we calculated a December 2015 capital national average case-weighted CCR of 0.024047 and a December 2016 capital national average case-weighted CCR of 0.022967. We then calculated the percentage change between the two national capital case-weighted CCRs by subtracting the December 2015 capital national average case-weighted CCR from the December 2016 capital national average case-weighted CCR and then dividing the result by the December 2015 capital national average case-weighted CCR. This resulted in a proposed national capital CCR adjustment factor of 0.955068.

As discussed in section III.B.3. of the preamble to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 and 50161) and in section III.H.3. of the preamble of the proposed rule and this final rule, in accordance with section 10324(a) of the Affordable Care Act, we created a wage index floor of 1.0000 for all hospitals located in States determined to be frontier States. We note that the frontier State floor adjustments were calculated and applied after rural floor budget neutrality adjustments were calculated for all labor market areas, in order to ensure that no hospital in a frontier State will receive a wage index less than 1.0000 due to the rural floor adjustment. In accordance with section 10324(a) of the Affordable Care Act, the frontier State adjustment will not be subject to budget neutrality, and will only be extended to hospitals geographically located within a frontier State. However, for purposes of estimating the outlier threshold for FY 2018, it was necessary to adjust the wage index of those eligible hospitals in a frontier State when calculating the outlier threshold that results in outlier payments being 5.1 percent of total payments for FY 2018. If we did not take the above into account, our estimate of total FY 2018 payments would be too low, and, as a result, our outlier threshold would be too high, such that estimated outlier payments would be less than our projected 5.1 percent of total payments.

As we did in establishing the FY 2009 outlier threshold (73 FR 57891), in our projection of FY 2018 outlier payments, we proposed not to make any adjustments for the possibility that hospitals' CCRs and outlier payments may be reconciled upon cost report settlement. We stated that we continue to believe that, due to the policy implemented in the June 9, 2003 Outlier Final Rule (68 FR 34494), CCRs will no longer fluctuate significantly and, therefore, few hospitals will actually have these ratios reconciled upon cost report settlement. In addition, it is difficult to predict the specific hospitals that will have CCRs and outlier payments reconciled in any given year. We note that we have instructed MACs to identify for CMS any instances where (1) a hospital's actual CCR for the cost reporting period fluctuates plus or minus 10 percentage points compared to the interim CCR used to calculate outlier payments when a bill is processed; and (2) the total outlier payments for the hospital exceeded $500,000.00 for that period. Our simulations assume that CCRs accurately measure hospital costs based on information available to us at the time we set the outlier threshold. For these reasons, we proposed not to make any assumptions regarding the effects of reconciliation on the outlier threshold calculation.

Comment: Commenters were concerned with CMS' decision not to consider outlier reconciliation in developing the outlier threshold and stated that CMS did not provide objective data concerning the number of hospitals that have been subjected to reconciliation and the amounts recovered during this process.

Response: The commenters' views were similar to comments received and responded to in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50376 through 50377), and we refer readers to that rule for our response.

As described in sections V.I. and V.J., respectively, of the preamble of this final rule, sections 1886(q) and 1886(o) of the Act establish the Hospital Readmissions Reduction Program and the Hospital VBP Program, respectively. We do not believe that it is appropriate to include the hospital VBP payment adjustments and the hospital readmissions payment adjustments in the outlier threshold calculation or the outlier offset to the standardized amount. Specifically, consistent with our definition of the base operating DRG payment amount for the Hospital Readmissions Reduction Program under § 412.152 and the Hospital VBP Program under § 412.160, outlier payments under section 1886(d)(5)(A) of the

Act are not affected by these payment adjustments. Therefore, outlier payments will continue to be calculated based on the unadjusted base DRG payment amount (as opposed to using the base-operating DRG payment amount adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment). Consequently, we proposed to exclude the hospital VBP payment adjustments and the hospital readmissions payment adjustments from the calculation of the outlier fixed-loss cost threshold.

We note that, to the extent section 1886(r) of the Act modifies the DSH payment methodology under section 1886(d)(5)(F) of the Act, the uncompensated care payment under section 1886(r)(2) of the Act, like the empirically justified Medicare DSH payment under section 1886(r)(1) of the Act, may be considered an amount payable under section 1886(d)(5)(F) of the Act such that it would be reasonable to include the payment in the outlier determination under section 1886(d)(5)(A) of the Act. As we have done since the implementation of uncompensated care payments in FY 2014, for FY 2018 we proposed allocating an estimated per-discharge uncompensated care payment amount to all cases for the hospitals eligible to receive the uncompensated care payment amount in the calculation of the outlier fixed-loss cost threshold methodology. We continue to believe that allocating an eligible hospital's estimated uncompensated care payment to all cases equally in the calculation of the outlier fixed-loss cost threshold would best approximate the amount we would pay in uncompensated care payments during the year because, when we make claim payments to a hospital eligible for such payments, we would be making estimated per-discharge uncompensated care payments to all cases equally. Furthermore, we continue to believe that using the estimated per-claim uncompensated care payment amount to determine outlier estimates provides predictability as to the amount of uncompensated care payments included in the calculation of outlier payments. Therefore, consistent with the methodology used since FY 2014 to calculate the outlier fixed-loss cost threshold, for FY 2018, we proposed to include estimated FY 2018 uncompensated care payments in the computation of the outlier fixed-loss cost threshold. Specifically, we proposed to use the estimated per-discharge uncompensated care payments to hospitals eligible for the uncompensated care payment for all cases in the calculation of the proposed outlier fixed-loss cost threshold methodology.

Using this methodology, we used the formula described in section I.C.1 of this Addendum to simulate and calculate the Federal payment rate and outlier payments for all claims. We proposed a threshold of $26,713 and calculated total operating Federal payments of $89,955,398,001 and total outlier payments of $4,587,838,750. We then divided total outlier payments by total operating Federal payments plus total outlier payments and determined that this threshold met the 5.1 percent target. As a result, we proposed an outlier fixed-loss cost threshold for FY 2018 equal to the prospective payment rate for the MS–DRG, plus any IME, empirically justified Medicare DSH payments, estimated uncompensated care payment, and any add-on payments for new technology, plus $26,713.

Comment: One commenter noted that dividing the total outlier payments of $4,587,838,750 by total operating Federal payments of $89,955,398,001 plus total outlier payments of $4,587,838,750 yields 4.85 percent instead of 5.1 percent.

Response: The commenter is correct. We inadvertently summed total operating Federal payments with total outlier payments in the number of $89,955,398,001 above. The corrected total operating Federal payments for the proposed rule is $85,367,559,251. Dividing the proposed total outlier payments of $4,587,838,750 by the corrected proposed total operating Federal payments of $85,367,559,251 plus proposed total outlier payments of $4,587,838,750 yields the 5.1 percent target. We thank the commenter for noting this error.

Comment: One commenter believed that it is important that CMS accurately calculate prior year actual payment comparisons to the 5.1 percent target. The commenter asserted that it is not possible for CMS to appropriately modify the methodology to achieve an accurate result if CMS is not aware of, or misinformed about, inaccuracies resulting from the prior year's methodology. The commenter cited the FY 2017 IPPS/LTCH PPS proposed rule as an example where CMS indicated that actual outlier payments for FY 2015 were approximately 4.68 percent of overall payments. The commenter stated that it was concerned that CMS believed the agency would reach the 5.1 percent target for FY 2015 only to learn that the original estimate was overestimated and still raise the threshold for the subsequent year.

The same commenter noted that the final outlier threshold established by CMS is always significantly lower than the threshold set forth in the proposed rule. The commenter believed the decline is most likely due to the use of updated CCRs or other data in calculating the final threshold. The commenter stated this emphasizes that CMS must use the most recent data available when the agency calculates the outlier threshold. The commenter cited as an example that, in the proposed rule, CMS used data from the December 2016 PSF file, but at the time the proposed rule was issued, the March 2017 PSF file was available.

Response: We responded to similar comments in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50378 through 50379) and refer the reader to that rule for our response.

Comment: One commenter asked if CMS used more updated data for the FY 2017 proposed rule than in prior years because the variance in the outlier fixed-loss cost threshold from the FY 2017 proposed rule ($23,681) to the FY 2017 final rule ($23,573) was much smaller than prior fiscal years (approximately $100 versus a variance of approximately $1,000 to $2,000 from FY 2009 through FY 2016).

Response: Regarding the data used for the FY 2017 proposed and final rule, we used the same update of the MedPAR data as in prior fiscal years. Specifically, we use the December update of the MedPAR for the proposed rule and the March update of the MedPAR for the final rule.

Comment: Some commenters believed that the outlier threshold should be further reduced because outlier payments this year are on target to fall below the 5.1 percent target. The commenter suggested that CMS consider calculating the threshold at the midpoint of the target (approximately 5.5 percent) in order to ensure that the final total of outlier payments is between the statutory requirements of 5 to 6 percent of total payments.

Some commenters recommended that the threshold be maintained at the FY 2017 outlier threshold because CMS has underpaid outlier payments in prior fiscal years with no adjustment to make up for the shortfalls. One commenter noted that CMS' estimate of FY 2016 outlier payments in the proposed rule was 5.37 percent, which is above the 5.1 percent target. The commenter favored a simplified methodology and believed that by applying a 2-year charge inflation factor and a 1-year CCR factor that CMS is inadvertently compounding its charge increase with lower costs and overstating the outlier threshold. The commenter suggested that CMS apply the following formula to compute the FY 2018 outlier threshold: Step 1—FY 2016 Difference = (FY 2016 estimate of 5.37 percent − 5.1 percent target = 0.27 percent) / 5.1 percent target = 5.29 percent; Step 2—Suggested FY 2018 Threshold = Threshold from FY 2017 of $23,570 * (100 + 5.29 from Step 1 = 105.29 percent) = $24,817. The commenter concluded that the FY 2018 fixed-loss cost threshold should not exceed $24,817.

Response: We responded to similar comments in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50379) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49783) and refer readers to those final rules for our complete responses.

Comment: One commenter asked that CMS consider whether it is appropriate to include extreme cases when calculating the threshold. The commenter explained that high charge cases have a significant impact on the threshold. The commenter observed that the amount of cases with over $1.5 million in charges has increased significantly from FY 2011 (926 cases) to FY 2016 (1,733 cases). The commenter believed that the impact of these cases will cause the threshold to rise and recommended that CMS consider the removal of high charge cases from the calculation of the threshold.

Response: We thank the commenter for its analysis. The methodology used to calculate the outlier threshold includes all claims in order to account for all different types of cases, including high charge cases, to ensure that CMS meets the 5.1 percent target. As the commenter pointed out, the volume of these cases continues to rise, making their impact on the threshold significant. We believe excluding these cases would artificially lower the threshold. We believe it is important to include all cases in the calculation of the threshold no matter how high or low the charges. Including these

cases with high charges lends more accuracy to the threshold, as these cases have an impact on the threshold and continue to rise in volume. Therefore, we disagree with the commenter.

After consideration of the public comments we received, we are not making any changes to our methodology in this final rule for FY 2018. Therefore, we are using the same methodology we proposed to calculate the final outlier threshold. We note that, as stated above, we will consider for FY 2019 using data that commenters can access earlier to validate the charge inflation factor.

Similar to the table provided in the proposed rule, for this final rule, we are providing the following table that displays covered charges and cases by quarter in the periods used to calculate the charge inflation factor based on the latest claims data from the MedPAR file.

Quarter	Covered charges (April 1, 2015, through March 31, 2016)	Cases (April 1, 2015, through March 31, 2016)	Covered charges (April 1, 2016, through March 31, 2017)	Cases (April 1, 2016, through March 31, 2017)
1	$141,152,765,310	2,511,643	$117,678,018,441	2,041,566
2	128,006,070,168	2,429,952	135,162,474,098	2,412,323
3	125,050,723,246	2,350,572	131,355,245,078	2,344,249
4	130,279,257,188	2,385,573	135,647,775,015	2,374,373
Total	524,488,815,912	9,677,740	519,843,512,632	9,172,511

Under our current methodology, to compute the 1-year average annualized rate-of-change in charges per case for FY 2018, we compared the average covered charge per case of $54,195 ($524,488,815,912/9,677,740) from the third quarter of FY 2015 through the second quarter of FY 2016 (April 1, 2015, through March 31, 2016) to the average covered charge per case of $56,674 ($519,843,512,632/9,172,511) from the third quarter of FY 2016 through the second quarter of FY 2017 (April 1, 2016, through March 31, 2017). This rate-of-change is 4.6 percent (1.04574) or 9.4 percent (1.09357) over 2 years. The billed charges are obtained from the claim from the MedPAR file and inflated by the inflation factor specified above.

Similar to the proposed rule, for this final rule, we have made available a more detailed summary table by provider with the monthly charges that were used to compute the charge inflation factor on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* (click on the link on the left titled ''FY 2018 IPPS Final Rule Home Page'' and then click the link ''FY 2018 Final Rule Data Files'').

As we have done in the past, we are establishing the FY 2018 outlier threshold using hospital CCRs from the March 2017 update to the Provider-Specific File (PSF)—the most recent available data at the time of the development of this final rule. For FY 2018, we also are continuing to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained below).

Therefore, as we did for the last 4 fiscal years, we are adjusting the CCRs from the March 2017 update of the PSF by comparing the percentage change in the national average case-weighted operating CCR and capital CCR from the March 2016 update of the PSF to the national average case-weighted operating CCR and capital CCR from the March 2017 update of the PSF. We note that we used total transfer-adjusted cases from FY 2016 to determine the national average case-weighted CCRs for both sides of the comparison.

Using the methodology above, for this final rule, we calculated a March 2016 operating national average case-weighted CCR of 0.269558 and a March 2017 operating national average case-weighted CCR of 0.265668. We then calculated the percentage change between the two national operating case-weighted CCRs by subtracting the March 2016 operating national average case-weighted CCR from the March 2017 operating national average case-weighted CCR and then dividing the result by the March 2016 national operating average case-weighted CCR. This resulted in a national operating CCR adjustment factor of 0.985569 (the factors used to determine this result were based on unrounded numbers).

We used the same methodology above to adjust the capital CCRs. Specifically, for this final rule, we calculated a March 2016 capital national average case-weighted CCR of 0.023751 and a March 2017 capital national average case-weighted CCR of 0.22615. We then calculated the percentage change between the two national capital case-weighted CCRs by subtracting the March 2016 capital national average case-weighted CCR from the March 2017 capital national average case-weighted CCR and then dividing the result by the March 2016 capital national average case-weighted CCR. This resulted in a national capital CCR adjustment factor of 0.952173 (the factors used to determine this result were based on unrounded numbers).

As discussed above, similar to the proposed rule, for FY 2018 we applied the following policies (see discussion above for more details):

- In accordance with section 10324(a) of the Affordable Care Act, we created a wage index floor of 1.0000 for all hospitals located in States determined to be frontier States.
- As we did in establishing the FY 2009 outlier threshold (73 FR 57891), in our projection of FY 2018 outlier payments, we did not make any adjustments for the possibility that hospitals' CCRs and outlier payments may be reconciled upon cost report settlement.
- We excluded the hospital VBP payment adjustments and the hospital readmissions payment adjustments from the calculation of the outlier fixed-loss cost threshold.
- We used the estimated per-discharge uncompensated care payments to hospitals eligible for the uncompensated care payment for all cases in the calculation of the outlier fixed-loss cost threshold methodology.

Using this methodology, we used the formula described in section I.C.1. of this Addendum to simulate and calculate the Federal payment rate and outlier payments for all claims. We calculated a threshold of $26,601 and calculated total operating Federal payments of $85,942,484,975 and total outlier payments of $4,618,707,285. We then divided total outlier payments by total operating Federal payments plus total outlier payments and determined that this threshold met the 5.1 percent target. As a result, we are finalizing an outlier fixed-loss cost threshold for FY 2018 equal to the prospective payment rate for the MS–DRG, plus any IME, empirically justified Medicare DSH payments, estimated uncompensated care payment, and any add-on payments for new technology, plus $26,601.

(2) Other Changes Concerning Outliers

As stated in the FY 1994 IPPS final rule (58 FR 46348), we establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. When we modeled the combined operating and capital outlier payments, we found that using a common threshold resulted in a lower percentage of outlier payments for capital-related costs than for operating costs. We project that the thresholds for FY 2018 will result in outlier payments that will equal 5.1 percent of operating DRG payments and 5.16 percent of capital payments based on the Federal rate.

In accordance with section 1886(d)(3)(B) of the Act, we reduced the FY 2018 standardized amount by the same percentage to account for the projected proportion of payments paid as outliers.

The outlier adjustment factors that were applied to the standardized amount based on the FY 2018 outlier threshold are as follows:

	Operating standardized amounts	Capital federal rate
National	0.948999	0.948400

We applied the outlier adjustment factors to the FY 2018 payment rates after removing the effects of the FY 2017 outlier adjustment factors on the standardized amount.

To determine whether a case qualifies for outlier payments, we apply hospital-specific CCRs to the total covered charges for the case. Estimated operating and capital costs

for the case are calculated separately by applying separate operating and capital CCRs. These costs are then combined and compared with the outlier fixed-loss cost threshold.

Under our current policy at § 412.84, we calculate operating and capital CCR ceilings and assign a statewide average CCR for hospitals whose CCRs exceed 3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals. Based on this calculation, for hospitals for which the MAC computes operating CCRs greater than 1.16 or capital CCRs greater than 0.155, or hospitals for which the MAC is unable to calculate a CCR (as described under § 412.84(i)(3) of our regulations), statewide average CCRs are used to determine whether a hospital qualifies for outlier payments. Table 8A listed in section VI. of this Addendum (and available only via the Internet on the CMS Web site) contains the statewide average operating CCRs for urban hospitals and for rural hospitals for which the MAC is unable to compute a hospital-specific CCR within the above range. These statewide average ratios will be effective for discharges occurring on or after October 1, 2017 and will replace the statewide average ratios from the prior fiscal year. Table 8B listed in section VI. of this Addendum (and available via the Internet on the CMS Web site) contains the comparable statewide average capital CCRs. As previously stated, the CCRs in Tables 8A and 8B will be used during FY 2018 when hospital-specific CCRs based on the latest settled cost report either are not available or are outside the range noted above. Table 8C listed in section VI. of this Addendum (and available via the Internet on the CMS Web site) contains the statewide average total CCRs used under the LTCH PPS as discussed in section V. of this Addendum.

We finally note that we published a manual update (Change Request 3966) to our outlier policy on October 12, 2005, which updated Chapter 3, Section 20.1.2 of the Medicare Claims Processing Manual. The manual update covered an array of topics, including CCRs, reconciliation, and the time value of money. We encourage hospitals that are assigned the statewide average operating and/or capital CCRs to work with their MAC on a possible alternative operating and/or capital CCR as explained in Change Request 3966. Use of an alternative CCR developed by the hospital in conjunction with the MAC can avoid possible overpayments or underpayments at cost report settlement, thereby ensuring better accuracy when making outlier payments and negating the need for outlier reconciliation. We also note that a hospital may request an alternative operating or capital CCR at any time as long as the guidelines of Change Request 3966 are followed. In addition, as mentioned above, we published an additional manual update (Change Request 7192) to our outlier policy on December 3, 2010, which also updated Chapter 3, Section 20.1.2 of the Medicare Claims Processing Manual. The manual update outlines the outlier reconciliation process for hospitals and Medicare contractors. To download and view the manual instructions on outlier reconciliation, we refer readers to the CMS Web site: *http://www.cms.hhs.gov/manuals/downloads/clm104c03.pdf.*

(3) FY 2016 Outlier Payments

Our current estimate, using available FY 2016 claims data, is that actual outlier payments for FY 2016 were approximately 5.41 percent of actual total MS–DRG payments. Therefore, the data indicate that, for FY 2016, the percentage of actual outlier payments relative to actual total payments is higher than we projected for FY 2016. Consistent with the policy and statutory interpretation we have maintained since the inception of the IPPS, we do not make retroactive adjustments to outlier payments to ensure that total outlier payments for FY 2016 are equal to 5.1 percent of total MS–DRG payments. As explained in the FY 2003 Outlier Final Rule (68 FR 34502), if we were to make retroactive adjustments to all outlier payments to ensure total payments are 5.1 percent of MS–DRG payments (by retroactively adjusting outlier payments), we would be removing the important aspect of the prospective nature of the IPPS. Because such an across-the-board adjustment would either lead to more or less outlier payments for all hospitals, hospitals would no longer be able to reliably approximate their payment for a patient while the patient is still hospitalized. We believe it would be neither necessary nor appropriate to make such an aggregate retroactive adjustment. Furthermore, we believe it is consistent with the statutory language at section 1886(d)(5)(A)(iv) of the Act not to make retroactive adjustments to outlier payments. This section calls for the Secretary to ensure that outlier payments are equal to or greater than 5 percent and less than or equal to 6 percent of projected or estimated (not actual) MS–DRG payments. We believe that an important goal of a PPS is predictability. Therefore, we believe that the fixed-loss outlier threshold should be projected based on the best available historical data and should not be adjusted retroactively. A retroactive change to the fixed-loss outlier threshold would affect all hospitals subject to the IPPS, thereby undercutting the predictability of the system as a whole.

We note that because the MedPAR claims data for the entire FY 2017 will not be available until after September 30, 2017, we are unable to provide an estimate of actual outlier payments for FY 2017 based on FY 2017 claims data in this final rule. We will provide an estimate of actual FY 2017 outlier payments in the FY 2019 IPPS/LTCH PPS proposed rule.

Comment: One commenter noted that, in the proposed rule, CMS stated that actual outlier payments for FY 2016 were approximately 5.37 percent of total MS–DRG payments. The commenter performed its own analysis and concluded that outlier payments for FY 2016 are approximately 5.27 percent of total MS–DRG payments. The commenter was concerned that CMS' estimate was overstated.

Response: We thank the commenter for the comments. We reviewed our data to ensure the estimate provided is accurate. Therefore, we believe we have provided a reliable estimate of the outlier percentage for FY 2016. The commenter did not provide details regarding the discrepancy. We welcome additional suggestions from the public, including the commenter, to improve the accuracy of our estimate of actual outlier payments.

5. FY 2018 Standardized Amount

The adjusted standardized amount is divided into labor-related and nonlabor-related portions. Tables 1A and 1B listed and published in section VI. of this Addendum (and available via the Internet on the CMS Web site) contain the national standardized amounts that we are applying to all hospitals, except hospitals located in Puerto Rico, for FY 2018. The standardized amount for hospitals in Puerto Rico is shown in Table 1C listed and published in section VI. of this Addendum (and available via the Internet on the CMS Web site). The amounts shown in Tables 1A and 1B differ only in that the labor-related share applied to the standardized amounts in Table 1A is 68.3 percent, and the labor-related share applied to the standardized amounts in Table 1B is 62 percent. In accordance with sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act, we are applying a labor-related share of 62 percent, unless application of that percentage would result in lower payments to a hospital than would otherwise be made. In effect, the statutory provision means that we will apply a labor-related share of 62 percent for all hospitals whose wage indexes are less than or equal to 1.0000.

In addition, Tables 1A and 1B include the standardized amounts reflecting the applicable percentage increases for FY 2018.

The labor-related and nonlabor-related portions of the national average standardized amounts for Puerto Rico hospitals for FY 2018 are set forth in Table 1C listed and published in section VI. of this Addendum (and available via the Internet on the CMS Web site). Similar to above, section 1886(d)(9)(C)(iv) of the Act, as amended by section 403(b) of Public Law 108–173, provides that the labor-related share for hospitals located in Puerto Rico be 62 percent, unless the application of that percentage would result in lower payments to the hospital.

The following table illustrates the changes from the FY 2017 national standardized amount to the FY 2018 national standardized amount. The second through fifth columns display the changes from the FY 2017 standardized amounts for each applicable FY 2018 standardized amount. The first row of the table shows the updated (through FY 2017) average standardized amount after restoring the FY 2017 offsets for outlier payments, geographic reclassification budget neutrality, new labor market delineation wage index transition budget neutrality and removing the FY 2017 2-midnight rule one-time prospective increase. The MS–DRG reclassification and recalibration and wage index budget neutrality adjustment factors are cumulative. Therefore, those FY 2017 adjustment factors are not removed from this table.

CHANGES FROM FY 2017 STANDARDIZED AMOUNTS TO THE FY 2018 STANDARDIZED AMOUNTS

	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
FY 2018 Base Rate after removing:				
1. FY 2017 Geographic Reclassification Budget Neutrality (0.988136).	If Wage Index is Greater Than 1.0000:	If Wage Index is Greater Than 1.0000:	If Wage Index is Greater Than 1.0000:	If Wage Index is Greater Than 1.0000:
2. FY 2017 Operating Outlier Offset (0.948998).	Labor (68.3%): $3,993.72.	Labor (68.3%): $3,993.72.	Labor (68.3%): $3,993.72.	Labor (68.3%): $3,993.72.
3. FY 2017 2-Midnight Rule One-Time Prospective Increase (1.006).	Nonlabor (30.4%): $1,853.60.	Nonlabor (30.4%): $1,853.60.	Nonlabor (30.4%): $1,853.60.	Nonlabor (30.4%): $1,853.60.
4. FY 2017 Labor Market Delineation Wage Index Transition Budget Neutrality Factor (0.999997).	If Wage Index is less Than or Equal to 1.0000:	If Wage Index is less Than or Equal to 1.0000:	If Wage Index is less Than or Equal to 1.0000:	If Wage Index is less Than or Equal to 1.0000:
	Labor (62%): $3,625.34 .... Nonlabor (38%): $2,221.98	Labor (62%): $3,625.34 .... Nonlabor (38%): $2,221.98	Labor (62%): $3,625.34 .... Nonlabor (38%): $2,221.98	Labor (62%): $3,625.34. Nonlabor (38%): $2,221.98.
FY 2018 Update Factor	1.0135	0.99325	1.00675	0.9865.
FY 2018 MS-DRG Recalibration Budget Neutrality Factor.	0.997432	0.997432	0.997432	0.997432.
FY 2018 Wage Index Budget Neutrality Factor.	1.001148	1.001148	1.001148	1.001148.
FY 2018 Reclassification Budget Neutrality Factor.	0.988008	0.988008	0.988008	0.988008.
FY 2018 Operating Outlier Factor.	0.948999	0.948999	0.948999	0.98999.
Adjustment for FY 2018 Required under Section 414 of Public Law 114–10 (MACRA) and Section 15005 of Public Law 114–255.	1.004588	1.004588	1.004588	1.004588.
National Standardized Amount for FY 2018 if Wage Index is Greater Than 1.0000; Labor/Non-Labor Share Percentage (68.3/31.7).	Labor: $3,807.12 ..... Nonlabor: $1,766.99	Labor: $3,731.05 ..... Nonlabor: $1,731.69	Labor: $3,781.76 ..... Nonlabor: $1,755.22	Labor: $3,705.70. Nonlabor: $1,719.92.
National Standardized Amount for FY 2018 if Wage Index is less Than or Equal to 1.0000; Labor/Non-Labor Share Percentage (62/38).	Labor: $3,455.95 ..... Nonlabor: $2,118.16	Labor: $3,386.90 ..... Nonlabor: $2,075.84	Labor: $3,432.93 ..... Nonlabor: $2,104.05	Labor: $3,363.88. Nonlabor: $2,061.74.

We note that, in recent years, we have estimated the MS–DRG recalibration budget neutrality factor, wage index budget neutrality factor, reclassification budget neutrality factor and operating outlier factor to six decimal places. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20176), we stated that while we are not proposing to make any changes at this time, we were interested in receiving comments from the public as to the continued necessity of six decimal places for these four estimates or if fewer decimal places would be sufficient. We did not receive any public comments regarding the necessity of six decimals. We will consider the use of fewer decimals in future rulemaking.

B. Adjustments for Area Wage Levels and Cost-of-Living

Tables 1A through 1C, as published in section VI. of this Addendum (and available via the Internet on the CMS Web site), contain the labor-related and nonlabor-related shares that we used to calculate the prospective payment rates for hospitals located in the 50 States, the District of Columbia, and Puerto Rico for FY 2018. This section addresses two types of adjustments to the standardized amounts that are made in determining the prospective payment rates as described in this Addendum.

1. Adjustment for Area Wage Levels

Sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act require that we make an adjustment to the labor-related portion of the national prospective payment rate to account for area differences in hospital wage levels. This adjustment is made by multiplying the labor-related portion of the adjusted standardized amounts by the appropriate wage index for the area in which the hospital is located. For FY 2018, as discussed in section IV.B.3. of the preamble of this final rule, we will apply a labor-related share of 68.3 percent for the national standardized amounts for all IPPS hospitals (including hospitals in Puerto Rico) that have a wage index value that is greater

than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, we will apply the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals (including hospitals in Puerto Rico) whose wage index values are less than or equal to 1.0000. In section III. of the preamble of this final rule, we discuss the data and methodology for the FY 2018 wage index.

2. Adjustment for Cost-of-Living in Alaska and Hawaii

Section 1886(d)(5)(H) of the Act provides discretionary authority to the Secretary to make adjustments as the Secretary deems appropriate to take into account the unique circumstances of hospitals located in Alaska and Hawaii. Higher labor-related costs for these two States are taken into account in the adjustment for area wages described above. To account for higher nonlabor-related costs for these two States, we multiply the nonlabor-related portion of the standardized amount for hospitals in Alaska and Hawaii by an adjustment factor. For FY 2011 and in prior fiscal years, we used the most recent cost-of-living adjustment (COLA) factors obtained from the U.S. Office of Personnel Management (OPM) Web site at *http://www.opm.gov/oca/cola/rates.asp* to update this nonlabor portion.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51797), we explained that sections 1911 through 1919 of the Nonforeign Area Retirement Equity Assurance Act, as contained in subtitle B of title XIX of the National Defense Authorization Act (NDAA) for Fiscal Year 2010 (Pub. L. 111–84, October 28, 2009), transitions the Alaska and Hawaii COLAs to locality pay. We finalized that, for FY 2012, as OPM transitioned away from COLAs, we would continue to use the same ''frozen'' COLA factors (published by OPM) that we used to adjust payments in FY 2011 (which were based on OPM's 2009 COLA factors) to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii. We refer readers to the FY 2012 IPPS/LTCH PPS final rule for a more detailed discussion of our rationale for continuing to use the frozen COLAs in FY 2012.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53700 and 53701), for FY 2013, we continued to use the same COLA factors that were used to adjust payments in FY 2012 (as originally used to adjust payments in FY 2011, which were based on OPM's 2009 COLA factors). We also established a methodology to update the COLA factors published by OPM every 4 years (at the same time as the update of the labor-related share of the IPPS market basket), beginning in FY 2014. We refer readers to the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28145 and 28146) for a detailed description of this methodology. For FY 2014, we updated the COLA factors for Alaska and Hawaii published by OPM for 2009 using the methodology finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53700 and 53701).

For FY 2018, we proposed to continue to update the COLA factors published by OPM for 2009 (as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay) using the methodology that we finalized in the FY 2013 IPPS/LTCH PPS final rule and implemented for the FY 2014 IPPS update. Specifically, we proposed to update the 2009 OPM COLA factors by a comparison of the growth in the Consumer Price Indices (CPIs) for Anchorage, AK, and Honolulu, HI, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). Because BLS publishes CPI data for only Anchorage and Honolulu, using the methodology we finalized in the FY 2013 IPPS/LTCH PPS final rule, we used the comparison of the growth in the overall CPI relative to the growth in the CPI for those cities to update the COLA factors for all areas in Alaska and Hawaii, respectively. We believe that the relative price differences between these cities and the United States (as measured by the CPIs mentioned above) are appropriate proxies for the relative price differences between the ''other areas'' of Alaska and Hawaii and the United States.

BLS publishes the CPI for All Items for Anchorage, Honolulu, and for the average U.S. city. However, consistent with our methodology finalized in the FY 2013 IPPS/LTCH PPS final rule, we created reweighted CPIs for each of the respective areas to reflect the underlying composition of the IPPS market basket nonlabor-related share. The current composition of the CPI for All Items for all of the respective areas is approximately 40 percent commodities and 60 percent services. However, the IPPS nonlabor-related share is comprised of a different mix of commodities and services. Therefore, we created reweighted indexes for Anchorage, Honolulu, and the average U.S. city using the respective CPI commodities index and CPI services index and using the approximate 55 percent commodities/45 percent services shares obtained from the proposed 2014-based IPPS market basket, which is being finalized without modification as discussed in section IV. of the preamble of this final rule. We created reweighted indexes using BLS data for 2009 through 2016—the most recent data available at the time of this final rulemaking. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50985 through 50987), we created reweighted indexes based on the FY 2010-based IPPS market basket (which was adopted for the FY 2014 IPPS update) and BLS data for 2009 through 2012 (the most recent BLS data at the time of the FY 2014 IPPS/LTCH PPS rulemaking).

We continue to believe this methodology is appropriate because we continue to make a COLA for hospitals located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standardized amount by a COLA factor. We note that OPM's COLA factors were calculated with a statutorily mandated cap of 25 percent. As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50985 through 50987), under the COLA update methodology we finalized in the FY 2013 IPPS/LTCH PPS final rule, we exercised our discretionary authority to adjust payments to hospitals in Alaska and Hawaii by incorporating this cap. In applying this finalized methodology for updating the COLA factors, for FY 2018, we proposed to continue to use such a cap, as our policy is based on OPM's COLA factors (updated by the methodology described above).

Applying this methodology, the COLA factors that we proposed to establish for FY 2018 to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii are shown in the table below. For comparison purposes, we also are showing the FY 2013 COLA factors (which were based on OPM's published COLA factors for 2009) and the FY 2014 COLA factors.

Lastly, as we finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53700 and 53701), we are updating the COLA factors based on our methodology every 4 years, at the same time as the update to the labor-related share of the IPPS market basket.

COST-OF-LIVING ADJUSTMENT FACTORS: ALASKA AND HAWAII HOSPITALS

Area	FY 2013	FY 2014 through FY 2017	Proposed FY 2018
Alaska:			
City of Anchorage and 80-kilometer (50-mile) radius by road	1.23	1.23	1.25
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.23	1.23	1.25
City of Juneau and 80-kilometer (50-mile) radius by road	1.23	1.23	1.25
Rest of Alaska	1.25	1.25	1.25
Hawaii:			
City and County of Honolulu	1.25	1.25	1.25
County of Hawaii	1.18	1.19	1.21
County of Kauai	1.25	1.25	1.25
County of Maui and County of Kalawao	1.25	1.25	1.25

We note that the reweighted CPI for Honolulu, HI grew faster than the reweighted CPI for the average U.S. city over the 2009 to 2016 time period, at 13.7 percent and 10.5 percent, respectively. As a result, for FY 2018, we calculated proposed COLA factors for the City and County of Honolulu, County of Kauai, County of Maui, and County of Kalawao to be 1.29 compared to the FY 2013 COLA factor of 1.25 (which was based on OPM's published COLA factors for 2009, as described above). However, as stated above, we are applying our methodology as finalized in the FY 2013 IPPS/LTCH PPS final rule to incorporate a cap of 1.25 for these areas. In addition, the proposed COLA factor we calculated for the County of Hawaii for FY 2018 is 1.21 compared to the FY 2013 COLA factor of 1.18. The COLA factors adopted in FY 2014 using this same methodology can be found in the table above.

Similarly, the reweighted CPI for Anchorage, AK grew faster than the reweighted CPI for the average U.S. city over the 2009 to 2016 time period, at 12.4 percent and 10.5 percent, respectively. As a result, for FY 2018, we calculated proposed COLA factors for the City of Anchorage, City of Fairbanks, and City of Juneau to be 1.25 compared to the FY 2013 COLA factor of 1.23. For FY 2018, we calculated a proposed COLA factor of 1.27 for the rest of Alaska compared to the FY 2013 COLA factor of 1.25. However, as stated above, we are applying our methodology as finalized in the FY 2013 IPPS/LTCH PPS final rule to incorporate a cap of 1.25 for the Rest of Alaska.

As stated above, the COLA factors adopted in the FY 2014 IPPS/LTCH PPS final rule were based on the same methodology we proposed to use to determine the FY 2018 COLA factors but utilizing BLS data from 2009 through 2012 (the most recent data available at the time of FY 2014 rulemaking) rather than through 2016 (the most recent data available at the time of this rulemaking). As we noted in the proposed rule, compared to the FY 2014 COLA factors, the proposed FY 2018 COLA factors are higher—with all areas either reaching or exceeding the cap of 1.25 except the County of Hawaii.

We did not receive any public comments on our proposal to continue to update the COLA factors published by OPM for 2009 using the methodology that we finalized in the FY 2013 IPPS/LTCH PPS final rule and implemented for the FY 2014 IPPS update. In this final rule, we are finalizing the COLA factors as proposed effective for FY 2018.

C. Calculation of the Prospective Payment Rates

General Formula for Calculation of the Prospective Payment Rates for FY 2018

In general, the operating prospective payment rate for all hospitals (including hospitals in Puerto Rico) paid under the IPPS, except SCHs, for FY 2018 equals the Federal rate (which includes uncompensated care payments).

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal national rate (which, as discussed in section V.G. of the preamble of this final rule, includes uncompensated care payments); the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

The prospective payment rate for SCHs for FY 2018 equals the higher of the applicable Federal rate, or the hospital-specific rate as described below.

1. Operating and Capital Federal Payment Rate and Outlier Payment Calculation

Note: The formula below is used for actual claim payment and is also used by CMS to project the outlier threshold for the upcoming fiscal year. The difference is the source of some of the variables in the formula. For example, operating and capital CCRs for actual claim payment are from the PSF while CMS uses an adjusted CCR (as described above) to project the threshold for the upcoming fiscal year. In addition, charges for a claim payment are from the bill while charges to project the threshold are from the MedPAR data with an inflation factor applied to the charges (as described earlier).

Step 1—Determine the MS–DRG and MS–DRG relative weight for each claim based on the ICD–10–CM procedure and diagnosis codes on the claim.

Step 2—Select the applicable average standardized amount depending on whether the hospital submitted qualifying quality data and is a meaningful EHR user, as described above.

Step 3—Compute the operating and capital Federal payment rate:

—Federal Payment Rate for Operating Costs = MS–DRG Relative Weight × [(Labor-Related Applicable Standardized Amount × Applicable CBSA Wage Index) + (Nonlabor-Related Applicable Standardized Amount × Cost-of-Living Adjustment)] × (1 + IME + (DSH * 0.25))

—Federal Payment for Capital Costs = MS–DRG Relative Weight × Federal Capital Rate × Geographic Adjustment Fact × (l + IME + DSH)

Step 4—Determine operating and capital costs:

—Operating Costs = (Billed Charges × Operating CCR)

—Capital Costs = (Billed Charges × Capital CCR).

Step 5—Compute operating and capital outlier threshold (CMS applies a geographic adjustment to the operating and capital outlier threshold to account for local cost variation):

—Operating CCR to Total CCR = (Operating CCR)/(Operating CCR + Capital CCR)

—Operating Outlier Threshold = [Fixed Loss Threshold × ((Labor-Related Portion × CBSA Wage Index) + Nonlabor-Related portion)] × Operating CCR to Total CCR + Federal Payment with IME, DSH + Uncompensated Care Payment + New Technology Add-On Payment Amount

—Capital CCR to Total CCR = (Capital CCR)/(Operating CCR + Capital CCR)

—Capital Outlier Threshold = (Fixed Loss Threshold × Geographic Adjustment Factor × Capital CCR to Total CCR) + Federal Payment with IME and DSH

Step 6—Compute operating and capital outlier payments:

—Marginal Cost Factor = 0.80 or 0.90 (depending on the MS–DRG)

—Operating Outlier Payment = (Operating Costs—Operating Outlier Threshold) × Marginal Cost Factor

—Capital Outlier Payment = (Capital Costs—Capital Outlier Threshold) × Marginal Cost Factor

The payment rate may then be further adjusted for hospitals that qualify for a low-volume payment adjustment under section 1886(d)(12) of the Act and 42 CFR 412.101(b). The base-operating DRG payment amount may be further adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment as described under sections 1886(q) and 1886(o) of the Act, respectively. Payments also may be reduced by the 1-percent adjustment under the HAC Reduction Program as described in section 1886(p) of the Act. We also make new technology add-on payments in accordance with section 1886(d)(5)(K) and (L) of the Act. Finally, we add the uncompensated care payment to the total claim payment amount. As noted in the formula above, we take uncompensated care payments and new technology add-on payments into consideration when calculating outlier payments.

2. Hospital-Specific Rate (Applicable Only to SCHs)

a. Calculation of Hospital-Specific Rate

Section 1886(b)(3)(C) of the Act provides that SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment. As noted above, under section 205 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted on April 16, 2015), the MDH program is set to expire at the end of FY 2017.

For a more detailed discussion of the calculation of the hospital-specific rates, we refer readers to the FY 1984 IPPS interim final rule (48 FR 39772); the April 20, 1990 final rule with comment period (55 FR 15150); the FY 1991 IPPS final rule (55 FR 35994); and the FY 2001 IPPS final rule (65 FR 47082).

b. Updating the FY 1982, FY 1987, FY 1996, FY 2002 and FY 2006 Hospital-Specific Rate for FY 2018

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase applicable to the hospital-specific rates for SCHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject

to the IPPS). Because the Act sets the update factor for SCHs equal to the update factor for all other IPPS hospitals, the update to the hospital-specific rates for SCHs is subject to the amendments to section 1886(b)(3)(B) of the Act made by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, the applicable percentage increases to the hospital-specific rates applicable to SCHs are the following:

FY 2018	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Market Basket Rate-of-Increase	2.7	2.7	2.7	2.7
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.675	−0.675
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−2.025	0.0	−2.025
MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.6	−0.6	−0.6	−0.6
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.75	−0.75	−0.75	−0.75
Applicable Percentage Increase Applied to Hospital-Specific Rate	1.35	−0.675	0.675	−1.35

For a complete discussion of the applicable percentage increase applied to the hospital-specific rates for SCHs, we refer readers to section V.B. of the preamble of this final rule.

In addition, because SCHs use the same MS–DRGs as other hospitals when they are paid based in whole or in part on the hospital-specific rate, the hospital-specific rate is adjusted by a budget neutrality factor to ensure that changes to the MS–DRG classifications and the recalibration of the MS–DRG relative weights are made in a manner so that aggregate IPPS payments are unaffected. Therefore, the hospital-specific rate for an SCH is adjusted by the MS–DRG reclassification and recalibration budget neutrality factor of 0.997432, as discussed in section III. of this Addendum. The resulting rate is used in determining the payment rate that an SCH will receive for its discharges beginning on or after October 1, 2017. We note that, in this final rule, for FY 2018, we are not making a documentation and coding adjustment to the hospital-specific rate. We refer readers to section II.D. of the preamble of this final rule for a complete discussion regarding our policies and previously finalized policies (including our historical adjustments to the payment rates) relating to the effect of changes in documentation and coding that do not reflect real changes in case-mix.

Also, as discussed in section V.M. of the preamble of this final rule, we are including a factor of (1/1.006) in the calculation of the FY 2018 hospital-specific rates. Specifically, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57058 through 57060), using our authority under section 1886(d)(5)(I)(i) of the Act, we finalized a policy to include a permanent factor of (1/0.998) and a temporary one-time factor of (1.006) in the calculation of the FY 2017 hospital-specific rates and to include a factor of (1/1.006) in the calculation of the FY 2018 hospital-specific rates to remove the temporary one-time factor of 1.006 applied in FY 2017 to address the effects of the 0.2 percent reduction to the rates for the 2-midnight policy in effect for FY 2014, FY 2015, and FY 2016. Therefore, in this final rule, for FY 2018, we are removing the temporary one-time prospective increase to the FY 2017 hospital-specific rates of 0.6 percent or a factor of 1.006.

III. Changes to Payment Rates for Acute Care Hospital Inpatient Capital-Related Costs for FY 2018

The PPS for acute care hospital inpatient capital-related costs was implemented for cost reporting periods beginning on or after October 1, 1991. Effective with that cost reporting period, over a 10-year transition period (which extended through FY 2001) the payment methodology for Medicare acute care hospital inpatient capital-related costs changed from a reasonable cost-based methodology to a prospective methodology (based fully on the Federal rate).

The basic methodology for determining Federal capital prospective rates is set forth in the regulations at 42 CFR 412.308 through 412.352. Below we discuss the factors that we used to determine the capital Federal rate for FY 2018, which will be effective for discharges occurring on or after October 1, 2017.

The 10-year transition period ended with hospital cost reporting periods beginning on or after October 1, 2001 (FY 2002). Therefore, for cost reporting periods beginning in FY 2002, all hospitals (except ''new'' hospitals under § 412.304(c)(2)) are paid based on the capital Federal rate. For FY 1992, we computed the standard Federal payment rate for capital-related costs under the IPPS by updating the FY 1989 Medicare inpatient capital cost per case by an actuarial estimate of the increase in Medicare inpatient capital costs per case. Each year after FY 1992, we update the capital standard Federal rate, as provided at § 412.308(c)(1), to account for capital input price increases and other factors. The regulations at § 412.308(c)(2) also provide that the capital Federal rate be adjusted annually by a factor equal to the estimated proportion of outlier payments under the capital Federal rate to total capital payments under the capital Federal rate. In addition, § 412.308(c)(3) requires that the capital Federal rate be reduced by an adjustment factor equal to the estimated proportion of payments for exceptions under § 412.348. (We note that, as discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53705), there is generally no longer a need for an exceptions payment adjustment factor.) However, in limited circumstances, an additional payment exception for extraordinary circumstances is provided for under § 412.348(f) for qualifying hospitals. Therefore, in accordance with § 412.308(c)(3), an exceptions payment adjustment factor may need to be applied if such payments are made. Section 412.308(c)(4)(ii) requires that the capital standard Federal rate be adjusted so that the effects of the annual DRG reclassification and the recalibration of DRG weights and changes in the geographic adjustment factor (GAF) are budget neutral.

Section 412.374 provides for payments to hospitals located in Puerto Rico under the IPPS for acute care hospital inpatient capital-related costs. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57061 through 57062), we revised § 412.374 to add paragraph (e) to provide that, effective with discharges on or after October 1, 2016, capital IPPS payments to hospitals located in Puerto Rico are based on 100 percent of the Federal rate.

A. Determination of the Federal Hospital Inpatient Capital-Related Prospective Payment Rate Update for FY 2018

In the discussion that follows, we explain the factors that we used to determine the capital Federal rate for FY 2018. In particular, we explain why the FY 2018 capital Federal rate will increase approximately 1.61 percent, compared to the FY 2017 capital Federal rate. As discussed in the impact analysis in Appendix A to this final rule, we estimate that capital payments per discharge will increase approximately 2.5 percent during that same period. Because capital payments constitute approximately 10 percent of hospital payments, a 1-percent change in the capital Federal rate yields only approximately a 0.1 percent change in actual payments to hospitals.

1. Projected Capital Standard Federal Rate Update

a. Description of the Update Framework

Under § 412.308(c)(1), the capital standard Federal rate is updated on the basis of an analytical framework that takes into account changes in a capital input price index (CIPI) and several other policy adjustment factors. Specifically, we adjust the projected CIPI rate of change as appropriate each year for case-mix index-related changes, for intensity, and

for errors in previous CIPI forecasts. The update factor for FY 2018 under that framework is 1.3 percent based on a projected 1.3 percent increase in the 2014-based CIPI, a 0.0 percentage point adjustment for intensity, a 0.0 percentage point adjustment for case-mix, a 0.0 percentage point adjustment for the DRG reclassification and recalibration, and a forecast error correction of 0.0 percentage point. As discussed in section III.C. of this Addendum, we continue to believe that the CIPI is the most appropriate input price index for capital costs to measure capital price changes in a given year. We also explain the basis for the FY 2018 CIPI projection in that same section of this Addendum. Below we describe the policy adjustments that we are applying in the update framework for FY 2018.

The case-mix index is the measure of the average DRG weight for cases paid under the IPPS. Because the DRG weight determines the prospective payment for each case, any percentage increase in the case-mix index corresponds to an equal percentage increase in hospital payments.

The case-mix index can change for any of several reasons:

- The average resource use of Medicare patient changes (''real'' case-mix change);
- Changes in hospital documentation and coding of patient records result in higher-weighted DRG assignments (''coding effects''); and
- The annual DRG reclassification and recalibration changes may not be budget neutral (''reclassification effect'').

We define real case-mix change as actual changes in the mix (and resource requirements) of Medicare patients as opposed to changes in documentation and coding behavior that result in assignment of cases to higher-weighted DRGs, but do not reflect higher resource requirements. The capital update framework includes the same case-mix index adjustment used in the former operating IPPS update framework (as discussed in the May 18, 2004 IPPS proposed rule for FY 2005 (69 FR 28816)). (We no longer use an update framework to make a recommendation for updating the operating IPPS standardized amounts as discussed in section II. of Appendix B to the FY 2006 IPPS final rule (70 FR 47707).)

For FY 2018, we are projecting a 0.5 percent total increase in the case-mix index. We estimated that the real case-mix increase will equal 0.5 percent for FY 2018. The net adjustment for change in case-mix is the difference between the projected real increase in case-mix and the projected total increase in case-mix. Therefore, the net adjustment for case-mix change in FY 2018 is 0.0 percentage point.

The capital update framework also contains an adjustment for the effects of DRG reclassification and recalibration. This adjustment is intended to remove the effect on total payments of prior year's changes to the DRG classifications and relative weights, in order to retain budget neutrality for all case-mix index-related changes other than those due to patient severity of illness. Due to the lag time in the availability of data, there is a 2-year lag in data used to determine the adjustment for the effects of DRG reclassification and recalibration. For example, we have data available to evaluate the effects of the FY 2016 DRG reclassification and recalibration as part of our update for FY 2018. We assume, for purposes of this adjustment, that the estimate of FY 2016 DRG reclassification and recalibration resulted in no change in the case-mix when compared with the case-mix index that would have resulted if we had not made the reclassification and recalibration changes to the DRGs. Therefore, we are making a 0.0 percentage point adjustment for reclassification and recalibration in the update framework for FY 2018.

The capital update framework also contains an adjustment for forecast error. The input price index forecast is based on historical trends and relationships ascertainable at the time the update factor is established for the upcoming year. In any given year, there may be unanticipated price fluctuations that may result in differences between the actual increase in prices and the forecast used in calculating the update factors. In setting a prospective payment rate under the framework, we make an adjustment for forecast error only if our estimate of the change in the capital input price index for any year is off by 0.25 percentage point or more. There is a 2-year lag between the forecast and the availability of data to develop a measurement of the forecast error. Historically, when a forecast error of the CIPI is greater than 0.25 percentage point in absolute terms, it is reflected in the update recommended under this framework. A forecast error of 0.2 percentage point was calculated for the FY 2016 update, for which there are historical data. That is, current historical data indicate that the forecasted FY 2016 CIPI (1.3 percent) used in calculating the FY 2016 update factor was 0.2 percentage points higher than actual realized price increases (1.1 percent). However, as this does not exceed the 0.25 percentage point threshold, we are not making an adjustment for forecast error in the update for FY 2018.

Under the capital IPPS update framework, we also make an adjustment for changes in intensity. Historically, we calculated this adjustment using the same methodology and data that were used in the past under the framework for operating IPPS. The intensity factor for the operating update framework reflected how hospital services are utilized to produce the final product, that is, the discharge. This component accounts for changes in the use of quality-enhancing services, for changes within DRG severity, and for expected modification of practice patterns to remove noncost-effective services. Our intensity measure is based on a 5-year average.

We calculate case-mix constant intensity as the change in total cost per discharge, adjusted for price level changes (the CPI for hospital and related services) and changes in real case-mix. Without reliable estimates of the proportions of the overall annual intensity changes that are due, respectively, to ineffective practice patterns and the combination of quality-enhancing new technologies and complexity within the DRG system, we assume that one-half of the annual change is due to each of these factors. The capital update framework thus provides an add-on to the input price index rate of increase of one-half of the estimated annual increase in intensity, to allow for increases within DRG severity and the adoption of quality-enhancing technology.

In this final rule, we are continuing to use a Medicare-specific intensity measure that is based on a 5-year adjusted average of cost per discharge for FY 2018 (we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50436) for a full description of our Medicare-specific intensity measure). Specifically, for FY 2018, we are using an intensity measure that is based on an average of cost per discharge data from the 5-year period beginning with FY 2011 and extending through FY 2015. Based on these data, we estimated that case-mix constant intensity declined during FYs 2011 through 2015. In the past, when we found intensity to be declining, we believed a zero (rather than a negative) intensity adjustment was appropriate. Consistent with this approach, because we estimate that intensity will decline during that 5-year period, we believe it is appropriate to continue to apply a zero intensity adjustment for FY 2018. Therefore, we are making a 0.0 percentage point adjustment for intensity in the update for FY 2018.

Above, we described the basis of the components we used to develop the 1.3 percent capital update factor under the capital update framework for FY 2018 as shown in the following table.

CMS FY 2018 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE

Capital Input Price Index*	1.3
Intensity:	0.0
Case-Mix Adjustment Factors:	
Real Across DRG Change	0.5
Projected Case-Mix Change	0.5
Subtotal	1.3
Effect of FY 2016 Reclassification and Recalibration	0.0
Forecast Error Correction	0.0
Total Update	1.3

*The capital input price index represents the 2014-based CIPI.

b. Comparison of CMS and MedPAC Update Recommendation

In its March 2017 Report to Congress, MedPAC did not make a specific update recommendation for capital IPPS payments for FY 2018. (We refer readers to MedPAC's Report to the Congress: Medicare Payment Policy, March 2017, Chapter 3, available on the Web site at: *http://www.medpac.gov*.)

2. Outlier Payment Adjustment Factor

Section 412.312(c) establishes a unified outlier payment methodology for inpatient operating and inpatient capital-related costs. A single set of thresholds is used to identify outlier cases for both inpatient operating and inpatient capital-related payments. Section 412.308(c)(2) provides that the standard Federal rate for inpatient capital-related costs be reduced by an adjustment factor equal to

the estimated proportion of capital-related outlier payments to total inpatient capital-related PPS payments. The outlier thresholds are set so that operating outlier payments are projected to be 5.1 percent of total operating IPPS DRG payments.

For FY 2017, we estimated that outlier payments for capital would equal 6.14 percent of inpatient capital-related payments based on the capital Federal rate in FY 2017. Based on the thresholds as set forth in section II.A. of this Addendum, we estimate that outlier payments for capital-related costs will equal 5.16 percent for inpatient capital-related payments based on the capital Federal rate in FY 2018. Therefore, we are applying an outlier adjustment factor of 0.9484 in determining the capital Federal rate for FY 2018. Thus, we estimate that the percentage of capital outlier payments to total capital Federal rate payments for FY 2018 will be lower than the percentage for FY 2017.

The outlier reduction factors are not built permanently into the capital rates; that is, they are not applied cumulatively in determining the capital Federal rate. The FY 2018 outlier adjustment of 0.9484 is a 1.04 percent change from the FY 2017 outlier adjustment of 0.9386. Therefore, the net change in the outlier adjustment to the capital Federal rate for FY 2018 is 1.0104(0.9484/0.9386). Thus, the outlier adjustment will increase the FY 2018 capital Federal rate by 1.04 percent compared to the FY 2017 outlier adjustment.

3. Budget Neutrality Adjustment Factor for Changes in DRG Classifications and Weights and the GAF

Section 412.308(c)(4)(ii) requires that the capital Federal rate be adjusted so that aggregate payments for the fiscal year based on the capital Federal rate after any changes resulting from the annual DRG reclassification and recalibration and changes in the GAF are projected to equal aggregate payments that would have been made on the basis of the capital Federal rate without such changes. The budget neutrality factor for DRG reclassifications and recalibration nationally is applied in determining the capital IPPS Federal rate, and is applicable for all hospitals, including those hospitals located in Puerto Rico.

To determine the national capital rate factors for FY 2018, we compared estimated aggregate capital Federal rate payments based on the FY 2017 MS–DRG classifications and relative weights and the FY 2017 GAF to estimated aggregate capital Federal rate payments based on the FY 2017 MS–DRG classifications and relative weights and the FY 2018 GAFs. To achieve budget neutrality for the changes in the national GAFs, based on calculations using updated data, we applied an incremental budget neutrality adjustment factor of 0.9994 for FY 2018 to the previous cumulative FY 2017 adjustment factor of 0.9850, yielding an adjustment factor of 0.9844 through FY 2018.

We then compared estimated aggregate capital Federal rate payments based on the FY 2017 MS–DRG relative weights and the FY 2018 GAFs to estimated aggregate capital Federal rate payments based on the cumulative effects of the FY 2018 MS–DRG classifications and relative weights and the FY 2018 GAFs. The incremental adjustment factor for DRG classifications and changes in relative weights is 0.9993. The cumulative adjustment factor for MS–DRG classifications and changes in relative weights and for changes in the GAFs through FY 2018 is 0.9837. (We note that all the values are calculated with unrounded numbers.)

The GAF/DRG budget neutrality adjustment factors are built permanently into the capital rates; that is, they are applied cumulatively in determining the capital Federal rate. This follows the requirement under § 412.308(c)(4)(ii) that estimated aggregate payments each year be no more or less than they would have been in the absence of the annual DRG reclassification and recalibration and changes in the GAFs.

The methodology used to determine the recalibration and geographic adjustment factor (GAF/DRG) budget neutrality adjustment is similar to the methodology used in establishing budget neutrality adjustments under the IPPS for operating costs. One difference is that, under the operating IPPS, the budget neutrality adjustments for the effect of geographic reclassifications are determined separately from the effects of other changes in the hospital wage index and the MS–DRG relative weights. Under the capital IPPS, there is a single GAF/DRG budget neutrality adjustment factor for changes in the GAF (including geographic reclassification) and the MS–DRG relative weights. In addition, there is no adjustment for the effects that geographic reclassification has on the other payment parameters, such as the payments for DSH or IME.

The cumulative adjustment factor of 0.9986 (the product of the incremental national GAF budget neutrality adjustment factor of 0.9994 and the incremental DRG budget neutrality adjustment factor of 0.9993) accounts for the MS–DRG reclassifications and recalibration and for changes in the GAFs. It also incorporates the effects on the GAFs of FY 2018 geographic reclassification decisions made by the MGCRB compared to FY 2017 decisions. However, it does not account for changes in payments due to changes in the DSH and IME adjustment factors.

As discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57062), we made an adjustment of (1/0.998) to the national capital Federal rate to remove the 0.2 percent reduction (an adjustment factor of 0.998) to the national capital Federal rate to offset the estimated increase in capital IPPS expenditures associated with the 2-midnight policy. This was consistent with the adjustment to the operating IPPS standardized amount and the hospital-specific payment rates. In addition, consistent with the approach for the operating IPPS standardized amount and hospital-specific payment rates and for the reasons discussed in the FY 2017 IPPS/LTCH PPS final rule, we made a one-time prospective adjustment of 1.006 in FY 2017 to the national capital Federal rate to address the effect of the 0.2 percent reduction to the national capital Federal rates in effect for FY 2014, FY 2015, and FY 2016. Furthermore, as provided for in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57294) we are removing this one-time prospective adjustment through an adjustment of (1/1.006) to the national capital Federal rate in FY 2018, consistent with the approach for the operating IPPS standardized amount and hospital-specific payment rates (as discussed in section V.M. of the preamble of this final rule). We refer readers to sections V.M. and VI.C. of the preamble of this final rule for a complete discussion of these issues.

4. Capital Federal Rate for FY 2018

For FY 2017, we established a capital Federal rate of $446.79 (81 FR 68947 through 68949 (Correction Notice)). We are establishing an update of 1.61 percent in determining the FY 2018 capital Federal rate for all hospitals. As a result of this update, the budget neutrality factors discussed earlier, and the adjustment to remove the one-time 0.6 percent adjustment made in FY 2017 to address the effect of the 0.2 percent reduction to the national capital Federal rates in effect for FY 2014, FY 2015, and FY 2016, as finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57294), we are establishing a national capital Federal rate of $453.97 for FY 2018. The national capital Federal rate for FY 2018 was calculated as follows:

- The FY 2018 update factor is 1.0130; that is, the update is 1.3 percent.
- The FY 2018 budget neutrality adjustment factor that is applied to the capital Federal rate for changes in the MS–DRG classifications and relative weights and changes in the GAFs is 0.9986.
- The FY 2018 outlier adjustment factor is 0.9484.
- The 2-midnight policy adjustment to remove the one-time 0.6 percent adjustment is 1/1.006.

(We note that, as discussed in section VI.C. of the preamble of this final rule, we are not making an additional MS–DRG documentation and coding adjustment to the capital IPPS Federal rate for FY 2018.)

Because the FY 2018 capital Federal rate has already been adjusted for differences in case-mix, wages, cost-of-living, indirect medical education costs, and payments to hospitals serving a disproportionate share of low-income patients, we are not making additional adjustments in the capital Federal rate for these factors, other than the budget neutrality factor for changes in the MS–DRG classifications and relative weights and for changes in the GAFs.

We are providing the following chart that shows how each of the factors and adjustments for FY 2018 affects the computation of the FY 2018 national capital Federal rate in comparison to the FY 2017 national capital Federal rate as presented in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57291 through 57295) as corrected in the Correction Notice published October 5, 2016 (81 FR 68954). The FY 2018 update factor has the effect of increasing the capital Federal rate by 1.3 percent compared to the FY 2017 capital Federal rate. The GAF/DRG budget neutrality adjustment factor has the effect of decreasing the capital Federal rate by 0.14 percent. The FY 2018 outlier adjustment factor has the effect of increasing the capital Federal rate by 1.04 percent compared to the FY 2017 capital Federal rate. The removal of

the one-time 0.6 percent adjustment for FY 2017 relating to the 2-midnight policy has the effect of decreasing the capital Federal rate by 0.60 percent. The combined effect of all the changes will increase the national capital Federal rate by approximately 1.61 percent compared to the FY 2017 national capital Federal rate.

COMPARISON OF FACTORS AND ADJUSTMENTS: FY 2017 CAPITAL FEDERAL RATE AND FY 2018 CAPITAL FEDERAL RATE

	FY 2017	FY 2018	Change	Percent change
Update Factor [1]	1.0090	1.0130	1.0130	1.30
GAF/DRG Adjustment Factor [1]	0.9990	0.9986	0.9986	−0.14
Outlier Adjustment Factor [2]	0.9386	0.9484	1.0104	1.04
Removal of One-Time 2-Midnight Policy Adjustment Factor	1.0060	1/1.006	0.9940	−0.60
Capital Federal Rate	$446.79	$453.97	1.0161	[3] 1.61

[1] The update factor and the GAF/DRG budget neutrality adjustment factors are built permanently into the capital Federal rates. Thus, for example, the incremental change from FY 2017 to FY 2018 resulting from the application of the 0.9986 GAF/DRG budget neutrality adjustment factor for FY 2018 is a net change of 0.9986 (or −0.14 percent).

[2] The outlier reduction factor is not built permanently into the capital Federal rate; that is, the factor is not applied cumulatively in determining the capital Federal rate. Thus, for example, the net change resulting from the application of the FY 2018 outlier adjustment factor is 0.9484/0.9386 or 1.0104 (or 1.04 percent).

[3] Percent change may not sum due to rounding.

In this final rule, we also are providing the following chart that shows how the final FY 2018 capital Federal rate differs from the proposed FY 2018 capital Federal rate as presented in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20179 through 20182).

COMPARISON OF FACTORS AND ADJUSTMENTS: PROPOSED FY 2018 CAPITAL FEDERAL RATE AND FINAL FY 2018 CAPITAL FEDERAL RATE

	Proposed FY 2018	Final FY 2018	Change	Percent change
Update Factor [1]	1.0120	1.0130	1.0010	0.10
GAF/DRG Adjustment Factor [1]	0.9992	0.9986	0.9994	−0.06
Outlier Adjustment Factor [2]	0.9434	0.9484	1.0053	0.53
Removal of One-Time 2-Midnight Policy Adjustment Factor	1/1.006	1/1.006	0.0000	−0.00
Capital Federal Rate	$451.37	$453.97	1.0458	0.58

B. Calculation of the Inpatient Capital-Related Prospective Payments for FY 2018

For purposes of calculating payments for each discharge during FY 2018, the capital Federal rate is adjusted as follows: (Standard Federal Rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME Adjustment Factor, if applicable). The result is the adjusted capital Federal rate.

Hospitals also may receive outlier payments for those cases that qualify under the thresholds established for each fiscal year. Section 412.312(c) provides for a single set of thresholds to identify outlier cases for both inpatient operating and inpatient capital-related payments. The outlier thresholds for FY 2018 are in section II.A. of this Addendum. For FY 2018, a case would qualify as a cost outlier if the cost for the case plus the (operating) IME and DSH payments (including both the empirically justified Medicare DSH payment and the estimated uncompensated care payment, as discussed in section II.A.4.g.(1) of this Addendum) is greater than the prospective payment rate for the MS–DRG plus the fixed-loss amount of $26,601.

Currently, as provided under § 412.304(c)(2), we pay a new hospital 85 percent of its reasonable costs during the first 2 years of operation unless it elects to receive payment based on 100 percent of the capital Federal rate. Effective with the third year of operation, we pay the hospital based on 100 percent of the capital Federal rate (that is, the same methodology used to pay all other hospitals subject to the capital PPS).

C. Capital Input Price Index

1. Background

Like the operating input price index, the capital input price index (CIPI) is a fixed-weight price index that measures the price changes associated with capital costs during a given year. The CIPI differs from the operating input price index in one important aspect—the CIPI reflects the vintage nature of capital, which is the acquisition and use of capital over time. Capital expenses in any given year are determined by the stock of capital in that year (that is, capital that remains on hand from all current and prior capital acquisitions). An index measuring capital price changes needs to reflect this vintage nature of capital. Therefore, the CIPI was developed to capture the vintage nature of capital by using a weighted-average of past capital purchase prices up to and including the current year.

We periodically update the base year for the operating and capital input price indexes to reflect the changing composition of inputs for operating and capital expenses. For this FY 2018 IPPS/LTCH PPS final rule, we are rebasing and revising the IPPS operating and capital market baskets to reflect a 2014 base year. For a complete discussion of this rebasing, we refer readers to section IV. of the preamble of this final rule.

2. Forecast of the CIPI for FY 2018

Based on IGI, Inc.'s second quarter 2017 forecast, for this final rule, we are forecasting the 2014-based CIPI to increase 1.3 percent in FY 2018. This reflects a projected 1.6 percent increase in vintage-weighted depreciation prices (building and fixed equipment, and movable equipment), and a projected 3.5 percent increase in other capital expense prices in FY 2018, partially offset by a projected 1.3 percent decline in vintage-weighted interest expense prices in FY 2018. The weighted average of these three factors produces the forecasted 1.3 percent increase for the 2014-based CIPI in FY 2018.

IV. Changes to Payment Rates for Excluded Hospitals: Rate-of-Increase Percentages for FY 2018

Payments for services furnished in children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) that are excluded from the IPPS are made on the basis of reasonable costs based on the hospital's own historical cost experience, subject to a rate-of-increase ceiling. A per discharge limit (the target amount as defined in § 413.40(a) of the regulations) is set for each hospital based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage specified in § 413.40(c)(3). In addition, in the

FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20029), we proposed that, for cost reporting periods beginning during FY 2018, the annual update to the target amount for long-term care neoplastic disease hospitals (hospitals described under § 412.23(j); now § 412.22(i) in this final rule) also would be the rate-of-increase percentage specified in § 413.0(c)(3). (We note that, in accordance with § 403.752(a), religious nonmedical health care institutions (RNHCIs) are also subject to the rate-of-increase limits established under § 413.40 of the regulations.)

As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20003 and 20004), the proposed FY 2018 rate-of-increase percentage for updating the target amounts for the 11 cancer hospitals, children's hospitals, the short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and RNHCIs is the estimated percentage increase in the IPPS operating market basket for FY 2018, in accordance with applicable regulations at § 413.40. Based on IGI's 2016 fourth quarter forecast, we estimated that the proposed 2014-based IPPS operating market basket update for FY 2018 was 2.9 percent (that is, the estimate of the market basket rate-of-increase). However, we proposed that if more recent data became available for the final rule, we would use them to calculate the IPPS operating market basket update for FY 2018. For this final rule, based on IGI's 2017 second quarter forecast (which is the most recent available data), we estimated that the 2014-based IPPS operating market basket update for FY 2018 is 2.7 percent (that is, the estimate of the market basket rate-of-increase). Therefore, for children's hospitals, the 11 cancer hospitals, hospitals located outside the 50 States, the District of Columbia and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa), as well as long-term care neoplastic disease hospitals, which will now be called extended neoplastic disease care hospitals as discussed in section VII. of the preamble to this final rule, and RNHCIs, the FY 2018 rate-of-increase percentage that will be applied to the FY 2017 target amounts in order to determine the FY 2018 target amounts is 2.7 percent.

The IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We refer readers to section VIII. of the preamble of this final rule and section V. of the Addendum to this final rule for the update changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2018. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

V. Changes to the Payment Rates for the LTCH PPS for FY 2018

A. LTCH PPS Standard Federal Payment Rate for 2018

1. Overview

In section VIII. of the preamble of this final rule, we discuss our annual updates to the payment rates, factors, and specific policies under the LTCH PPS for FY 2018.

Under § 412.523(c)(3)(ii) of the regulations, for LTCH PPS rate years beginning with RY 2004 through RY 2006, we updated the standard Federal payment rate annually by a factor to adjust for the most recent estimate of the increases in prices of an appropriate market basket of goods and services for LTCHs. We established this policy of annually updating the standard Federal payment rate because, at that time, we believed that was the most appropriate method for updating the rate for years after the initial implementation of the LTCH PPS in FY 2003. Therefore, under § 412.523(c)(3)(ii), for RYs 2004 through 2006, the annual update to the LTCH PPS standard Federal payment rate was equal to the previous rate year's Federal rate updated by the most recent estimate of increases in the appropriate market basket of goods and services included in covered inpatient LTCH services.

In determining the annual update to the standard Federal payment rate for RY 2007, based on our ongoing monitoring activity, we believed that, rather than solely using the most recent estimate of the LTCH PPS market basket update as the basis of the annual update factor, it was appropriate to adjust the standard Federal payment rate to account for the effect of documentation and coding in a prior period that was unrelated to patients' severity of illness (71 FR 27818). Accordingly, we established under § 412.523(c)(3)(iii) that the annual update to the standard Federal payment rate for RY 2007 was zero percent based on the most recent estimate of the LTCH PPS market basket at that time, offset by an adjustment to account for changes in case-mix in prior periods due to the effect of documentation and coding that were unrelated to patients' severity of illness. For RY 2008 through FY 2011, we also made an adjustment to account for the effect of documentation and coding that was unrelated to patients' severity of illness in establishing the annual update to the standard Federal payment rate as set forth in the regulations at §§ 412.523(c)(3)(iv) through (c)(3)(vii). For FYs 2012 through 2017, we updated the standard Federal payment rate by the most recent estimate of the LTCH PPS market basket at that time, including additional statutory adjustments required by sections 1886(m)(3)(A)(i) (citing sections 1886(b)(3)(B)(xi)(II), 1886(m)(3)(A)(ii), and 1886(m)(4) of the Act as set forth in the regulations at §§ 412.523(c)(3)(viii) through (c)(3)(xiii)).

Section 1886(m)(3)(A) of the Act, as added by section 3401(c) of the Affordable Care Act, specifies that, for rate year 2010 and each subsequent rate year, any annual update to the standard Federal payment rate shall be reduced:

- For rate year 2010 through 2019, by the other adjustment specified in section 1886(m)(3)(A)(ii) and (m)(4) of the Act; and
- For rate year 2012 and each subsequent year, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (which we refer to as ''the multifactor productivity (MFP) adjustment'') as discussed in section VIII.E.2. of the preamble of this final rule.

Section 1886(m)(3)(B) of the Act provides that the application of paragraph (3) of section 1886(m) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year. (As noted in section VIII.C.2.b. of the preamble of this final rule, the annual update to the LTCH PPS occurs on October 1 and we have adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010. Therefore, for purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the Affordable Care Act, we use the term ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.) Notwithstanding those provisions, however, section 411(e) of Public Law 114–10 (the MACRA) requires a 1 percent update in FY 2018.

For FY 2017, consistent with our historical practice, we established an update to the LTCH PPS standard Federal payment rate based on the full estimated LTCH PPS market basket increase of 2.8 percent and the 1.05 percentage point reductions required by sections 1886(m)(3)(A)(i) and 1886(m)(3)(A)(ii) with 1886(m)(4)(F) of the Act. Accordingly, at § 412.523(c)(3)(xiii) of the regulations, we established an annual update of 1.75 percent to the standard Federal payment rate for FY 2017 (81 FR 57296 through 57297). In addition, as discussed in that same final rule, the annual update for FY 2017 was further reduced by 2.0 percentage points for LTCHs that failed to submit quality reporting data in accordance with the requirements of the LTCH QRP under section 1886(m)(5) of the Act.

Section 411(e) of the MACRA amended section 1886(m)(3) of the Act by providing an additional special rule for FY 2018. Specifically, as amended, section 1886(m)(3)(C) of the Act requires that the annual update for FY 2018, after applications of the reductions for the MFP adjustment and the ''other adjustment'' (under section 1886(m)(3)(A)) is 1 percent. (For additional details, refer to section VIII.C.2. of the preamble of this final rule.) Accordingly, in this final rule, we are providing an annual update to the LTCH PPS standard Federal payment rate of 1 percent for FY 2018 as required by section 411(e)(2) of the MACRA. For LTCHs that fail to submit the required quality reporting data for FY 2017 in accordance with the LTCH QRP, the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act. Accordingly, we are providing an annual update to the LTCH PPS standard Federal payment rate of -1.0 percent for LTCHs that fail to submit the required quality reporting data for FY 2018 (that is, the full update of 1 percent and less 2.0 percentage points for failure to submit quality reporting data as required by section 1886(m)(5) of the Act).

2. Development of the FY 2018 LTCH PPS Standard Federal Payment Rate

Consistent with our historical practice, for FY 2018, we are applying the annual update to the LTCH PPS standard Federal payment rate from the previous year. Furthermore, in determining the LTCH PPS standard Federal payment rate for FY 2018, we also are making

certain regulatory adjustments, consistent with past practices. Specifically, in determining the FY 2018 LTCH PPS standard Federal payment rate, we applied a budget neutrality adjustment factor for the changes related to the area wage adjustment (that is, changes to the wage data and labor-related share) in accordance with § 412.523(d)(4) and a budget neutrality adjustment factor for the change to the SSO payment methodology (discussed in VIII.D. of the preamble of this final rule).

For FY 2017, we established an annual update to the LTCH PPS standard Federal payment rate of 1.75 percent based on the full estimated LTCH PPS market basket increase of 2.8 percent, less the MFP adjustment of 0.3 percentage point consistent with section 1886(m)(3)(A)(i) of the Act and less the 0.75 percentage point required by sections 1886(m)(3)(A)(ii) and (m)(4)(F) of the Act. Accordingly, at § 412.523(c)(3)(xiii), we established an annual update to the LTCH PPS standard Federal payment rate for FY 2017 of 1.75 percent. That is, we applied an update factor of 1.0175 to the FY 2016 Federal rate of $41,762.85 to determine the FY 2017 LTCH PPS standard Federal payment rate. We also applied an area wage level budget neutrality factor for FY 2017 of 0.999593 to the LTCH PPS standard Federal payment rate to ensure that any changes to the area wage level adjustment would not result in any change in estimated aggregate LTCH PPS payments. Consequently, we established an LTCH PPS standard Federal payment rate for FY 2017 of $42,476.41 (calculated as $41,762.85 × 1.0175 × 0.999593) (81 FR 57297).

In this final rule, as required by statute, we are establishing an annual update to the LTCH PPS standard Federal payment rate of 1 percent for FY 2018 (as described above). Accordingly, under § 412.523(c)(3)(xiii), we are applying a factor of 1.01 to the FY 2017 LTCH PPS standard Federal payment rate of $42,476.41 to determine the FY 2018 LTCH PPS standard Federal payment rate. Also, under finalized § 412.523(c)(3)(iv), in conjunction with the provisions of § 412.523(c)(4), we are applying an annual update to the LTCH PPS standard Federal payment rate of –1.0 percent (that is, a update factor of 0.99) for FY 2018 for LTCHs that fail to submit the required quality reporting data for FY 2018 as required under the LTCH QRP. Consistent with § 412.523(d)(4), we also are applying an area wage level budget neutrality factor to the FY 2018 LTCH PPS standard Federal payment rate of 1.0006434, based on the best available data at this time, to ensure that any changes to the area wage level adjustment (that is, the annual update of the wage index values and labor-related share) would not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard Federal rate payments. Finally, we are applying a budget neutrality adjustment of 0.9651 for our changes to the SSO payment methodology (discussed in VIII.D. of the preamble of this final rule). Accordingly, we are establishing an LTCH PPS standard Federal payment rate of $41,430.56 (calculated as $42,476.41 × 1.01 × 1.0006434 × 0.9651) for FY 2018. For LTCHs that fail to submit quality reporting data for FY 2018, in accordance with the requirements of the LTCHQRP under section 1886(m)(5) of the Act, we are establishing an LTCH PPS standard Federal payment rate of $40,610.16 (calculated as $42,476.41 × 0.99 × 1.0006434 × 0.9651) for FY 2018.

B. Adjustment for Area Wage Levels Under the LTCH PPS for FY 2018

1. Background

Under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS standard Federal payment rate to account for differences in LTCH area wage levels under § 412.525(c). The labor-related share of the LTCH PPS standard Federal payment rate is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index. The applicable LTCH PPS wage index is computed using wage data from inpatient acute care hospitals without regard to reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act.

When we implemented the LTCH PPS, we established a 5-year transition to the full area wage level adjustment. The area wage level adjustment was completely phased-in for cost reporting periods beginning in FY 2007. Therefore, for cost reporting periods beginning on or after October 1, 2006, the applicable LTCH area wage index values are the full LTCH PPS area wage index values calculated based on acute care hospital inpatient wage index data without taking into account geographic reclassification under section 1886(d)(8) and section 1886(d)(10) of the Act. For additional information on the phase-in of the area wage level adjustment under the LTCH PPS, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56015 through 56019) and the RY 2008 LTCH PPS final rule (72 FR 26891).

2. Geographic Classifications (Labor Market Areas) for the LTCH PPS Standard Federal Payment Rate

In adjusting for the differences in area wage levels under the LTCH PPS, the labor-related portion of an LTCH's Federal prospective payment is adjusted by using an appropriate area wage index based on the geographic classification (labor market area) in which the LTCH is located. Specifically, the application of the LTCH PPS area wage level adjustment under existing § 412.525(c) is made based on the location of the LTCH—either in an ''urban area,'' or a ''rural area,'' as defined in § 412.503. Under § 412.503, an ''urban area'' is defined as a Metropolitan Statistical Area (MSA) (which includes a Metropolitan division, where applicable), as defined by the Executive OMB and a ''rural area'' is defined as any area outside of an urban area. (Information on OMB's MSA delineations based on the 2010 standards can be found at: *https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/fedreg_2010/06282010_metro_standards-Complete.pdf.*)

The CBSA-based geographic classifications (labor market area definitions) currently used under the LTCH PPS, effective for discharges occurring on or after October 1, 2014, are based on the OMB labor market area delineations based on the 2010 Decennial Census data. The current statistical areas (which were implemented beginning with FY 2015) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No. 13–01. We adopted these labor market area delineations because they are based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas. We also believe that these OMB delineations will ensure that the LTCH PPS area wage level adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level. We noted that this policy was consistent with the IPPS policy adopted in FY 2015 under § 412.64(b)(1)(ii)(D) of the regulations (79 FR 49951 through 49963). (For additional information on the CBSA-based labor market area (geographic classification) delineations currently used under the LTCH PPS and the history of the labor market area definitions used under the LTCH PPS, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50180 through 50185).)

In general, it is our historical practice to update the CBSA-based labor market area delineations annually based on the most recent updates issued by OMB. Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. As discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913 through 56914), OMB issued OMB Bulletin No. 15–01 on July 15, 2015 to update and supersede Bulletin No. 13–10. Bulletin No. 15–01 and its attachment provide detailed information on the update to statistical areas since the February 28, 2013 release of Bulletin No. 13–10 and are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012, and July 1, 2013. A copy of this bulletin may be obtained on the Web site at: *https://obamawhitehouse.archives.gov/sites/default/files/omb/bulletins/2015/15-01.pdf.*

We believe that these revisions to the CBSA-based labor market area delineations will ensure that the LTCH PPS area wage level adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas (81 FR 57298). Therefore, we are continuing to use the CSBA-based labor market area delineations adopted under the LTCH PPS, effective October 1, 2017 (as adopted in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57298)). Moreover, the FY 2018 LTCH PPS wage index values in Tables 12A and 12B listed in section VI. of the Addendum of this final rule (which are available via the Internet on the CMS Web site) reflect the revisions to the CBSA-based labor market

area delineations described above. We note that, as discussed in section III.A.2. of the preamble of this final rule, the revisions to the CBSA-based delineations also were adopted under the IPPS, effective beginning October 1, 2016.

3. Labor-Related Share for the LTCH PPS Standard Federal Payment Rate

Under the payment adjustment for the differences in area wage levels under § 412.525(c), the labor-related share of an LTCH's standard Federal payment rate payment is adjusted by the applicable wage index for the labor market area in which the LTCH is located. The LTCH PPS labor-related share currently represents the sum of the labor-related portion of operating costs and a labor-related portion of capital costs using the applicable LTCH PPS market basket. Additional background information on the historical development of the labor-related share under the LTCH PPS can be found in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817 and 27829 through 27830) and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51766 through 51769 and 51808).

For FY 2013, we rebased and revised the market basket used under the LTCH PPS by adopting the newly created FY 2009-based LTCH-specific market basket. In addition, beginning in FY 2013, we determined the labor-related share annually as the sum of the relative importance of each labor-related cost category of the 2009-based LTCH-specific market basket for the respective fiscal year based on the best available data. (For more details, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53477 through 53479).) As noted previously, we rebased and revised the 2009-based LTCH-specific market basket to reflect a 2013 base year. In conjunction with that policy, as discussed in section VIII.C. of the preamble of this final rule, we are establishing that the LTCH PPS labor-related share for FY 2018 is the sum of the FY 2018 relative importance of each labor-related cost category in the 2013-based LTCH market basket using the most recent available data. Specifically, we are establishing that the labor-related share for FY 2018 includes the sum of the labor-related portion of operating costs from the 2013-based LTCH market basket (that is, the sum of the FY 2018 relative importance share of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-related Services) and a portion of the Capital-Related cost weight from the 2013-based LTCH PPS market basket. Based on IGI's second quarter 2017 forecast of the 2013-based LTCH market basket, we are establishing a labor-related share under the LTCH PPS for FY 2018 of 66.2 percent. This labor-related share is determined using the same methodology as employed in calculating all previous LTCH PPS labor-related shares. Consistent with our historical practice, as we proposed, we used more recent data available to determine the final FY 2018 labor-related share in this final rule.

The labor-related share for FY 2018 is the sum of the FY 2018 relative importance of each labor-related cost category, and reflects the different rates of price change for these cost categories between the base year (2013) and FY 2018. The sum of the relative importance for FY 2018 for operating costs (Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-Related Services) is 62.0 percent. The portion of capital-related costs that is influenced by the local labor market is estimated to be 46 percent (the same percentage applied to the 2009-based LTCH-specific market basket). Because the relative importance for capital-related costs under our policies is 9.2 percent of the 2013-based LTCH market basket in FY 2018, we are taking 46 percent of 9.2 percent to determine the labor-related share of capital-related costs for FY 2018 (0.46×9.2). The result is 4.2 percent, which we added to 62.0 percent for the operating cost amount to determine the total labor-related share for FY 2018. Therefore, the labor-related share under the LTCH PPS for FY 2018 is 66.2 percent.

4. Wage Index for FY 2018 for the LTCH PPS Standard Federal Payment Rate

Historically, we have established LTCH PPS area wage index values calculated from acute care IPPS hospital wage data without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act (67 FR 56019). The area wage level adjustment established under the LTCH PPS is based on an LTCH's actual location without regard to the ''urban'' or ''rural'' designation of any related or affiliated provider.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57299 through 57301), we calculated the FY 2017 LTCH PPS area wage index values using the same data used for the FY 2017 acute care hospital IPPS (that is, data from cost reporting periods beginning during FY 2013), without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act, as these were the most recent complete data available at that time. In that same final rule, we indicated that we computed the FY 2017 LTCH PPS area wage index values, consistent with the urban and rural geographic classifications (labor market areas) that were in place at that time and consistent with the pre-reclassified IPPS wage index policy (that is, our historical policy of not taking into account IPPS geographic reclassifications in determining payments under the LTCH PPS). As with the IPPS wage index, wage data for multicampus hospitals with campuses located in different labor market areas (CBSAs) are apportioned to each CBSA where the campus (or campuses) are located. We also continued to use our existing policy for determining area wage index values for areas where there are no IPPS wage data.

Consistent with our historical methodology, as discussed in the FY 2018 IPPS/LTCH PPS proposed rule, to determine the applicable area wage index values for the FY 2018 LTCH PPS standard Federal payment rate, under the broad authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, as we proposed, we used wage data collected from cost reports submitted by IPPS hospitals for cost reporting periods beginning during FY 2014, without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act because these data are the most recent complete data available. We also note that these are the same data we are using to compute the FY 2018 acute care hospital inpatient wage index, as discussed in section III. of the preamble of this final rule. We computed the FY 2018 LTCH PPS standard Federal payment rate area wage index values consistent with the ''urban'' and ''rural'' geographic classifications (that is, labor market area delineations, including the updates, as previously discussed in section V.B. of this Addendum) and our historical policy of not taking into account IPPS geographic reclassifications under sections 1886(d)(8) and 1886(d)(10) of the Act in determining payments under the LTCH PPS. As we also proposed, we are continuing to apportion wage data for multicampus hospitals with campuses located in different labor market areas to each CBSA where the campus or campuses are located, consistent with the IPPS policy. Lastly, consistent with our existing methodology for determining the LTCH PPS wage index values, for FY 2018, we are continuing to use our existing policy for determining area wage index values for areas where there are no IPPS wage data. Under our existing methodology, the LTCH PPS wage index value for urban CBSAs with no IPPS wage data will be determined by using an average of all of the urban areas within the State, and the LTCH PPS wage index value for rural areas with no IPPS wage data will be determined by using the unweighted average of the wage indices from all of the CBSAs that are contiguous to the rural counties of the State.

Based on the FY 2014 IPPS wage data that we used to determine the FY 2018 LTCH PPS standard Federal payment rate area wage index values in this final rule, there are no IPPS wage data for the urban area of Hinesville, GA (CBSA 25980). Consistent with the methodology discussed above, we calculated the FY 2018 wage index value for CBSA 25980 as the average of the wage index values for all of the other urban areas within the State of Georgia (that is, CBSAs 10500, 12020, 12060, 12260, 15260, 16860, 17980, 19140, 23580, 31420, 40660, 42340, 46660 and 47580), as shown in Table 12A, which is listed in section VI. of the Addendum to this final rule and available via the Internet on the CMS Web site). We note that, as IPPS wage data are dynamic, it is possible that urban areas without IPPS wage data will vary in the future.

Based on the FY 2014 IPPS wage data that we used to determine the FY 2018 LTCH PPS standard Federal payment rate area wage index values in this final rule, there are no rural areas without IPPS hospital wage data. Therefore, it is not necessary to use our established methodology to calculate a LTCH PPS standard Federal payment rate wage index value for proposed rural areas with no IPPS wage data for FY 2018. We note that, as IPPS wage data are dynamic, it is possible that the number of rural areas without IPPS wage data will vary in the future. The FY 2018 LTCH PPS standard Federal payment

rate wage index values that will be applicable for LTCH PPS standard Federal payment rate discharges occurring on or after October 1, 2017, through September 30, 2018, are presented in Table 12A (for urban areas) and Table 12B (for rural areas), which are listed in section VI. of the Addendum of this final rule and available via the Internet on the CMS Web site.

5. Budget Neutrality Adjustment for Changes to the LTCH PPS Standard Federal Payment Rate Area Wage Level Adjustment

Historically, the LTCH PPS wage index and labor-related share are updated annually based on the latest available data. Under § 412.525(c)(2), any changes to the area wage index values or labor-related share are to be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are unaffected; that is, will be neither greater than nor less than estimated aggregate LTCH PPS payments without such changes to the area wage level adjustment. Under this policy, we determine an area wage-level adjustment budget neutrality factor that will be applied to the standard Federal payment rate to ensure that any changes to the area wage level adjustments are budget neutral such that any changes to the area wage index values or labor-related share would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Accordingly, under § 412.523(d)(4), we apply an area wage level adjustment budget neutrality factor in determining the standard Federal payment rate, and we also established a methodology for calculating an area wage level adjustment budget neutrality factor. (For additional information on the establishment of our budget neutrality policy for changes to the area wage level adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771 through 51773 and 51809).)

In this final rule, for FY 2018 LTCH PPS standard Federal payment rate cases, in accordance with § 412.523(d)(4), as we proposed, we applied an area wage level adjustment budget neutrality factor to adjust the LTCH PPS standard Federal payment rate to account for the estimated effect of the adjustments or updates to the area wage level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS payments using a methodology that is consistent with the methodology we established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51773). Specifically, as we proposed in the FY 2018 IPPS/LTCH PPS proposed rule, we determined an area wage level adjustment budget neutrality factor that will be applied to the LTCH PPS standard Federal payment rate under § 412.523(d)(4) for FY 2018 using the following methodology:

Step 1—We simulated estimated aggregate LTCH PPS standard Federal payment rate payments using the FY 2017 wage index values and the FY 2017 labor-related share of 66.5 percent (as established in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57099 and 57100)).

Step 2—We simulated estimated aggregate LTCH PPS standard Federal payment rate payments using the FY 2018 wage index values (as shown in Tables 12A and 12B listed in the Addendum to this final rule and available via the Internet on the CMS Web site) and the FY 2018 labor-related share of 66.2 percent (based on the latest available data as previously discussed in this Addendum).

Step 3—We calculated the ratio of these estimated total LTCH PPS standard Federal payment rate payments by dividing the estimated total LTCH PPS standard Federal payment rate payments using the FY 2017 area wage level adjustments (calculated in Step 1) by the estimated total LTCH PPS standard Federal payment rate payments using the FY 2018 area wage level adjustments (calculated in Step 2) to determine the area wage level adjustment budget neutrality factor for FY 2018 LTCH PPS standard Federal payment rate payments.

Step 4—We then applied the FY 2018 area wage level adjustment budget neutrality factor from Step 3 to determine the FY 2018 LTCH PPS standard Federal payment rate after the application of the FY 2018 annual update (discussed previously in section V.A. of this Addendum).

We note that, with the exception of cases subject to the transitional blend payment rate provisions in the first 2 years and certain temporary exemptions for certain spinal cord specialty hospitals and certain severe wound cases, under the dual rate LTCH PPS payment structure, only LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid based on the LTCH PPS standard Federal payment rate. Because the area wage level adjustment under § 412.525(c) is an adjustment to the LTCH PPS standard Federal payment rate, we only used data from claims that would have qualified for payment at the LTCH PPS standard Federal payment rate if such rate had been in effect at the time of discharge to calculate the FY 2017 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor described above.

For this final rule, using the steps in the methodology previously described, we determined a FY 2018 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor of 1.0006434. Accordingly, in section V.A. of the Addendum to this final rule, to determine the FY 2018 LTCH PPS standard Federal payment rate, we applied an area wage level adjustment budget neutrality factor of 1.0006434, in accordance with § 412.523(d)(4). The FY 2018 LTCH PPS standard Federal payment rate shown in Table 1E of the Addendum to this final rule reflects this adjustment factor.

C. Cost-of-Living Adjustment (COLA) for LTCHs Located in Alaska and Hawaii

Under § 412.525(b), a cost-of-living adjustment (COLA) is provided for LTCHs located in Alaska and Hawaii to account for the higher costs incurred in those States. Specifically, we apply a COLA to payments to LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standard Federal payment rate by the applicable COLA factors established annually by CMS. Higher labor-related costs for LTCHs located in Alaska and Hawaii are taken into account in the adjustment for area wage levels previously described.

Under our current methodology, we update the COLA factors for Alaska and Hawaii every 4 years (at the same time as the update to the labor-related share of the IPPS market basket) (77 FR 53712 through 53713). This methodology is based on a comparison of the growth in the Consumer Price Indexes (CPIs) for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). It also includes a 25-percent cap on the CPI-updated COLA factors. Under our current policy, we update the COLA factors using the methodology described above every 4 years; the first year began in FY 2014. For FY 2014, we updated the COLA factors for Alaska and Hawaii published by OPM for 2009 using the methodology finalized in FY 2013. (For additional details on our current methodology for updating the COLA factors for Alaska and Hawaii, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53481 through 53482).) As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20186 through 20187) and this final rule, we continue to believe that determining updated COLA factors using this methodology would appropriately adjust the nonlabor-related portion of the LTCH PPS standard Federal payment rate for LTCHs located in Alaska and Hawaii.

For FY 2018, we are continuing to update the COLA factors published by OPM for 2009 (as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay) using the methodology that we finalized in the FY 2013 IPPS/LTCH PPS final rule and implemented for the FY 2014 IPPS update. Specifically, we are updating the 2009 OPM COLA factors by a comparison of the growth in the Consumer Price Indices (CPIs) for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). Because BLS publishes CPI data for only Anchorage and Honolulu, using the methodology we finalized in the FY 2013 IPPS/LTCH PPS final rule, we use the comparison of the growth in the overall CPI relative to the growth in the CPI for those cities to update the COLA factors for all areas in Alaska and Hawaii, respectively. We believe that the relative price differences between these cities and the U.S. (as measured by the CPIs mentioned above) are appropriate proxies for the relative price differences between the ''other areas'' of Alaska and Hawaii and the United States.

BLS publishes the CPI for All Items for Anchorage, Honolulu, and for the average U.S. city. However, consistent with our methodology finalized in the FY 2013 IPPS/LTCH PPS final rule, we are creating reweighted CPIs for each of the respective areas to reflect the underlying composition of the IPPS market basket nonlabor-related share. The current composition of the CPI for All Items for all of the respective areas is approximately 40 percent commodities and 60 percent services. However, the IPPS

nonlabor-related share is comprised of a different mix of commodities and services. Therefore, we create reweighted indexes for Anchorage, Honolulu, and the average U.S. city using the respective CPI commodities index and CPI services index using the approximate 55 percent commodities/45 percent services shares obtained from the proposed 2014-based IPPS market basket. We create reweighted indexes using BLS data for 2009 through 2016—the most recent data available at the time of this rulemaking. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50985 through 50987), we created reweighted indexes based on the FY 2010-based IPPS market basket (which was adopted for the FY 2014 update) and BLS data for 2009 through 2012 (the most recent BLS data at the time of the FY 2014 IPPS/LTCH PPS rulemaking).

We continue to believe this methodology is appropriate because we continue to make a COLA for LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the LTCH PPS standard Federal rate by a COLA factor. We note that OPM's COLA factors were calculated with a statutorily mandated cap of 25 percent. As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50987), when developing the COLA update methodology we finalized in the FY 2013 IPPS/LTCH PPS final rule, we exercised our discretionary authority to adjust payments to LTCHs in Alaska and Hawaii by incorporating this cap. In applying this finalized methodology for updating the COLA factors, our policy for FY 2018 continues to use a 25-percent cap, as our policy is based on OPM's COLA factors (updated by the methodology described earlier).

Applying this methodology, the COLA factors that we are establishing for FY 2018 to adjust the nonlabor related portion of the LTCH PPS standard Federal rate for LTCHs located in Alaska and Hawaii are shown in the table below. For comparison purposes, we also are showing the FY 2013 COLA factors (which were based on OPM's published COLA factors for 2009) and the COLA factors for FYs 2014 through 2017.

Lastly, as we finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53700 and 53701), we are updating the COLA factors based on our methodology every 4 years, at the same time as the update to the labor-related share of the IPPS market basket.

COST-OF-LIVING ADJUSTMENT FACTORS FOR ALASKA AND HAWAII UNDER THE LTCH PPS FOR FY 2018

Area	FY 2013	FY 2014 through FY 2017	FY 2018
Alaska:			
City of Anchorage and 80-kilometer (50-mile) radius by road	1.23	1.23	1.25
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.23	1.23	1.25
City of Juneau and 80-kilometer (50-mile) radius by road	1.23	1.23	1.25
Rest of Alaska	1.25	1.25	1.25
Hawaii:			
City and County of Honolulu	1.25	1.25	1.25
County of Hawaii	1.18	1.19	1.21
County of Kauai	1.25	1.25	1.25
County of Maui and County of Kalawao	1.25	1.25	1.25

We note that the reweighted CPI for Honolulu, HI grew faster than the reweighted CPI for the average U.S. city over the 2009 to 2016 time period at 13.7 percent and 10.5 percent, respectively. As a result, for FY 2018, we calculated a COLA factor of 1.29 for the City and County of Honolulu, County of Kauai, and County of Maui and County of Kalawao. However, as stated earlier, we are applying our methodology as finalized in the FY 2013 IPPS/LTCH PPS final rule to incorporate a cap of 1.25 for these areas and thus proposed a COLA factor of 1.25 for the City and County of Honolulu, the County of Kauai, and the County of Maui and County of Kalawao. In addition, the proposed COLA factor we calculated for the County of Hawaii for FY 2018 is 1.21 compared to the FY 2013 COLA factor of 1.18. The COLA factors adopted in FY 2014 using this same methodology can be found in the table above.

Similarly, the reweighted CPI for Anchorage, AK grew faster than the reweighted CPI for the average U.S. city over the 2009 to 2016 time period, at 12.4 percent and 10.5 percent, respectively. As a result, for FY 2018, we calculated COLA factors for the City of Anchorage, City of Fairbanks, and City of Juneau to be 1.25 compared to the FY 2013 COLA factor of 1.23. For FY 2018, we calculated a COLA factor of 1.27 for the Rest of Alaska compared to the FY 2013 COLA factor of 1.25. However, as stated above, we are applying our methodology as finalized in the FY 2013 IPPS/LTCH PPS final rule to incorporate a cap of 1.25 for the rest of Alaska.

As stated above, the COLA factors adopted in the FY 2014 IPPS/LTCH PPS final rule were based on the same methodology used to determine the FY 2018 COLA factors but utilizing BLS data from 2009 through 2012 (the most recent data available at the time of the FY 2014 rulemaking) rather than through 2016 (the most recent data available at the time of this rulemaking). As we noted in the proposed rule, compared to the FY 2014 COLA factors, the proposed FY 2018 COLA factors are higher—with all areas either reaching or exceeding the cap of 1.25 except the County of Hawaii.

We did not receive any public comments in response to our discussion of the proposed FY 2018 COLA factors in the FY 2018 IPPS/LTCH PPS proposed rule. In this final rule, we are finalizing the COLA factors as proposed, effective for FY 2018.

D. Adjustment for LTCH PPS High-Cost Outlier (HCO) Cases

1. HCO Background

From the beginning of the LTCH PPS, we have included an adjustment to account for cases in which there are extraordinarily high costs relative to the costs of most discharges. Under this policy, additional payments are made based on the degree to which the estimated cost of a case (which is calculated by multiplying the Medicare allowable covered charge by the hospital's overall hospital CCR) exceeds a fixed-loss amount. This policy results in greater payment accuracy under the LTCH PPS and the Medicare program, and the LTCH sharing the financial risk for the treatment of extraordinarily high-cost cases.

We retained the basic tenets of our HCO policy in FY 2016 when we implemented the dual rate LTCH PPS payment structure under section 1206 of Public Law 113–67. LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid at the LTCH PPS standard Federal payment rate, which includes, as applicable, HCO payments under § 412.523(e). LTCH discharges that do not meet the criteria for exclusion are paid at the site neutral payment rate, which includes, as applicable, HCO payments under § 412.522(c)(2)(i). In the same rule, we established separate fixed-loss amounts and targets for the two different LTCH PPS payment rates. Under this bifurcated policy, the historic 8 percent HCO target was retained for LTCH PPS standard Federal payment rate cases, with the fixed-loss amount calculated using only data from LTCH cases that would have been paid at the LTCH PPS standard Federal payment rate if that rate had been in effect at the time of those discharges. For site neutral payment rate cases, we adopted the operating IPPS HCO target (currently 5.1 percent) and set the fixed-loss amount for site neutral payment rate cases at the value of the IPPS fixed-loss amount. Under the HCO policy for both payment rates, an LTCH receives 80 percent of the difference between the estimated cost of the case and the applicable HCO threshold, which is the sum of the LTCH PPS payment for the case and the applicable fixed-loss amount for such case.

In order to maintain budget neutrality, consistent with the budget neutrality requirement for HCO payments to LTCH PPS standard Federal rate payment cases, we also

adopted a budget neutrality requirement for HCO payments to site neutral payment rate cases by applying a budget neutrality factor to the LTCH PPS payment for those site neutral payment rate cases. (We refer readers to § 412.522(c)(2)(i) of the regulations for further details.) We note that, during the 2-year transitional period, the site neutral payment rate HCO budget neutrality factor did not apply to the LTCH PPS standard Federal payment rate portion of the blended rate at § 412.522(c)(3) payable to site neutral payment rate cases. (For additional details on the HCO policy adopted for site neutral payment rate cases under the dual rate LTCH PPS payment structure, including the budget neutrality adjustment for HCO payments to site neutral payment rate cases, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49617 through 49623).)

2. Determining LTCH CCRs Under the LTCH PPS

a. Background

As noted above, CCRs are used to determine payments for HCO adjustments for both payment rates under the LTCH PPS, and also are currently used to determine payments for SSO cases under § 412.529 as well as payments for site neutral payment rate cases. (We note that the provisions of § 412.529 are only applicable to LTCH PPS standard Federal payment rate cases). However, we stated in the FY 2018 IPPS/LTCH PPS proposed rule that if our proposed SSO payment method is finalized, CCRs would no longer be used to determine the payment adjustment for SSO cases. Therefore, as we are finalizing our proposed SSO payment methodology, this discussion will only apply to HCO and site neutral payment rate calculations in FY 2018.

As noted earlier, in determining HCO, SSO payments prior to FY 2018, and the site neutral payment rate (regardless of whether the case is also an HCO) payments, we generally calculate the estimated cost of the case by multiplying the LTCH's overall CCR by the Medicare allowable charges for the case. An overall CCR is used because the LTCH PPS uses a single prospective payment per discharge that covers both inpatient operating and capital-related costs. The LTCH's overall CCR is generally computed based on the sum of LTCH operating and capital costs (as described in Section 150.24, Chapter 3, of the Medicare Claims Processing Manual (Pub. 100–4)) as compared to total Medicare charges (that is, the sum of its operating and capital inpatient routine and ancillary charges), with those values determined from either the most recently settled cost report or the most recent tentatively settled cost report, whichever is from the latest cost reporting period. However, in certain instances, we use an alternative CCR, such as the statewide average CCR, a CCR that is specified by CMS, or one that is requested by the hospital. (We refer readers to § 412.525(a)(4)(iv) of the regulations for further details regarding HCO adjustments for either LTCH PPS payment rate, § 412.529(f)(4) for SSO adjustments under the current policy, and § 412.522(c)(1)(ii) for the site neutral payment rate, respectively.)

The LTCH's calculated CCR is then compared to the LTCH total CCR ceiling. Under our established policy, an LTCH with a calculated CCR in excess of the applicable maximum CCR threshold (that is, the LTCH total CCR ceiling, which is calculated as 3 standard deviations from the national geometric average CCR) is generally assigned the applicable statewide CCR. This policy is premised on a belief that calculated CCRs above the LTCH total CCR ceiling are most likely due to faulty data reporting or entry, and CCRs based on erroneous data should not be used to identify and make payments for outlier cases.

b. LTCH Total CCR Ceiling

Consistent with our historical practice, we used the most recent data to determine the LTCH total CCR ceiling for FY 2018 in this final rule. Specifically, in this final rule, using our established methodology for determining the LTCH total CCR ceiling based on IPPS total CCR data from the March 2017 update of the Provider Specific File (PSF), which is the most recent data available, we are establishing an LTCH total CCR ceiling of 1.280 under the LTCH PPS for FY 2018 in accordance with § 412.525(a)(4)(iv)(C)(*2*) for HCO cases under either payment rate and § 412.522(c)(1)(ii) for the site neutral payment rate. (For additional information on our methodology for determining the LTCH total CCR ceiling, we refer readers to the FY 2007 IPPS final rule (71 FR 48118 through 48119).)

c. LTCH Statewide Average CCRs

Our general methodology for determining the statewide average CCRs used under the LTCH PPS is similar to our established methodology for determining the LTCH total CCR ceiling because it is based on ''total'' IPPS CCR data. (For additional information on our methodology for determining statewide average CCRs under the LTCH PPS, we refer readers to the FY 2007 IPPS final rule (71 FR 48119 through 48120).) Under the LTCH PPS HCO policy for cases paid under either payment rate at § 412.525(a)(4)(iv)(C)(2), the current SSO policy at § 412.529(f)(4)(iii)(B), and the site neutral payment rate at § 412.522(c)(1)(ii), the MAC may use a statewide average CCR, which is established annually by CMS, if it is unable to determine an accurate CCR for an LTCH in one of the following circumstances: (1) New LTCHs that have not yet submitted their first Medicare cost report (a new LTCH is defined as an entity that has not accepted assignment of an existing hospital's provider agreement in accordance with § 489.18); (2) LTCHs whose calculated CCR is in excess of the LTCH total CCR ceiling; and (3) other LTCHs for whom data with which to calculate a CCR are not available (for example, missing or faulty data). (Other sources of data that the MAC may consider in determining an LTCH's CCR include data from a different cost reporting period for the LTCH, data from the cost reporting period preceding the period in which the hospital began to be paid as an LTCH (that is, the period of at least 6 months that it was paid as a short-term, acute care hospital), or data from other comparable LTCHs, such as LTCHs in the same chain or in the same region.)

Consistent with our historical practice of using the best available data, in this final rule, using our established methodology for determining the LTCH statewide average CCRs, based on the most recent complete IPPS ''total CCR'' data from the March 2017 update of the PSF, we are establishing LTCH PPS statewide average total CCRs for urban and rural hospitals that will be effective for discharges occurring on or after October 1, 2017, through September 30, 2018, in Table 8C listed in section VI. of the Addendum to this final rule (and available via the Internet on the CMS Web site). Consistent with our historical practice, as we proposed, we used more recent data to determine the LTCH PPS statewide average total CCRs for FY 2018 in this final rule.

Under the current LTCH PPS labor market areas, all areas in Delaware, the District of Columbia, New Jersey, and Rhode Island are classified as urban. Therefore, there are no rural statewide average total CCRs listed for those jurisdictions in Table 8C. This policy is consistent with the policy that we established when we revised our methodology for determining the applicable LTCH statewide average CCRs in the FY 2007 IPPS final rule (71 FR 48119 through 48121) and is the same as the policy applied under the IPPS. In addition, although Connecticut has areas that are designated as rural, in our calculation of the LTCH statewide average CCRs, there was no data available from short-term, acute care IPPS hospitals to compute a rural statewide average CCR or there were no short-term, acute care IPPS hospitals or LTCHs located in that area as of March 2017.

Therefore, consistent with our existing methodology, we used the national average total CCR for rural IPPS hospitals for rural Connecticut in Table 8C. While Massachusetts also has rural areas, the statewide average CCR for rural areas in Massachusetts is based on one provider whose CCR is an atypical 1.222. Because this is much higher than the statewide urban average and furthermore implies costs exceeded charges, as with Connecticut, we used the national average total CCR for rural hospitals for hospitals located in rural Massachusetts. Furthermore, consistent with our existing methodology, in determining the urban and rural statewide average total CCRs for Maryland LTCHs paid under the LTCH PPS, we continued to use, as a proxy, the national average total CCR for urban IPPS hospitals and the national average total CCR for rural IPPS hospitals, respectively. We used this proxy because we believe that the CCR data in the PSF for Maryland hospitals may not be entirely accurate (as discussed in greater detail in the FY 2007 IPPS final rule (71 FR 48120)).

d. Reconciliation of HCO and SSO Payments

Under the HCO policy for cases paid under either payment rate at § 412.525(a)(4)(iv)(D) and SSO cases prior to FY 2018 at § 412.529(f)(4)(iv), the payments for HCO and SSO cases are subject to reconciliation. Specifically, any such payments are reconciled at settlement based on the CCR that is calculated based on the cost report coinciding with the discharge. However, under our changes to the SSO payment methodology discussed in section VIII.D. of

the preamble of this final rule, we removed estimated cost as a consideration for payment to SSO cases. As such, consistent with our changes to the SSO payment methodology, SSO payments are no longer be subject to reconciliation. Specifically, as we proposed, we are revising paragraph (f) of § 412.529 to specify that SSO payments will be reconciled only for discharges occurring before October 1, 2017.

For additional information on the reconciliation policy, we refer readers to Sections 150.26 through 150.28 of the Medicare Claims Processing Manual (Pub. 100–4), as added by Change Request 7192 (Transmittal 2111; December 3, 2010), and the RY 2009 LTCH PPS final rule (73 FR 26820 through 26821).

3. High-Cost Outlier Payments for LTCH PPS Standard Federal Payment Rate Cases

a. Changes to High-Cost Outlier Payments for LTCH PPS Standard Federal Payment Rate Cases

When we implemented the LTCH PPS, we established a fixed-loss amount so that total estimated outlier payments are projected to equal 8 percent of total estimated payments under the LTCH PPS (67 FR 56022 through 56026). Furthermore, § 412.523(d)(1) requires the LTCH PPS standard Federal payment rate be adjusted by a reduction factor of 8 percent, the estimated proportion of outlier payments under § 412.525(a) payable to LTCH PPS standard Federal payment rate cases. Section 15004(b) of the 21st Century Cures Act (Pub. L. 114–255) amended section 1886(m) of the Act by adding new paragraph (7), which specifies certain treatment of HCO payments for fiscal years beginning on or after October 1, 2017 (FY 2018). Specifically, section 1886(m)(7)(A) of the Act requires, beginning in FY 2018, that the LTCH PPS standard Federal payment rate be reduced as if estimated HCO payments for standard Federal payment rate cases would be equal to 8 percent of estimated aggregate payments for standard Federal payment rate cases for a given year. In other words, section 1886(m)(7)(A) of the Act makes our existing regulatory budget neutrality requirement at § 412.523(d)(1) for the 8 percent HCO target for standard Federal payment rate cases a statutory requirement beginning in FY 2018. In addition, section 1886(m)(7)(B) of the Act requires, beginning in FY 2018, that the fixed-loss amount for HCO payments for LTCH PPS standard Federal payment rate cases be determined so that the estimated aggregate amount of HCO payments for such cases in a given year are equal to 99.6875 percent of the 8 percent estimated aggregate payments for standard Federal payment rate cases (that is, 7.975 percent). In other words, sections 1886(m)(7)(A) and (7)(B) require that we adjust the standard Federal payment rate each year to ensure budget neutrality for HCO payments as if estimated aggregate HCO payments made for standard Federal payment rate discharges remain at 8 percent, while the fixed-loss amount for the HCO payments is set each year so that the estimated aggregate HCO payments for standard Federal payment rate cases are 7.975 percent of estimated aggregate payments for standard Federal payment rate cases.

More specifically, section 1886(m)(7)(A) of the Act stipulates that, for fiscal years beginning on or after October 1, 2017, the Secretary shall reduce the standard Federal payment rate as if the estimated aggregate amount of HCO payments for standard Federal payment rate discharges for each such fiscal year would be equal to 8 percent of estimated aggregate payments for standard Federal payment rate discharges for each such fiscal year; while section 1886(m)(7)(B) of the Act states that the Secretary shall set the fixed loss amount for HCO payments such that the estimated aggregate amount of HCO payments made for standard Federal payment rate discharges for fiscal years beginning on or after October 1, 2017, shall be equal to 99.6875 percent of 8 percent of estimated aggregate payments for standard Federal payment rate discharges for each such fiscal year. Furthermore, section 1886(m)(7)(C) of the Act requires that any reduction in payments resulting from the application of paragraph (B) shall not be taken into account in applying any budget neutrality provision. Finally, section 1886(m)(7)(D) of the Act provides there will be no effect on HCO payments to site neutral payment rate cases by this certain treatment of HCO payments by requiring that this paragraph shall not apply with respect to the computation of the applicable site neutral payment rate under section 1886(m)(6) of the Act.

To codify the treatment of HCO payments provided by section 15004(b) of the 21st Century Cures Act (discussed earlier), as we proposed, we are revising § 412.525(a) by redesignating paragraph (2) as paragraph (2)(i) and adding paragraph (2)(ii) which would specify that, for FY 2018 and subsequent years, the fixed-loss amount for LTCH discharges described under § 412.522(a)(2) is determined such that the estimated proportion of outlier payments under § 412.522(a) that are payable for such discharges is projected to be equal to 99.6875 percent of 8 percent. We also are making conforming changes to § 412.523(d)(1) to specify that the provisions under § 412.525(a)(2)(ii) will not affect the reduction factor of 8 percent that is applied to the LTCH PPS standard Federal payment rate under § 412.523(d)(1).

b. Establishment of the Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2018

When we implemented the LTCH PPS, we established a fixed loss amount so that total estimated outlier payments are projected to equal 8 percent of total estimated payments under the LTCH PPS (67 FR 56022 through 56026). When we implemented the dual rate LTCH PPS payment structure beginning in FY 2016, we established that, in general, the historical LTCH PPS HCO policy will continue to apply to LTCH PPS standard Federal payment rate cases. That is, the fixed-loss amount and target for LTCH PPS standard Federal payment rate cases is determined using the LTCH PPS HCO policy adopted when the LTCH PPS was first implemented, but we limited the data used under that policy to LTCH cases that would have been LTCH PPS standard Federal payment rate cases if the statutory changes had been in effect at the time of those discharges.

To determine the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases, we estimate outlier payments and total LTCH PPS payments for each LTCH PPS standard Federal payment rate case (or for each case that would have been a LTCH PPS standard Federal payment rate case if the statutory changes had been in effect at the time of the discharge) using claims data from the MedPAR files. Historically, the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases results in estimated total outlier payments being projected to be equal to 8 percent of projected total LTCH PPS payments for LTCH PPS standard Federal payment rate cases. We use MedPAR claims data and CCRs based on data from the most recent PSF (or from the applicable statewide average CCR if an LTCH's CCR data are faulty or unavailable) to establish an applicable fixed-loss threshold amount for LTCH PPS standard Federal payment rate cases. For FY 2018 and subsequent fiscal years, as we proposed, we are continuing to use the same general approach as in previous years, but the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases will be estimated so that total HCO payments are 7.975 percent (that is, 99.6875 percent of 8 percent) of projected total LTCH PPS payments for LTCH PPS standard Federal payment rate cases, consistent with section 1886(m)(7)(B) of the Act (as discussed above).

In the FY 2018 IPS/LTCH PPS proposed rule (82 FR 20189), we proposed to continue to use our current methodology to calculate an applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2018 using the best available data that would maintain estimated HCO payments at the projected 7.975 percent of total estimated LTCH PPS payments for LTCH PPS standard Federal payment rate cases (based on the rates and policies for these cases presented in that proposed rule).

Specifically, based on the most recent complete LTCH data available at that time (that is, LTCH claims data from the December 2016 update of the FY 2016 MedPAR file and CCRs from the December 2016 update of the PSF), we determined that a proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2018 of $30,081 would result in estimated outlier payments projected to be equal to 7.975 percent of estimated FY 2018 payments for such cases. Under this proposal, we would continue to make an additional HCO payment for the cost of an LTCH PPS standard Federal payment rate case that exceeds the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the adjusted LTCH PPS standard Federal payment rate payment and the fixed-loss amount for LTCH PPS standard Federal payment rate cases of $30,081). We also noted that the proposed fixed-loss amount for HCO cases paid under the LTCH PPS standard Federal payment rate in FY 2018 of $30,081 is notably higher than the FY 2017 fixed-loss amount for LTCH PPS standard Federal payment rate cases of $21,943, and

explained that the increase is largely attributable to rate-of-change in the Medicare allowable charges on the claims data in the MedPAR file.

Based on the most recent available data at the time of the proposed rule, we found that the current FY 2017 HCO threshold of $21,943 results in estimated HCO payments for LTCH PPS standard Federal payment rate cases of approximately 8.6 percent of the estimated total LTCH PPS payments in FY 2016, which exceeds the 8 percent target by 0.6 percentage points. We also noted that fluctuations in the fixed-loss amount occurred in the first few years after the implementation of the LTCH PPS, due, in part, to the changes in LTCH behavior (such as Medicare beneficiary treatment patterns) in response to the new payment system and the lack of data and information available to predict how those changes would affect the estimate costs of LTCH cases. As we gained more experience with the effects and implementation of the LTCH PPS, the annual changes on the fixed-loss amount generally stabilized relative to the fluctuations that occurred in the early years of the LTCH PPS. Therefore, we did not propose any changes to our method for the inflation factor applied to update the costs of each case (that is, an inflation factor based on the most recent estimate of the 2013-based LTCH market basket as determined by the Office of the Actuary) in determining the proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2018. We stated our continued belief that it is appropriate to continue to use our historical approach until we gain experience with the effects and implementation of the dual rate LTCH PPS payment structure that began with discharges occurring in cost reporting periods beginning on or after October 1, 2015, and the types of cases paid at the LTCH PPS standard Federal payment rate under this dual rate payment structure. We stated that we may revisit this issue in the future if data demonstrate such a change is warranted, and would propose any changes in the future through the notice-and-comment rulemaking process. Furthermore, we invited public comments on potential improvements to the determination of the fixed-loss amount for LTCH PPS standard Federal payment rate cases, including the most appropriate method of determining an inflation factor for projecting the costs of each case when determining the fixed-loss threshold.

Comment: A few commenters expressed concern with the increase in the proposed FY 2018 fixed-loss amount for LTCH PPS standard Federal payment rate cases as compared to the current fixed-loss amount for such cases. Some of these commenters expressed general support for using the required target amount of 7.975 percent for HCO payments for LTCH PPS standard Federal payment rate cases. Some commenters stated that they are concerned about the potential instability in the fixed-loss amount from year to year and requested that CMS continue to be transparent about the possible causes for such large year-to-year changes in the fixed-loss amount and how much of this variability may be attributable to the new dual rate LTCH PPS payment. In addition to using the most recent LTCH claims data and CCRs, some commenters suggested we consider whether the new dual rate LTCH PPS payment structure warrants the use of other relevant data or a change in the inflation factor for projecting the costs of each case when determining the fixed-loss amount, but did not make any specific recommendations for other data or factors.

Response: We understand the commenters' concern with the proposed increase to the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2018, and we appreciate the commenters' support for our proposed use of a HCO target amount of 7.975 percent for LTCH PPS standard Federal payment rate cases. As we discussed in the proposed rule, based on the best available data at that time and using our historical methodology, we estimate that the current FY 2017 HCO fixed-loss amount of $21,943 results in estimated HCO payments for LTCH PPS standard Federal payment rate cases in excess of the FY 2017 target of 8 percent by 0.6 percentage points. Additionally, we note that we invited public comment on potential improvements to the determination of the fixed-loss amount for LTCH PPS standard Federal payment rate cases, including the most appropriate method of determining an inflation factor for projecting the costs of each case when determining the fixed-loss threshold but received no specific suggestions from comments.

As discussed in the proposed rule, fluctuations in the fixed-loss amount have occurred previously under LTCH PPS, due, in part, to the changes in LTCH behavior in response to the changes in Medicare payments and the lack of data and information available to predict how those changes affect the estimate costs of LTCH cases. As was the case when there were fluctuations in the fixed-loss amount in the early years of the LTCH PPS, we expect annual changes to the fixed-loss amount to generally stabilize as experience is gained under the new dual rate LTCH PPS payment structure. We intend to continue to monitor annual changes in the HCO fixed-loss amount, including factors that drive any such changes. We appreciate the general feedback commenters' noted for potential improvements to the determination of the fixed-loss amount for LTCH PPS standard Federal payment rate cases, including the use of other relevant data or a change in the inflation factor for projecting the costs of each case when determining the fixed-loss amount. As we indicated in the proposed rule, we may revisit this issue in the future if data demonstrate such a change is warranted, and would propose any changes in the future through the notice-and-comment rulemaking process. For these reasons we continue to maintain our historical methodology and thus believe it is necessary and appropriate to increase to the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2017 to maintain estimated HCO payments would equal 8 percent of estimated total LTCH PPS payments for such cases as required under § 412.525(a). We note, as in greater detail discussed below, the fixed-loss amount for FY 2018 for LTCH PPS standard Federal payment rate cases we are establishing in this final rule, after consideration of public comments and based on the most recent LTCH claims data from the MedPAR file and the latest CCRs from the PSF, does result in a fixed-loss amount for such cases that is lower than the proposed fixed-loss amount. We also note that based on the most recent available data for this final rule (discussed below), the current FY 2017 HCO threshold of $21,943 results in estimated HCO payments for LTCH PPS standard Federal payment rate cases which exceeds the FY 2017 target of 8 percent target by 0.1 percentage points. (We also note the change in our estimate of FY 2017 HCO payments between the proposed and final rule decreased from 8.6 percent to 8.1 percent, and this change is largely attributable to updates to CCRs from the December 2016 update of the PSF to the March 2017 update of the PSF.)

After consideration of the public comments we received, for the reasons discussed above, we are finalizing our proposal to continue to use the current LTCH PPS HCO payment methodology for LTCH PPS standard Federal payment rate cases for FY 2018 without modification, as we proposed. Therefore, in this final rule, for FY 2018, we determined an applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases using data from LTCH PPS standard Federal payment rate cases (or cases that would have been LTCH PPS standard Federal payment rate cases had the dual rate LTCH PPS payment structure been in effect at the time of those discharges). The fixed-loss amount for LTCH PPS standard Federal payment rate cases will continue to be determined so that estimated HCO payments will be projected to equal 7.975 percent of estimated total LTCH PPS standard Federal payment rate cases. Furthermore, in accordance with § 412.523(d)(1), a budget neutrality factor will continue to be applied to LTCH PPS standard Federal payment rate cases to offset that 8 percent so that HCO payments for LTCH PPS standard Federal payment rate cases will be budget neutral. Below we present our calculation of the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2018, which, except for the statutory changes to the HCO target from 8 percent to 7.975 percent, is consistent with the methodology used to establish the FY 2017 LTCH PPS fixed-loss amount, as we proposed.

In this final rule, we are continuing to use our current methodology to calculate an applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2018 using the best available data that will maintain estimated HCO payments at the projected 7.975 percent of total estimated LTCH PPS payments for LTCH PPS standard Federal payment rate cases (based on the payment rates and policies for these cases presented in this final rule). Specifically, based on the most recent available data available (that is, LTCH claims data from the March 2017 update of the FY 2016 MedPAR file and CCRs from the March 2017 update of the PSF), we determined a fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2018 results that

will result in estimated outlier payments of 7.975 percent of estimated FY 2018 payments for such cases. Under the broad authority of section 123(a)(1) of the BBRA and section 307(b)(1) of the BIPA, we are establishing a fixed-loss amount of $27,382 for LTCH PPS standard Federal payment rate cases for FY 2018. Under our policy, we will continue to make an additional HCO payment for the cost of an LTCH PPS standard Federal payment rate case that exceeds the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the adjusted LTCH PPS standard Federal payment rate payment and the fixed-loss amount for LTCH PPS standard Federal payment rate cases of $27,382).

We note that the fixed-loss amount for HCO cases paid under the LTCH PPS standard Federal payment rate in FY 2018 of $27,382 is somewhat lower than proposed FY 2018 fixed-loss amount of $30,081 but notably higher than the FY 2017 fixed-loss amount for LTCH PPS standard Federal payment rate cases of $21,943. However, based on the most recent available data at the time of this final rule, we found that the current FY 2017 HCO threshold of $21,943 results in estimated HCO payments for LTCH PPS standard Federal payment rate cases of approximately 8.1 percent of the estimated total LTCH PPS payments in FY 2017, which exceeds the 8 percent target by 0.1 percentage points. We continue to believe, as discussed in detail in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25287), this increase is largely attributable to rate-of-change (that is, increase) in the Medicare allowable charges on the claims data in the MedPAR file. In addition, using the historic 8-percent target for projected aggregate outlier payments (absent the required changes under the 21st Century Cures Act for comparison purposes), the HCO threshold would be $27,240, which represents a 24-percent increase from the final FY 2017 HCO threshold of $21,943. This increase is in line with the 34 percent increase in the HCO threshold between FY 2016 and FY 2017, and is consistent with our expectation that annual changes to the fixed-loss amount to generally stabilize as experience is gained under the new dual rate LTCH PPS payment structure. For these reasons, we continue to believe it is necessary and appropriate to increase the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2018 to maintain estimated HCO payments that would equal to 7.975 percent of estimated total LTCH PPS payments for such cases as required under § 412.525(a)(2)(ii).

c. Application of the High-Cost Outlier Policy to Short Stay Outlier (SSO) Cases

Under our implementation of the dual rate LTCH PPS payment structure required by statute, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20190), we proposed that LTCH PPS standard Federal payment rate cases (that is, LTCH discharges that meet the criteria for exclusion from the site neutral payment rate) would continue to be paid based on the LTCH PPS standard Federal payment rate, and would include all of the existing payment adjustments under § 412.525(d), such as the adjustments for SSO cases under § 412.529. Under some rare circumstances, an LTCH discharge can qualify as an SSO case (as defined in the regulations at § 412.529 in conjunction with § 412.503) and also as an HCO case, as discussed in the August 30, 2002 final rule (67 FR 56026). In this scenario, a patient could be hospitalized for less than five-sixths of the geometric average length of stay for the specific MS–LTC–DRG, and yet incur extraordinarily high treatment costs. If the estimated costs exceeded the HCO threshold (that is, the SSO payment plus the applicable fixed-loss amount), the discharge is eligible for payment as an HCO. (We noted that, under our change to the SSO policy discussed in section VIII.D. of this final rule, SSO cases would still be eligible to qualify for an HCO payment.) Therefore, for an SSO case in FY 2018, as proposed, we are establishing that the HCO payment will be 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the fixed-loss amount of $27,382 and the amount paid under the SSO policy as specified in § 412.529).

4. High-Cost Outlier Payments for Site Neutral Payment Rate Cases

Under § 412.525(a), site neutral payment rate cases receive an additional HCO payment for costs that exceed the HCO threshold that is equal to 80 percent of the difference between the estimated cost of the case and the applicable HCO threshold (80 FR 49618 through 49629). In the following discussion, we note that the statutory transitional payment method for cases that are paid the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 or FY 2017 uses a blended payment rate, which is determined as 50 percent of the site neutral payment rate amount for the discharge and 50 percent of the standard Federal prospective payment rate amount for the discharge (§ 412.522(c)(3)). The transitional blended payment rate uses the same blend percentages (that is, 50 percent) for both years of the 2-year transition period. For FY 2018, the site neutral payment rate effective date for a given LTCH is determined based on the date on which that LTCH's cost reporting period begins during FY 2018. Specifically, for a given LTCH, those site neutral payment rate cases discharged in FY 2018 and in a cost reporting period that begins *before* October 1, 2017 continue to be paid under the blended payment rate. However, site neutral payment rate cases discharged in FY 2018 during the LTCH's cost reporting period beginning on or *after* October 1, 2017 will no longer be paid under the blended payment rate and instead will be paid the site neutral payment rate amount as determined under § 412.522(c)(1). As such, for FY 2018 discharges paid under the transitional payment method, the discussion below pertains only to the site neutral rate portion in § 412.522(c)(3)(i)) of the blended payment rate (as well as to FY 2018 discharges paid the site neutral payment rate amount determined under § 412.522(c)(1)).

When we implemented the application of the site neutral payment rate in FY 2016, in examining the appropriate fixed-loss amount for site neutral payment rate cases issue, we considered how LTCH discharges based on historical claims data would have been classified under the dual rate LTCH PPS payment structure and the CMS' Office of the Actuary projections regarding how LTCHs will likely respond to our implementation of policies resulting from the statutory payment changes. We again relied on these considerations and actuarial projections in FY 2017 because the historical claims data available in FY 2017 predated the LTCH PPS dual rate payment system. Similarly, for FY 2018, we continue to rely on these considerations and actuarial projections because, due to the rolling effective date of the site neutral payment policy, not all claims in FY 2016 were subject to the site neutral payment system.

For both FY 2016 and FY 2017, at that time our actuaries projected that the proportion of cases that would qualify as LTCH PPS standard Federal payment rate cases versus site neutral payment rate cases under the statutory provisions would remain consistent with what is reflected in the historical LTCH PPS claims data. Although our actuaries did not project an immediate change in the proportions found in the historical data, they did project cost and resource changes to account for the lower payment rates. Our actuaries also projected that the costs and resource use for cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate and would likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what is found based on the historical data. As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49619), this actuarial assumption is based on our expectation that site neutral payment rate cases would generally be paid based on an IPPS comparable per diem amount under the statutory LTCH PPS payment changes that began in FY 2016, which, in the majority of cases, is much lower than the payment that would have been paid if these statutory changes were not enacted. (We note, in section I.J.1 of the Regulatory Impact in Appendix A of this final rule, we summarize and respond to a comment that references to this actuarial assumption.) In light of these projections and expectations, we discussed that we believed that the use of a single fixed-loss amount and HCO target for all LTCH PPS cases would be problematic. In addition, we discussed that we did not believe that it would be appropriate for comparable LTCH PPS site neutral payment rate cases to receive dramatically different HCO payments from those cases that would be paid under the IPPS (80 FR 49617 through 49619 and 81 FR 57305 through 57307). For those reasons, we stated that we believed that the most appropriate fixed-loss amount for site neutral payment rate cases for both FY 2016 and FY 2017 would be equal to the IPPS fixed-loss amount for that year. Therefore, we established the fixed-loss amount for site neutral payment rate cases as the FY 2016 and FY 2017 IPPS fixed-loss amounts, in FY 2016 and FY 2017 respectively. In particular,

in FY 2017, we established that the fixed-loss amount for site neutral payment rate cases is the FY 2017 IPPS fixed-loss amount of $23,570.

As noted earlier, because not all claims in the data used for this final rule were subject to the site neutral payment rate system, we continue to rely on the same considerations and actuarial projections used in FY 2016 and FY 2017 when developing a fixed-loss amount for site neutral payment rate cases for FY 2018. Because our actuaries continue to project that site neutral payment rate cases in FY 2018 will continue to mirror an IPPS case paid under the same MS–DRG, we continue to believe that it would be inappropriate for comparable LTCH PPS site neutral payment rate cases to receive dramatically different HCO payments from those cases that would be paid under the IPPS. More specifically, as with FY 2016 and FY 2017, our actuaries project that the costs and resource use for FY 2018 cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate and will likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what is found based on the historical data. (Based on the most recent FY 2016 LTCH claims data, approximately 58 percent of LTCH cases would have been paid the LTCH PPS standard Federal payment rate and approximately 42 percent of LTCH cases would have been paid the site neutral payment rate if those rates had been in effect at that time for all LTCH discharges occurring in FY 2016, regardless of LTCHs' cost reporting period beginning dates.)

For these reasons, we continue to believe that the most appropriate fixed-loss amount for site neutral payment rate cases for FY 2018 is the IPPS fixed-loss amount for FY 2018. Therefore, consistent with past practice, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20191), for FY 2018, we proposed that the applicable HCO threshold for site neutral payment rate cases is the sum of the site neutral payment rate for the case and the IPPS fixed-loss amount. That is, we proposed a fixed-loss amount for site neutral payment rate cases of $26,713, which was the same proposed FY 2018 IPPS fixed-loss amount discussed in section II.A.4.g.(1) of the Addendum to the proposed rule. We continue to believe that this policy would reduce differences between HCO payments for similar cases under the IPPS and site neutral payment rate cases under the LTCH PPS and promote fairness between the two systems. Accordingly, for FY 2018, we proposed to calculate a HCO payment for site neutral payment rate cases with costs that exceed the HCO threshold amount, which is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of proposed site neutral payment rate payment and the proposed fixed-loss amount for site neutral payment rate cases of $26,713).

Comment: Some commenters expressed support for our proposal to continue to use the FY 2017 IPPS fixed-loss amount and 5.1 percent HCO target for LTCH discharges paid at the site neutral payment rate in FY 2018.

Response: We appreciate the commenters support for our proposal to continue to use the FY 2018 IPPS fixed-loss amount and 5.1 percent HCO target for LTCH discharges paid at the site neutral payment rate in FY 2018. Given the current expectation that cases paid at the site neutral payment rate would likely be similar to IPPS cases assigned to the same MS–DRG, we continue to believe the most appropriate fixed-loss amount for site neutral payment rate cases is the IPPS fixed-loss amount for that fiscal year. As we indicated in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49619), to the extent experience under the revised LTCH PPS indicates site neutral payment rate cases differ sufficiently from these expectations, we agree it would be appropriate to revisit in future rulemaking the most appropriate fixed-loss amount used to determine HCO payments for site neutral payment rate cases. As we discuss in greater detail in section I.J.1., the Regulatory Impact Analysis, in Appendix A of this final rule, given the rolling nature of the start of the transition to the site neutral payment rate, many LTCH claims from FY 2016 were not subject to the site neutral payment rate at all as many LTCHs did not begin their FY 2016 cost reporting period until the fourth quarter of that fiscal year. In addition, all claims which were subject to the site neutral payment rate in FY 2016 were paid under the blended payment rate which included a payment based on 50 percent of the LTCH PPS standard Federal payment rate. As such, FY 2016 claims may not yet reflect the expected change in cost and resources once the payment for site neutral payment rate cases is fully based on the site neutral payment rate.

After consideration of public comments we received, we are finalizing without modification, our proposals to use the FY 2018 IPPS fixed-loss amount and 5.1 percent HCO target for LTCH discharges paid at the site neutral payment rate in FY 2018. Therefore, for FY 2018, as we proposed, we are establishing that the applicable HCO threshold for site neutral payment rate cases is the sum of the site neutral payment rate for the case and the IPPS fixed loss amount. That is, we are establishing a fixed-loss amount for site neutral payment rate cases of $26,601, which is the same FY 2018 IPPS fixed-loss amount discussed in section II.A.4.g.(1). of the Addendum to this final rule. We continue to believe that this policy will reduce differences between HCO payments for similar cases under the IPPS and site neutral payment rate cases under the LTCH PPS and promote fairness between the two systems. Accordingly, under this policy, for FY 2018, we will calculate a HCO payment for site neutral payment rate cases with costs that exceed the HCO threshold amount, which is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of site neutral payment rate payment and the fixed loss amount for site neutral payment rate cases of $26,601).

In establishing a HCO policy for site neutral payment rate cases, we established a budget neutrality adjustment under § 412.522(c)(2)(i). We established this requirement because we believed, and continue to believe, that the HCO policy for site neutral payment rate cases should be budget neutral, just as the HCO policy for LTCH PPS standard Federal payment rate cases are budget neutral, meaning that estimated site neutral payment rate HCO payments should not result in any change in estimated aggregate LTCH PPS payments.

To ensure that estimated HCO payments payable to site neutral payment rate cases in FY 2018 would not result in any increase in estimated aggregate FY 2018 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), it is necessary to reduce site neutral payment rate payments (or the portion of the blended payment rate payment for FY 2018 discharges occurring in LTCH cost reporting periods beginning before October 1, 2017) by 5.1 percent to account for the estimated additional HCO payments payable to those cases in FY 2018. In order to achieve this, for FY 2018, in general, as we proposed, we are continuing to use the policy adopted for FY 2017.

As discussed earlier, consistent with the IPPS HCO payment threshold, we expect a fixed-loss threshold of $26,601 results in HCO payments for site neutral payment rate cases equal to 5.1 percent of the site neutral payment rate payments that are based on the IPPS comparable per diem amount. As such, to ensure estimated HCO payments payable for site neutral payment rate cases in FY 2018 would not result in any increase in estimated aggregate FY 2018 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), it is necessary to reduce the site neutral payment rate amount paid under § 412.522(c)(1)(i) by 5.1 percent to account for the estimated additional HCO payments payable for site neutral payment rate cases in FY 2018. In order to achieve this, for FY 2018, we proposed to apply a budget neutrality factor of 0.949 (that is, the decimal equivalent of a 5.1 percent reduction, determined as $1.0 - 5.1/100 = 0.949$) to the site neutral payment rate for those site neutral payment rate cases paid under § 412.522(c)(1)(i). We noted that, consistent with the policy adopted for FY 2017, under this proposed policy the HCO budget neutrality adjustment would not be applied to the HCO portion of the site neutral payment rate amount (80 FR 57309).

Comment: As was the case in the FY 2016 and FY 2017 rulemaking cycle, commenters again objected to the proposed site neutral payment rate HCO budget neutrality adjustment, claiming that it results in savings to the Medicare program instead of being budget neutral. The commenters' primary objection was again based on their belief that, because the IPPS base rates used in the IPPS comparable per diem amount calculation of the site neutral payment rate include a budget neutrality adjustment for IPPS HCO payments (that is, a 5.1 percent adjustment on the operating IPPS standardized amount), an ''additional'' budget neutrality factor is not necessary and is, in fact, duplicative.

Response: We continue to disagree with the commenters that a budget neutrality adjustment for site neutral payment rate HCO payments is inappropriate, unnecessary, or duplicative. As we discussed in response to

similar comments (81 FR 57308 through 57309 and 80 FR 49621 through 49622), we have the authority to adopt the site neutral payment rate HCO policy in a budget neutral manner. More importantly, we continue to believe this budget neutrality adjustment is appropriate for reasons outlined in our response to the nearly identical comments in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57308 through 57309) and our response to similar comments in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49621 through 49622).

After consideration of the public comments we received, we are finalizing our proposal to apply a budget neutrality adjustment for HCO payments made to site neutral payment rate cases. Therefore, to ensure that estimated HCO payments payable to site neutral payment rate cases in FY 2018 will not result any increase in estimated aggregate FY 2018 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), it is necessary to reduce the site neutral payment rate portion of the blended rate payment by 5.1 percent to account for the estimated additional HCO payments payable to those cases in FY 2018. In order to achieve this, for FY 2018, in this final rule, to, as proposed, we are applying a budget neutrality factor of 0.949 (that is, the decimal equivalent of a 5.1 percent reduction, determined as 1.0—5.1/100 = 0.949) to the site neutral payment rate (without any applicable HCO payment).

E. Update to the IPPS Comparable/ Equivalent Amounts To Reflect the Statutory Changes to the IPPS DSH Payment Adjustment Methodology

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50766), we established a policy to reflect the changes to the Medicare IPPS DSH payment adjustment methodology made by section 3133 of the Affordable Care Act in the calculation of the ''IPPS comparable amount'' under the SSO policy at § 412.529 and the ''IPPS equivalent amount'' under the 25-percent threshold payment adjustment policy at § 412.534 and § 412.536. Historically, the determination of both the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' includes an amount for inpatient operating costs ''for the costs of serving a disproportionate share of low-income patients.'' Under the statutory changes to the Medicare DSH payment adjustment methodology that began in FY 2014, in general, eligible IPPS hospitals receive an empirically justified Medicare DSH payment equal to 25 percent of the amount they otherwise would have received under the statutory formula for Medicare DSH payments prior to the amendments made by the Affordable Care Act. The remaining amount, equal to an estimate of 75 percent of the amount that otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured, is made available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The additional uncompensated care payments are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all IPPS hospitals that receive Medicare DSH payments.

To reflect the statutory changes to the Medicare DSH payment adjustment methodology in the calculation of the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' under the LTCH PPS, we stated that we will include a reduced Medicare DSH payment amount that reflects the projected percentage of the payment amount calculated based on the statutory Medicare DSH payment formula prior to the amendments made by the Affordable Care Act that will be paid to eligible IPPS hospitals as empirically justified Medicare DSH payments and uncompensated care payments in that year (that is, a percentage of the operating Medicare DSH payment amount that has historically been reflected in the LTCH PPS payments that is based on IPPS rates). We also stated that the projected percentage will be updated annually, consistent with the annual determination of the amount of uncompensated care payments that will be made to eligible IPPS hospitals. We believe that this approach results in appropriate payments under the LTCH PPS and is consistent with our intention that the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' under the LTCH PPS closely resemble what an IPPS payment would have been for the same episode of care, while recognizing that some features of the IPPS cannot be translated directly into the LTCH PPS (79 FR 50766 through 50767).

For FY 2018, as discussed in greater detail in section V.G.3. of the preamble of this final rule, based on the most recent data available, our estimate of 75 percent of the amount that would otherwise have been paid as Medicare DSH payments (under the methodology outlined in section 1886(r)(2) of the Act) is adjusted to 58.01 percent of that amount to reflect the change in the percentage of individuals who are uninsured. The resulting amount is then used to determine the amount available to make uncompensated care payments to eligible IPPS hospitals in FY 2018. In other words, the amount of the Medicare DSH payments that would have been made prior to the amendments made by the Affordable Care Act will be adjusted to 43.51 percent (the product of 75 percent and 58.01 percent) and the resulting amount will be used to calculate the uncompensated care payments to eligible hospitals. As a result, for FY 2018, we project that the reduction in the amount of Medicare DSH payments pursuant to section 1886(r)(1) of the Act, along with the payments for uncompensated care under section 1886(r)(2) of the Act, will result in overall Medicare DSH payments of 68.51 percent of the amount of Medicare DSH payments that would otherwise have been made in the absence of the amendments made by the Affordable Care Act (that is, 25 percent + 43.51 percent = 68.51 percent).

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20192), for FY 2018, we proposed to establish that the calculation of the ''IPPS comparable amount'' under § 412.529 and the ''IPPS equivalent amount'' under § 412.538 would include an applicable operating Medicare DSH payment amount that is equal to 68.51 percent of the operating Medicare DSH payment amount that would have been paid based on the statutory Medicare DSH payment formula but for the amendments made by the Affordable Care Act. Furthermore, consistent with our historical practice, we proposed that if more recent data became available, if appropriate, we would use that data to determine this factor in the final rule.

We did not receive any public comments on our proposal. In addition, there is no more recent data available that would affect the calculations in the proposed rule. Therefore, we are finalizing our proposal that the calculation of the ''IPPS comparable amount'' under § 412.529 and the ''IPPS equivalent amount'' under § 412.538 would include an applicable operating Medicare DSH payment amount that is equal to 68.51 percent of the operating Medicare DSH payment amount that would have been paid based on the statutory Medicare DSH payment formula but for the amendments made by the Affordable Care Act.

F. Computing the Adjusted LTCH PPS Federal Prospective Payments for FY 2018

Section 412.525 sets forth the adjustments to the LTCH PPS standard Federal payment rate. Under the dual rate LTCH PPS payment structure, only LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate. Under § 412.525(c), the proposed LTCH PPS standard Federal payment rate is adjusted to account for differences in area wages by multiplying the proposed labor-related share of the LTCH PPS standard Federal payment rate for a case by the applicable LTCH PPS wage index (the FY 2018 values are shown in Tables 12A through 12B listed in section VI. of the Addendum of this final rule and are available via the Internet on the CMS Web site). The LTCH PPS standard Federal payment rate is also adjusted to account for the higher costs of LTCHs located in Alaska and Hawaii by the applicable COLA factors (the FY 2018 factors are shown in the chart in section V.C. of this Addendum) in accordance with § 412.525(b). In this final rule, we are establishing an LTCH PPS standard Federal payment rate for FY 2018 of $41,430.56, as discussed in section V.A. of the Addendum to this final rule. We illustrate the methodology to adjust the LTCH PPS standard Federal payment rate for FY 2018 in the following example:

Example

During FY 2018, a Medicare discharge that meets the criteria to be excluded from the site neutral payment rate, that is, an LTCH PPS standard Federal payment rate case, is from an LTCH that is located in Chicago, Illinois (CBSA 16974). The FY 2018 LTCH PPS wage index value for CBSA 16974 is 1.0547 (obtained from Table 12A listed in section VI. of the Addendum of this final rule and available via the Internet on the CMS Web site). The Medicare patient case is classified into MS–LTC–DRG 189 (Pulmonary Edema & Respiratory Failure), which has a relative weight for FY 2018 of 0.9655 (obtained from Table 11 listed in section VI. of the Addendum of this final rule and available via the Internet on the CMS Web site). The LTCH

submitted quality reporting data for FY 2018 in accordance with the LTCHQRP under section 1886(m)(5) of the Act.

To calculate the LTCH's total adjusted Federal prospective payment for this Medicare patient case in FY 2018, we computed the wage-adjusted proposed Federal prospective payment amount by multiplying the unadjusted FY 2018 LTCH PPS standard Federal payment rate ($41,430.56) by the labor-related share (66.2 percent) and the wage index value (1.0547). This wage-adjusted amount was then added to the nonlabor-related portion of the unadjusted LTCH PPS standard Federal payment rate (33.8 percent; adjusted for cost of living, if applicable) to determine the adjusted LTCH PPS standard Federal payment rate, which is then multiplied by the MS–LTC–DRG relative weight (0.9655) to calculate the total adjusted LTCH PPS standard Federal prospective payment for FY 2018 ($41,449.71). The table below illustrates the components of the calculations in this example.

Unadjusted LTCH PPS Standard Federal Prospective Payment Rate	$41,430.56
Labor-Related Share	× 0.662
Labor-Related Portion of the LTCH PPS Standard Federal Payment Rate	= $27,427.03
Wage Index (CBSA 16974)	× 1.0547
Wage-Adjusted Labor Share of LTCH PPS Standard Federal Payment Rate	= $28,927.29
Nonlabor-Related Portion of the LTCH PPS Standard Federal Payment Rate ($41,430.56 × 0.338)	+ $14,003.53
Adjusted LTCH PPS Standard Federal Payment Amount	= $42,930.82
MS–LTC–DRG 189 Relative Weight	× 0.9655
Total Adjusted LTCH PPS Standard Federal Prospective Payment	= $41,449.71

VI. Tables Referenced in This Final Rule and Available Only Through the Internet on the CMS Web site

This section lists the tables referred to throughout the preamble of this final rule and in this Addendum. In the past, a majority of these tables were published in the **Federal Register** as part of the annual proposed and final rules. However, similar to FYs 2012 through 2017, for the FY 2018 rulemaking cycle, the IPPS and LTCH tables will not be published in the **Federal Register** in the annual IPPS/LTCH PPS proposed and final rules and will be available only through the Internet. Specifically, all IPPS tables listed below, with the exception of IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E will be available only through the Internet. IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E are displayed at the end of this section and will continue to be published in the **Federal Register** as part of the annual proposed and final rules.

As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49807), we streamlined and consolidated the wage index tables for FY 2016 and subsequent fiscal years.

As discussed in sections II.F.14., II.F.15.b., II.F.16., II.F.17.a., and II.F.19.a.1., a.3., and c.1. of the preamble of this final rule, we developed the following ICD–10–CM and ICD–10–PCS code tables for FY 2018: Table 6A.—New Diagnosis Codes; Table 6B.—New Procedure Codes; Table 6C.—Invalid Diagnosis Codes; Table 6D.—Invalid Procedure Codes; Table 6E.—Revised Diagnosis Code Titles; Table 6F.—Revised Procedure Code Titles; Table 6G.1.—Secondary Diagnosis Order Additions to the CC Exclusion List; Table 6G.2.—Principal Diagnosis Order Additions to the CC Exclusion List; Table 6H.1.—Secondary Diagnosis Order Deletions to the CC Exclusion List; Table 6H.2.—Principal Diagnosis Order Deletions to the CC Exclusion List; Table 6I.—Complete MCC List; Table 6I.1.—Additions to the MCC List; Table 6J.—Complete CC List; Table 6I.2.—Deletions to the MCC List; Table 6J.1.—Additions to the CC List; Table 6J.2—Deletions to the CC List; Table 6K.—Complete List of CC Exclusions; Table 6L.—Principal Diagnosis Is Its Own MCC List—FY 2018; Table 6M.—Principal Diagnosis Is Its Own CC List—FY 2018; and Table 6P.—ICD–10–CM and ICD–10–PCS Code Designations, MCE and MS–DRG Changes. Table 6P contains multiple tables, 6P.1a through 6P.4p, that include the ICD–10–CM and ICD–10–PCS code lists relating to specific MCE and MS–DRG changes. In addition, under the HAC Reduction Program established by section 3008 of the Affordable Care Act, a hospital's total payment may be reduced by 1 percent if it is in the lowest HAC performance quartile. However, as discussed in section V.I. of the preamble of this final rule, we are not providing the hospital-level data as a table associated with this final rule. The hospital-level data for the FY 2018 HAC Reduction Program will be made publicly available once it has undergone the review and corrections process.

Finally, Table 18 associated with this final rule contains the Factor 3 for purposes of determining the FY 2018 uncompensated care payment for all hospitals and identifies whether or not a hospital is projected to receive Medicare DSH payments and, therefore, eligible to receive the additional payment for uncompensated care for FY 2018. A hospital's Factor 3 determines the proportion of the aggregate amount available for uncompensated care payments that a Medicare DSH eligible hospital will receive under section 3133 of the Affordable Care Act.

Readers who experience any problems accessing any of the tables that are posted on the CMS Web sites identified below should contact Michael Treitel at (410) 786–4552.

The following IPPS tables for this FY 2018 final rule are available only through the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Click on the link on the left side of the screen titled, ''FY 2018 IPPS Final Rule Home Page'' or ''Acute Inpatient—Files for Download.''

Table 2.—Case-Mix Index and Wage Index Table by CCN—FY 2018
Table 3.—Wage Index Table by CBSA—FY 2018
Table 5.—List of Medicare Severity Diagnosis-Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay—FY 2018
Table 6A.—New Diagnosis Codes—FY 2018
Table 6B.—New Procedure Codes—FY 2018
Table 6C.—Invalid Diagnosis Codes—FY 2018
Table 6D.—Invalid Procedure Codes—FY 2018
Table 6E.—Revised Diagnosis Code Titles—FY 2018
Table 6F.—Revised Procedure Code Titles—FY 2018
Table 6G.1.—Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2018
Table 6G.2.—Principal Diagnosis Order Additions to the CC Exclusions List—FY 2018
Table 6H.1.—Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2018
Table 6H.2.—Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2018
Table 6I.—Complete MCC List—FY 2018
Table 6I.1.—Additions to the MCC List—FY 2018
Table 6I.2.—Deletions to the MCC List—FY 2018
Table 6J.—Complete CC List—FY 2018
Table 6J.1.—Additions to the CC List—FY 2018
Table 6J.2.—Deletions to the CC List—FY 2018
Table 6K.—Complete List of CC Exclusions—FY 2018
Table 6L.—Principal Diagnosis Is Its Own MCC List—FY 2018
Table 6M.—Principal Diagnosis Is Its Own CC List—FY 2018
Table 6P.—ICD–10–CM and ICD–10–PCS Code Designations, MCE and MS–DRG Changes—FY 2018
Table 7A.—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2016 MedPAR Update—March 2017 GROUPER V34.0 MS–DRGs
Table 7B.—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2016 MedPAR Update—March 2017 GROUPER V35.0 MS–DRGs
Table 8A.—FY 2018 Statewide Average Operating Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals (Urban and Rural)
Table 8B.—FY 2018 Statewide Average Capital Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals

Table 10.—New Technology Add-On Payment Thresholds for Applications for FY 2019
Table 15.—FY 2018 Readmissions Adjustment Factors
Table 16A.—Proxy Hospital Value-Based Purchasing (VBP) Program Adjustment Factors for FY 2018
Table 18.—FY 2018 Uncompensated Care Payment Factor 3

The following LTCH PPS tables for this FY 2018 final rule are available only through the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1677–F:

Table 8C.—FY 2018 Statewide Average Total Cost-to-Charge Ratios (CCRs) for LTCHs (Urban and Rural)
Table 11.—MS–LTC–DRGs, Relative Weights, Geometric Average Length of Stay, and Short-Stay Outlier (SSO) Threshold for LTCH PPS Discharges Occurring from October 1, 2017 through September 30, 2018
Table 12A.—LTCH PPS Wage Index for Urban Areas for Discharges Occurring from October 1, 2017 through September 30, 2018
Table 12B.—LTCH PPS Wage Index for Rural Areas for Discharges Occurring from October 1, 2017 through September 30, 2018
Table 13A.—Composition of Low Volume Quintiles for MS–LTC–DRGs—FY 2018
Table 13B.—No Volume MS LTC–DRG Crosswalk for FY 2018

TABLE 1A—NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR

[(68.3 percent labor share/31.7 percent nonlabor share if wage index is greater than 1)—FY 2018]

Hospital submitted quality data and is a meaningful EHR user (update = 1.35 percent)		Hospital submitted quality data and is NOT a meaningful EHR user (update = −0.675 percent)		Hospital did NOT submit quality data and is a meaningful EHR User (update = 0.675 percent)		Hospital did NOT submit quality data and is NOT a meaningful EHR user (update = −1.35 percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$3,807.12	$1,766.99	$3,731.05	$1,731.69	$3,781.76	$1,755.22	$3,705.70	$1,719.92

TABLE 1B—NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR

[(62 percent labor share/38 percent nonlabor share if wage index is less than or equal to 1)—FY 2018]

Hospital submitted quality data and is a meaningful EHR user (update = 1.35 percent)		Hospital submitted quality data and is NOT a meaningful EHR user (update = −0.675 percent)		Hospital did NOT submit quality data and is a meaningful EHR User (update = 0.675 percent)		Hospital did NOT submit quality data and is NOT a meaningful EHR user (update = −1.35 percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$3,455.95	$2,118.16	$3,386.90	$2,075.84	$3,432.93	$2,104.05	$3,363.88	$2,061.74

TABLE 1C—ADJUSTED OPERATING STANDARDIZED AMOUNTS FOR HOSPITALS IN PUERTO RICO, LABOR/NONLABOR

[(National: 62 percent labor share/38 percent nonlabor share because wage index is less than or equal to 1);—FY 2018]

Standardized amount	Rates if wage index is greater than 1		Rates if wage index is less than or equal to 1	
	Labor	Nonlabor	Labor	Nonlabor
National [1]	Not Applicable	Not Applicable	$3,455.95	$2,118.16

[1] For FY 2018, there are no CBSAs in Puerto Rico with a national wage index greater than 1.

TABLE 1D—CAPITAL STANDARD FEDERAL PAYMENT RATE

[FY 2018]

	Rate
National	$453.97

TABLE 1E—LTCH PPS STANDARD FEDERAL PAYMENT RATE

[FY 2018]

	Full update (1 percent)	Reduced update * (−1.0 percent)
Standard Federal Rate	$41,430.56	$40,610.16

* For LTCHs that fail to submit quality reporting data for FY 2018 in accordance with the LTCH Quality Reporting Program (LTCH QRP), the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

Appendix A: Economic Analyses

I. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) (Having

an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

We have determined that this final rule is a major rule as defined in 5 U.S.C. 804(2). We estimate that the changes for FY 2018 acute care hospital operating and capital payments will redistribute amounts in excess of $100 million to acute care hospitals. The applicable percentage increase to the IPPS rates required by the statute, in conjunction with other payment changes in this final rule, will result in an estimated $2.4 billion increase in FY 2018 payments, including a $1.7 billion increase in FY 2018 operating payments, a $0.8 billion increase in uncompensated care payments, a $0.2 billion increase in FY 2018 capital payments, and a $0.3 billion decrease in low volume payments. These changes are relative to payments made in FY 2017. The impact analysis of the capital payments can be found in section I.I. of this Appendix. In addition, as described in section I.J. of this Appendix, LTCHs are expected to experience a decrease in payments by $110 million in FY 2018 relative to FY 2017.

Our operating impact estimate includes the 0.4588 percent adjustment required under section 15005 of the 21st Century Cures Act (Pub. L. 114–255) applied to the IPPS standardized amount, as discussed in section II.D. of the preamble of this final rule. In addition, our operating payment impact estimate includes the 1.35 percent hospital update to the standardized amount (which includes the estimated 2.7 percent market basket update less 0.6 percentage point for the multifactor productivity adjustment and less 0.75 percentage point required under the Affordable Care Act). Our operating payment impact estimate also includes an adjustment factor of (1/1.006) to the FY 2018 rates to remove the 1.006 temporary one-time adjustment made in FY 2017 to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 as a result of the 2-midnight policy (we refer readers to section V.M. of the preamble of this final rule for an explanation of this adjustment). The estimates of IPPS operating payments to acute care hospitals do not reflect any changes in hospital admissions or real case-mix intensity, which will also affect overall payment changes.

The analysis in this Appendix, in conjunction with the remainder of this document, demonstrates that this final rule is consistent with the regulatory philosophy and principles identified in Executive Orders 12866 and 13563, the RFA, and section 1102(b) of the Act. This final rule will affect payments to a substantial number of small rural hospitals, as well as other classes of hospitals, and the effects on some hospitals may be significant. Finally, in accordance with the provisions of Executive Order 12866, the Executive Office of Management and Budget has reviewed this final rule.

B. Statement of Need

This final rule is necessary in order to make payment and policy changes under the Medicare IPPS for Medicare acute care hospital inpatient services for operating and capital-related costs as well as for certain hospitals and hospital units excluded from the IPPS. This final rule also is necessary to make payment and policy changes for Medicare hospitals under the LTCH PPS.

C. Objectives of the IPPS and the LTCH PPS

The primary objective of the IPPS and the LTCH PPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe that the changes in this final rule will further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries. We expect that these changes will ensure that the outcomes of the prospective payment systems are reasonable and equitable while avoiding or minimizing unintended adverse consequences.

Because this final rule contains a range of policies, we refer readers to the section of the final rule where each policy is discussed. These sections include the rational for our decisions, including the need for the policy.

D. Limitations of Our Analysis

The following quantitative analysis presents the projected effects of our policy changes, as well as statutory changes effective for FY 2018, on various hospital groups. We estimate the effects of individual policy changes by estimating payments per case while holding all other payment policies constant. We use the best data available, but, generally, we do not attempt to make adjustments for future changes in such variables as admissions, lengths of stay, or case-mix. In addition, we discuss limitations of our analysis for specific policies in the discussion of those policies as needed.

E. Hospitals Included in and Excluded From the IPPS

The prospective payment systems for hospital inpatient operating and capital-related costs of acute care hospitals encompass most general short-term, acute care hospitals that participate in the Medicare program. There were 31 Indian Health Service hospitals in our database, which we excluded from the analysis due to the special characteristics of the prospective payment methodology for these hospitals. Among other short-term, acute care hospitals, hospitals in Maryland are paid in accordance with the Maryland All-Payer Model, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, 5 short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling.

As of July 2017, there were 3,292 IPPS acute care hospitals included in our analysis. This represents approximately 55 percent of all Medicare-participating hospitals. The majority of this impact analysis focuses on this set of hospitals. There also are approximately 1,387 CAHs. These small, limited service hospitals are paid on the basis of reasonable costs rather than under the IPPS. IPPS-excluded hospitals and units, which are paid under separate payment systems, include IPFs, IRFs, LTCHs, RNHCIs, children's hospitals, 11 cancer hospitals, extended neoplastic disease care hospitals, and 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. With the exception of the IPFQR provisions presented in section IX.D. of the preamble of this final rule, changes in the prospective payment systems for IPFs and IRFs are made through separate rulemaking. Payment impacts of changes to the prospective payment systems for these IPPS-excluded hospitals and units are not included in this final rule. The impact of the update and policy changes to the LTCH PPS for FY 2018 is discussed in section I.J. of this Appendix.

F. Effects on Hospitals and Hospital Units Excluded From the IPPS

As of July 2017, there were 98 children's hospitals, 11 cancer hospitals, 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa, 1 extended neoplastic disease care hospital, and 18 RNHCIs being paid on a reasonable cost basis subject to the rate-of-increase ceiling under § 413.40. (In accordance with § 403.752(a) of the regulation, RNHCIs are paid under § 413.40.) Among the remaining providers, 276 rehabilitation hospitals and 864 rehabilitation units, and approximately 419 LTCHs, are paid the Federal prospective per discharge rate under the IRF PPS and the LTCH PPS, respectively, and 517 psychiatric hospitals and 1,104 psychiatric units are paid the Federal per diem amount under the IPF PPS. As stated previously, IRFs and IPFs are not affected by the rate updates discussed in this final rule. The impacts of the changes on LTCHs are discussed in section I.J. of this Appendix. For children's hospitals, the 11 cancer hospitals, the 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, extended neoplastic disease care hospitals, and RNHCIs, the update of the rate-of-increase limit (or target amount) is the estimated FY 2018 percentage increase in the 2014-based IPPS operating market basket, consistent with section 1886(b)(3)(B)(ii) of the Act, and §§ 403.752(a) and 413.40 of the regulations. As discussed in section IV. of the preamble of this final rule, we are rebasing and revising the IPPS operating market

basket to a 2014 base year. Therefore, we used the percentage increase in the 2014-based IPPS operating market basket to update the target amounts for FY 2018 and subsequent years for children's hospitals, the 11 cancer hospitals, the 5 short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, extended neoplastic disease care hospitals, and RNHCs that are paid based on reasonable costs subjects to the rate-of-increase limits. Consistent with current law, based on IGI's 2017 second quarter forecast of the 2014-based IPPS market basket increase, we are estimating the FY 2018 update to be 2.7 percent (that is, the estimate of the market basket rate-of-increase). We used the most recent data available for this final rule to calculate the IPPS operating market basket update for FY 2018. However, the Affordable Care Act requires an adjustment for multifactor productivity (currently 0.6 percentage point for FY 2018) and a 0.75 percentage point reduction to the market basket update, resulting in a 1.35 percent applicable percentage increase for IPPS hospitals that submit quality data and are meaningful EHR users, as discussed in section V.B. of the preamble of this final rule. Children's hospitals, the 11 cancer hospitals, the 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, extended neoplastic disease care hospitals, and RNHCIs that continue to be paid based on reasonable costs subject to rate-of-increase limits under § 413.40 of the regulations are not subject to the reductions in the applicable percentage increase required under the Affordable Care Act. Therefore, for those hospitals paid under § 413.40 of the regulations, the update is the percentage increase in the 2014-based IPPS operating market basket for FY 2018, estimated at 2.7 percent, without the reductions described previously under the Affordable Care Act.

The impact of the update in the rate-of-increase limit on those excluded hospitals depends on the cumulative cost increases experienced by each excluded hospital since its applicable base period. For excluded hospitals that have maintained their cost increases at a level below the rate-of-increase limits since their base period, the major effect is on the level of incentive payments these excluded hospitals receive. Conversely, for excluded hospitals with cost increases above the cumulative update in their rate-of-increase limits, the major effect is the amount of excess costs that would not be paid.

We note that, under § 413.40(d)(3), an excluded hospital that continues to be paid under the TEFRA system and whose costs exceed 110 percent of its rate-of-increase limit receives its rate-of-increase limit plus the lesser of: (1) 50 percent of its reasonable costs in excess of 110 percent of the limit; or (2) 10 percent of its limit. In addition, under the various provisions set forth in § 413.40, hospitals can obtain payment adjustments for justifiable increases in operating costs that exceed the limit.

G. Quantitative Effects of the Policy Changes Under the IPPS for Operating Costs

1. Basis and Methodology of Estimates

In this final rule, we are announcing policy changes and payment rate updates for the IPPS for FY 2018 for operating costs of acute care hospitals. The FY 2018 updates to the capital payments to acute care hospitals are discussed in section I.I. of this Appendix.

Based on the overall percentage change in payments per case estimated using our payment simulation model, we estimate that total FY 2018 operating payments will increase by 1.3 percent compared to FY 2017. In addition to the applicable percentage increase, this amount reflects the FY 2018 adjustment required under section 15005 of the 21st Century Cures Act described in section II.D. of the preamble of this final rule of 0.4588 percent to the IPPS national standardized amounts. This amount also reflects the adjustment factor of (1/1.006) to remove the 1.006 temporary one-time adjustment made in FY 2017 to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 related to the 2-midnight policy, which is discussed in section V.M. of the preamble of this final rule. The impacts do not reflect changes in the number of hospital admissions or real case-mix intensity, which will also affect overall payment changes. We have prepared separate impact analyses of the changes to each system. This section deals with the changes to the operating inpatient prospective payment system for acute care hospitals. Our payment simulation model relies on the most recent available data to enable us to estimate the impacts on payments per case of certain changes in this final rule. However, there are other changes for which we do not have data available that would allow us to estimate the payment impacts using this model. For those changes, we have attempted to predict the payment impacts based upon our experience and other more limited data.

The data used in developing the quantitative analyses of changes in payments per case presented in this section are taken from the FY 2016 MedPAR file and the most current Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the changes to the operating PPS do not incorporate cost data, data from the most recently available hospital cost reports were used to categorize hospitals. Our analysis has several qualifications. First, in this analysis, we do not make adjustments for future changes in such variables as admissions, lengths of stay, or underlying growth in real case-mix. Second, due to the interdependent nature of the IPPS payment components, it is very difficult to precisely quantify the impact associated with each change. Third, we use various data sources to categorize hospitals in the tables. In some cases, particularly the number of beds, there is a fair degree of variation in the data from the different sources. We have attempted to construct these variables with the best available source overall. However, for individual hospitals, some miscategorizations are possible.

Using cases from the FY 2016 MedPAR file, we simulate payments under the operating IPPS given various combinations of payment parameters. As described previously, Indian Health Service hospitals and hospitals in Maryland were excluded from the simulations. The impact of payments under the capital IPPS, and the impact of payments for costs other than inpatient operating costs, are not analyzed in this section. Estimated payment impacts of the capital IPPS for FY 2018 are discussed in section I.I. of this Appendix.

We discuss the following changes:

- The effects of the application of the adjustment required under section 15005 of the 21st Century Cures Act and the applicable percentage increase (including the market basket update, the multifactor productivity adjustment, and the applicable percentage reduction in accordance with the Affordable Care Act) to the standardized amount and hospital-specific rates.
- The effects of the adjustment of (1/1.006) to remove the 1.006 temporary one-time adjustment made in FY 2017 to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 related to the 2-midnight policy, as discussed in section V.M. of the preamble of this final rule.
- The effects of the changes to the relative weights and MS–DRG GROUPER.
- The effects of the changes in hospitals' wage index values reflecting updated wage data from hospitals' cost reporting periods beginning during FY 2014, compared to the FY 2013 wage data, to calculate the FY 2018 wage index.
- The effects of the geographic reclassifications by the MGCRB (as of publication of this final rule) that will be effective for FY 2018.
- The effects of the rural floor and imputed floor with the application of the national budget neutrality factor to the wage index.
- The effects of the frontier State wage index adjustment under the statutory provision that requires hospitals located in States that qualify as frontier States to not have a wage index less than 1.0. This provision is not budget neutral.
- The effects of the implementation of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes. This provision is not budget neutral.
- The effects of the expiration of the special payment status for MDHs at the end of FY 2017 under current law as a result of which MDHs that currently receive the higher of payments made based on the Federal rate or the payments made based on the Federal rate plus 75 percent of the difference between payments based on the Federal rate and the hospital-specific rate will be paid based on the Federal rate starting in FY 2018.
- The total estimated change in payments based on the FY 2018 policies relative to payments based on FY 2017 policies that include the applicable percentage increase of 1.35 percent (or 2.7 percent market basket update with a reduction of 0.6 percentage point for the multifactor productivity

adjustment, and a 0.75 percentage point reduction, as required under the Affordable Care Act).

To illustrate the impact of the FY 2018 changes, our analysis begins with a FY 2017 baseline simulation model using: The FY 2017 applicable percentage increase of 1.65 percent and the documentation and coding adjustment of −1.5 percent to the Federal standardized amount; the adjustment of (1/0.998) to permanently remove the −0.2 percent reduction to the rate put in place in FY 2014 to offset the estimated increase in IPPS expenditures as a result of the 2-midnight policy; the 1.006 temporary adjustment to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 related to the 2-midnight policy; the FY 2017 MS–DRG GROUPER (Version 34); the FY 2017 CBSA designations for hospitals based on the OMB definitions from the 2010 Census; the FY 2017 wage index; and no MGCRB reclassifications. Outlier payments are set at 5.1 percent of total operating MS–DRG and outlier payments for modeling purposes.

Section 1886(b)(3)(B)(viii) of the Act, as added by section 5001(a) of Public Law 109–171, as amended by section 4102(b)(1)(A) of the ARRA (Pub. L. 111–5) and by section 3401(a)(2) of the Affordable Care Act (Pub. L. 111–148), provides that, for FY 2007 and each subsequent year through FY 2014, the update factor will include a reduction of 2.0 percentage points for any subsection (d) hospital that does not submit data on measures in a form and manner and at a time specified by the Secretary. Beginning in FY 2015, the reduction is one-quarter of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act, or one-quarter of the market basket update. Therefore, for FY 2018, hospitals that do not submit quality information under rules established by the Secretary and that are meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act will receive an applicable percentage increase of 0.675 percent. At the time that this impact was prepared, 82 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2018 because they failed the quality data submission process or did not choose to participate but are meaningful EHR users. For purposes of the simulations shown later in this section, we modeled the payment changes for FY 2018 using a reduced update for these hospitals.

For FY 2018, in accordance with section 1886(b)(3)(B)(ix) of the Act, a hospital that has been identified as not a meaningful EHR user will be subject to a reduction of three-quarters of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act. Therefore, for FY 2018, hospitals that are identified as not meaningful EHR users and do submit quality information under section 1886(b)(3)(B)(viii) of the Act will receive an applicable percentage increase of −0.675 percent. At the time that this impact analysis was prepared, 103 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2018 because they are identified as not meaningful EHR users that do submit quality information under section 1886(b)(3)(B)(viii) of the Act. For purposes of the simulations shown in this section, we modeled the payment changes for FY 2018 using a reduced update for these hospitals.

Hospitals that are identified as not meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act and also do not submit quality data under section 1886(b)(3)(B)(viii) of the Act will receive an applicable percentage increase of −1.35 percent, which reflects a one-quarter reduction of the market basket update for failure to submit quality data and a three-quarter reduction of the market basket update for being identified as not a meaningful EHR user. At the time that this impact was prepared, 21 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2018 because they are identified as not meaningful EHR users that do not submit quality data under section 1886(b)(3)(B)(viii) of the Act.

Each policy change, statutory or otherwise, is then added incrementally to this baseline, finally arriving at an FY 2018 model incorporating all of the changes. This simulation allows us to isolate the effects of each change.

Our final comparison illustrates the percent change in payments per case from FY 2017 to FY 2018. Two factors not discussed separately have significant impacts here. The first factor is the update to the standardized amount. In accordance with section 1886(b)(3)(B)(i) of the Act, we are updating the standardized amounts for FY 2018 using an applicable percentage increase of 1.35 percent. This includes our forecasted IPPS operating hospital market basket increase of 2.7 percent with a 0.6 percentage point reduction for the multifactor productivity adjustment and a 0.75 percentage point reduction as required under the Affordable Care Act. Hospitals that fail to comply with the quality data submission requirements and are meaningful EHR users will receive an update of 0.675 percent. This update includes a reduction of one-quarter of the market basket update for failure to submit these data. Hospitals that do comply with the quality data submission requirements but are not meaningful EHR users will receive an update of −0.675 percent, which includes a reduction of three-quarters of the market basket update. Furthermore, hospitals that do not comply with the quality data submission requirements and also are not meaningful EHR users will receive an update of −1.35 percent. Under section 1886(b)(3)(B)(iv) of the Act, the update to the hospital-specific amounts for SCHs is also equal to the applicable percentage increase, or 1.35 percent if the hospital submits quality data and is a meaningful EHR user.

A second significant factor that affects the changes in hospitals' payments per case from FY 2017 to FY 2018 is the change in hospitals' geographic reclassification status from one year to the next. That is, payments may be reduced for hospitals reclassified in FY 2017 that are no longer reclassified in FY 2018. Conversely, payments may increase for hospitals not reclassified in FY 2017 that are reclassified in FY 2018.

2. Analysis of Table I

Table I displays the results of our analysis of the changes for FY 2018. The table categorizes hospitals by various geographic and special payment consideration groups to illustrate the varying impacts on different types of hospitals. The top row of the table shows the overall impact on the 3,292 acute care hospitals included in the analysis.

The next four rows of Table I contain hospitals categorized according to their geographic location: All urban, which is further divided into large urban and other urban; and rural. There are 2,492 hospitals located in urban areas included in our analysis. Among these, there are 1,340 hospitals located in large urban areas (populations over 1 million), and 1,152 hospitals in other urban areas (populations of 1 million or fewer). In addition, there are 800 hospitals in rural areas. The next two groupings are by bed-size categories, shown separately for urban and rural hospitals. The final groupings by geographic location are by census divisions, also shown separately for urban and rural hospitals.

The second part of Table I shows hospital groups based on hospitals' FY 2018 payment classifications, including any reclassifications under section 1886(d)(10) of the Act. For example, the rows labeled urban, large urban, other urban, and rural show that the numbers of hospitals paid based on these categorizations after consideration of geographic reclassifications (including reclassifications under sections 1886(d)(8)(B) and 1886(d)(8)(E) of the Act that have implications for capital payments) are 2,373, 1,354, 1,019, and 919, respectively.

The next three groupings examine the impacts of the changes on hospitals grouped by whether or not they have GME residency programs (teaching hospitals that receive an IME adjustment) or receive Medicare DSH payments, or some combination of these two adjustments. There are 2,204 nonteaching hospitals in our analysis, 839 teaching hospitals with fewer than 100 residents, and 249 teaching hospitals with 100 or more residents.

In the DSH categories, hospitals are grouped according to their DSH payment status, and whether they are considered urban or rural for DSH purposes. The next category groups together hospitals considered urban or rural, in terms of whether they receive the IME adjustment, the DSH adjustment, both, or neither.

The next three rows examine the impacts of the changes on rural hospitals by special payment groups (SCHs, and RRCs). There were 263 RRCs, 316 SCHs, and 131 hospitals that are both SCHs and RRCs.

The next series of groupings are based on the type of ownership and the hospital's Medicare utilization expressed as a percent of total patient days. These data were taken from the FY 2015 or FY 2014 Medicare cost reports.

The next two groupings concern the geographic reclassification status of hospitals. The first grouping displays all urban hospitals that were reclassified by the MGCRB for FY 2018. The second grouping shows the MGCRB rural reclassifications.

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TABLE I.—IMPACT ANALYSIS OF CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2018

	Number of Hospitals[1]	Hospital Rate Update and Adjustments (1)[2]	FY 2018 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	FY 2018 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2018 MGCRB Reclassifications (4)[5]	Rural and Imputed Floor with Application of National Budget Neutrality (5)[6]	Application of the Frontier Wage Index and Out-Migration Adjustment (6)[7]	Expiration of MDH Status (7)[8]	All FY 2018 Changes (8)[9]
All Hospitals	3,292	1.2	0	0	0	0	0.1	-0.1	1.3
By Geographic Location:									
Urban hospitals	2,492	1.2	0	0	-0.1	0	0.1	0	1.4
Large urban areas	1,340	1.2	0	-0.1	-0.5	-0.1	0	0	1.4
Other urban areas	1,152	1.2	0	0.1	0.3	0.2	0.2	-0.1	1.5
Rural hospitals	800	0.9	0.2	0	1.4	-0.2	0.2	-0.9	0.2
Bed Size (Urban):									
0-99 beds	648	1.1	0.4	0.1	-0.6	0.1	0.2	-0.7	0.9
100-199 beds	763	1.2	0.2	0.1	0	0.3	0.2	-0.1	1.5
200-299 beds	441	1.2	0.1	0	0.1	0.1	0.1	0	1.5
300-499 beds	426	1.2	0	-0.1	-0.1	0	0.1	0	1.4
500 or more beds	214	1.2	-0.2	0	-0.2	-0.2	0.1	0	1.5
Bed Size (Rural):									
0-49 beds	318	0.9	0.3	0	0.5	-0.2	0.3	-1.6	-0.4
50-99 beds	282	0.9	0.2	0	0.6	-0.1	0.4	-2.2	-1.4
100-149 beds	117	0.8	0.1	-0.1	1.1	-0.2	0.1	-0.1	0.8
150-199 beds	44	0.9	0.1	0	2.2	-0.2	0.1	0	1.3
200 or more beds	39	0.9	0	0.2	2.9	-0.2	0	0	1.6
Urban by Region:									
New England	114	1.2	0	-0.5	1.2	1.4	0.1	-0.2	1.4
Middle Atlantic	315	1.2	0	-0.1	0.6	-0.3	0.1	0	1.1
South Atlantic	404	1.2	0	0.1	-0.4	-0.2	0	-0.1	1.5
East North Central	385	1.2	0.1	0.1	-0.2	-0.4	0	0	1.7
East South Central	147	1.2	0	-0.2	-0.3	-0.3	0	0	1.3
West North Central	160	1.1	-0.1	0.7	-0.9	-0.3	0.7	-0.1	1.8
West South Central	378	1.2	0	0.5	-0.5	-0.3	0	-0.1	1.7
Mountain	162	1.1	0	-0.2	0	0.1	0.3	0	0.6
Pacific	375	1.1	-0.1	-0.4	-0.2	0.9	0.1	0	1.5
Puerto Rico	52	1.2	-0.5	1.4	-1	0.2	0.1	0	1.1
Rural by Region:									
New England	20	1	0.1	1.1	2.1	-0.3	0.2	-2.2	0.6
Middle Atlantic	53	0.8	0.2	0	0.8	-0.2	0.2	-1.7	-0.9
South Atlantic	125	1	0.2	-0.1	1.8	-0.2	0.2	-0.8	-0.1
East North Central	115	0.9	0.1	-0.3	1.2	-0.1	0.1	-1.7	-0.9
East South Central	154	1.1	0.3	0.1	2.4	-0.3	0.1	-0.3	1.1
West North Central	97	0.6	-0.1	0	0.3	0	0.3	-0.3	0.6
West South Central	154	0.9	0.3	0	1.5	-0.2	0.2	-0.7	0.6
Mountain	58	0.6	0.2	-0.1	0.2	-0.1	0.3	0	0.9
Pacific	24	0.6	0	-0.1	1.2	-0.1	0	0	0.4

	Number of Hospitals[1]	Hospital Rate Update and Adjustments (1)[2]	FY 2018 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	FY 2018 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2018 MGCRB Reclassifications (4)[5]	Rural and Imputed Floor with Application of National Budget Neutrality (5)[6]	Application of the Frontier Wage Index and Out-Migration Adjustment (6)[7]	Expiration of MDH Status (7)[8]	All FY 2018 Changes (8)[9]
By Payment Classification:									
Urban hospitals	2,373	1.2	0	0	-0.3	0	0.1	0	1.4
Large urban areas	1,354	1.2	0	-0.1	-0.5	-0.1	0	0	1.4
Other urban areas	1,019	1.2	0	0.1	-0.1	0.2	0.2	0	1.5
Rural areas	919	1	0.1	0.1	1.6	-0.1	0.2	-0.7	0.8
Teaching Status:									
Nonteaching	2,204	1.1	0.2	0	0.2	0.2	0.1	-0.3	1.2
Fewer than 100 residents	839	1.2	0.1	0	-0.1	0	0.2	0	1.4
100 or more residents	249	1.2	-0.2	-0.1	-0.1	-0.1	0	0	1.4
Urban DSH:									
Non-DSH	551	1.2	0	0	-0.2	-0.1	0.2	-0.3	0.9
100 or more beds	1,543	1.2	0	0	-0.3	0	0.1	0	1.4
Less than 100 beds	370	1.1	0.3	0	-0.2	0.1	0.2	-0.1	1.6
Rural DSH:									
SCH	257	0.6	0	0	-0.1	0	0	0	0.6
RRC	293	1	0	0.1	2.1	-0.1	0.2	-0.3	1.6
100 or more beds	34	1.2	0.2	0	1.8	-0.2	0.1	-0.1	0.4
Less than 100 beds	244	1.1	0.5	0	0.5	-0.3	0.7	-4.8	-3.8
Urban teaching and DSH:									
Both teaching and DSH	863	1.2	-0.1	0	-0.4	-0.1	0.1	0	1.4
Teaching and no DSH	92	1.2	0	-0.1	-0.2	-0.2	0.1	0	1
No teaching and DSH	1,050	1.2	0.2	0	-0.2	0.3	0.1	0	1.5
No teaching and no DSH	368	1.2	0.1	0.1	-0.4	-0.1	0.2	0	1.5
Special Hospital Types:									
RRC	263	1.2	0.1	0.1	2.5	-0.1	0.3	-0.4	1.8
SCH	316	0.7	-0.2	0.3	-0.2	-0.1	0	0	0.8
SCH and RRC	131	0.7	-0.1	0.1	0.3	0	0	0	0.9
Type of Ownership:									
Voluntary	1,914	1.2	0	0	0	0	0.1	-0.1	1.3
Proprietary	863	1.2	0.2	0.1	0	0	0.1	-0.1	1.6
Government	513	1.1	0	-0.1	-0.2	0.1	0.1	-0.1	1.3
Medicare Utilization as a Percent of Inpatient Days:									
0-25	554	1.2	0	0	-0.3	0.1	0.1	0	1.4
25-50	2,149	1.2	0	0	0	-0.1	0.1	-0.1	1.4
50-65	485	1.1	0.1	0.1	0.6	0.2	0.2	-0.6	0.8
Over 65	103	1	0.6	0.3	-0.9	-0.2	0.3	-4	-1.9

	Number of Hospitals[1]	Hospital Rate Update and Adjustments (1)[2]	FY 2018 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	FY 2018 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2018 MGCRB Reclassifications (4)[5]	Rural and Imputed Floor with Application of National Budget Neutrality (5)[6]	Application of the Frontier Wage Index and Out-Migration Adjustment (6)[7]	Expiration of MDH Status (7)[8]	All FY 2018 Changes (8)[9]
FY 2018 Reclassifications by the Medicare Geographic Classification Review Board:									
All Reclassified Hospitals	858	1.1	0.1	0.1	2.2	-0.1	0	-0.2	1.5
Non-Reclassified Hospitals	2,434	1.2	0	0	-0.9	0	0.2	-0.1	1.3
Urban Hospitals Reclassified	590	1.2	0.1	0.1	2.2	-0.1	0	-0.1	1.6
Urban Nonreclassified Hospitals	1,858	1.2	0	0	-0.9	0	0.1	0	1.4
Rural Hospitals Reclassified	268	0.9	0.1	0	2.3	-0.2	0	-0.5	0.6
Rural Nonreclassified Hospitals	485	0.9	0.2	0	-0.3	-0.1	0.4	-1.4	-0.5
All Section 401 Reclassified Hospitals:	166	1.1	0	0.1	1.9	0	0.3	-0.5	1.4
Other Reclassified Hospitals (Section 1886(d)(8)(B))	47	1.1	0.5	0.3	3.4	-0.3	0	-1.2	0.6

[1] Because data necessary to classify some hospitals by category were missing, the total number of hospitals in each category may not equal the national total. Discharge data are from FY 2016, and hospital cost report data are from reporting periods beginning in FY 2014 and FY 2015.

[2] This column displays the payment impact of the hospital rate update and other adjustments, including the 1.35 percent adjustment to the national standardized amount and the hospital-specific rate (the estimated 2.7 percent market basket update reduced by 0.6 percentage point for the multifactor productivity adjustment and the 0.75 percentage point reduction under the Affordable Care Act), the 0.4588 percent adjustment to the national standardized amount required under section 15005 of the 21st Century Cures Act and a factor of (1/1.006) to remove the 1.006 temporary one-time adjustment made in FY 2017 to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 related to the 2-midnight policy.

[3] This column displays the payment impact of the changes to the Version 35 GROUPER, the changes to the relative weights and the recalibration of the MS-DRG weights based on FY 2016 MedPAR data in accordance with section 1886(d)(4)(C)(iii) of the Act. This column displays the application of the recalibration budget neutrality factor of 0.997432 in accordance with section 1886(d)(4)(C)(iii) of the Act.

[4] This column displays the payment impact of the update to wage index data using FY 2014 and 2013 cost report data and the OMB labor market area delineations based on 2010 Decennial Census data. This column displays the payment impact of the application of the wage budget neutrality factor, which is calculated separately from the recalibration budget neutrality factor, and is calculated in accordance with section 1886(d)(3)(E)(i) of the Act. The wage budget neutrality factor is 1.001148.

[5] Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB. The effects demonstrate the FY 2018 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2018. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the geographic budget neutrality factor of 0.988008.

[6] This column displays the effects of the rural floor and imputed floor. The Affordable Care Act requires the rural floor budget neutrality adjustment to be 100 percent national level adjustment. The rural floor budget neutrality factor (which includes the imputed floor) applied to the wage index is 0.993348.

[7] This column shows the combined impact of the policy required under section 10324 of the Affordable Care Act that hospitals located in frontier States have a wage index no less than 1.0 and of section 1886(d)(13) of the Act, as added by section 505 of Pub. L. 108-173, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes. These are not budget neutral policies.

[8] This column displays the impact of the expiration of MDH status for FY 2018, a non-budget neutral payment provision.

[9] This column shows the estimated change in payments from FY 2017 to FY 2018.

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a. Effects of the Hospital Update, Adjustment Required Under Section 15005 of the 21st Century Cures Act, and Other Adjustments (Column 1)

As discussed in section V.B. of the preamble of this final rule, this column includes the hospital update, including the 2.7 percent market basket update, the reduction of 0.6 percentage point for the multifactor productivity adjustment, and the 0.75 percentage point reduction in accordance with the Affordable Care Act. In addition, as discussed in section II.D. of the preamble of this final rule, this column includes the FY 2018 adjustment of 0.4588 percent on the national standardized amount required under section 15005 of the 21st Century Cures Act and, as discussed in section V.M. of the preamble of this final rule, the adjustment factor of (1/1.006) to remove the 1.006 temporary one-time adjustment made in FY 2017 to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 related to the 2-midnight policy. As a result, we are making a 1.2 percent update to the national standardized amount. This column also includes the update to the hospital-specific rates which includes the 2.7 percent market basket update, the reduction of 0.6 percentage point for the multifactor productivity adjustment, and the 0.75 percentage point reduction in accordance with the Affordable Care Act and, as discussed in section V.M. of the preamble of this final rule, the adjustment factor of (1/1.006) to remove the 1.006 temporary one-time adjustment made in FY 2017 to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 related to the 2-midnight policy. As a result, we are making a 0.75 percent update to the hospital-specific rates.

Overall, hospitals will experience a 1.2 percent increase in payments primarily due to the combined effects of the hospital update and the 0.4588 percent adjustment on the national standardized amount and the hospital update to the hospital-specific rate as well as the adjustment factor of (1/1.006) to remove the 1.006 temporary one-time adjustment made in FY 2017 to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 related to the 2-midnight policy to both the national standardized amount and the hospital-specific rate. Hospitals that are paid under the hospital-specific rate will experience a 0.75 percent increase in payments; therefore, hospital categories containing hospitals paid under the hospital-specific rate will experience a lower than average increase in payments.

b. Effects of the Changes to the MS–DRG Reclassifications and Relative Cost-Based Weights With Recalibration Budget Neutrality (Column 2)

Column 2 shows the effects of the changes to the MS–DRGs and relative weights with the application of the recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate classification changes in order to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. Consistent with section 1886(d)(4)(C)(iii) of the Act, we calculated a recalibration budget neutrality factor to account for the changes in MS–DRGs and relative weights to ensure that the overall payment impact is budget neutral.

As discussed in section II.E. of the preamble of this final rule, the FY 2018 MS–DRG relative weights will be 100 percent cost-based and 100 percent MS–DRGs. For FY 2018, the MS–DRGs are calculated using the FY 2016 MedPAR data grouped to the Version 35 (FY 2018) MS–DRGs. The methodology to calculate the relative weights and the reclassification changes to the GROUPER are described in more detail in section II.G. of the preamble of this final rule.

The ''All Hospitals'' line in Column 2 indicates that changes due to the MS–DRGs and relative weights will result in a 0.0 percent change in payments with the application of the recalibration budget neutrality factor of 0.997432 to the standardized amount. Hospital categories that generally treat more surgical cases than medical cases will experience a decrease in their payments under the relative weights for reasons that include the policies regarding operating room procedures described in section II.G. of the preamble of this final rule. Rural hospitals will experience a 0.2 percent increase in payments in part because rural hospitals tend to treat fewer surgical cases than medical cases, while teaching hospitals with more than 100 residents will experience a −0.2 percent decrease in payments in part because those hospitals treat more surgical cases than medical cases.

c. Effects of the Wage Index Changes (Column 3)

Column 3 shows the impact of updated wage data using FY 2014 cost report data, with the application of the wage budget neutrality factor. The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on the Core Based Statistical Areas (CBSAs) established by OMB. The current statistical standards used in FY 2018 are based on OMB standards published on February 28, 2013 (75 FR 37246 and 37252), and 2010 Decennial Census data (OMB Bulletin No. 13–01), as updated in OMB Bulletin No. 15–01. (We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963) for a full discussion on our adoption of the OMB labor market area delineations based on the 2010 Decennial Census data, effective beginning with the FY 2015 IPPS wage index, and to section III.A.2. of the preamble of the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913) for a discussion of our adoption of the CBSA updates in OMB Bulletin No. 15–01, which were effective beginning with the FY 2017 wage index.)

Section 1886(d)(3)(E) of the Act requires that, beginning October 1, 1993, we annually update the wage data used to calculate the wage index. In accordance with this requirement, the wage index for acute care hospitals for FY 2018 is based on data submitted for hospital cost reporting periods beginning on or after October 1, 2013 and before October 1, 2014. The estimated impact of the updated wage data using the FY 2014 cost report data and the OMB labor market area delineations on hospital payments is isolated in Column 3 by holding the other payment parameters constant in this simulation. That is, Column 3 shows the percentage change in payments when going from a model using the FY 2017 wage index, based on FY 2013 wage data, the labor-related share of 69.6 percent, under the OMB delineations and having a 100-percent occupational mix adjustment applied, to a model using the FY 2018 pre-reclassification wage index based on FY 2014 wage data with the labor-related share of 68.3 percent, under the OMB delineations, also having a 100-percent occupational mix adjustment applied, while holding other payment parameters such as use of the Version 35 MS–DRG GROUPER constant. The FY 2018 occupational mix adjustment is based on the CY 2013 occupational mix survey.

In addition, the column shows the impact of the application of the wage budget neutrality to the national standardized amount. In FY 2010, we began calculating separate wage budget neutrality and recalibration budget neutrality factors, in accordance with section 1886(d)(3)(E) of the Act, which specifies that budget neutrality to account for wage index changes or updates made under that subparagraph must be made without regard to the 62 percent labor-related share guaranteed under section 1886(d)(3)(E)(ii) of the Act. Therefore, for FY 2018, we calculated the wage budget neutrality factor to ensure that payments under updated wage data and the labor-related share of 68.3 percent are budget neutral without regard to the lower labor-related share of 62 percent applied to hospitals with a wage index less than or equal to 1.0. In other words, the wage budget neutrality is calculated under the assumption that all hospitals receive the higher labor-related share of the standardized amount. The FY 2018 wage budget neutrality factor is 1.001148, and the overall payment change is 0.0 percent.

Column 3 shows the impacts of updating the wage data using FY 2014 cost reports. Overall, the new wage data and the labor-related share, combined with the wage budget neutrality adjustment, will lead to no change for all hospitals as shown in Column 3.

In looking at the wage data itself, the national average hourly wage will increase 1.02 percent compared to FY 2017. Therefore, the only manner in which to maintain or exceed the previous year's wage index was to match or exceed the 1.02 percent increase in the national average hourly wage. Of the 3,298 hospitals with wage data for both FYs 2017 and 2018, 1,612 or 51.1 percent will experience an average hourly wage increase of 1.02 percent or more.

The following chart compares the shifts in wage index values for hospitals due to changes in the average hourly wage data for FY 2018 relative to FY 2017. Among urban hospitals, 4 will experience a decrease of 10 percent or more, and 4 urban hospitals will

experience an increase of 10 percent or more. Ninety-nine urban hospitals will experience an increase or decrease of at least 5 percent or more but less than 10 percent. Among rural hospitals, none will experience an increase of at least 5 percent or more, but 2 rural hospitals will experience a decrease of greater than or equal to 5 percent but less than 10 percent. Three rural hospitals will experience decreases of 10 percent or more. However, 787 rural hospitals will experience increases or decreases of less than 5 percent, while 2,390 urban hospitals will experience increases or decreases of less than 5 percent. Nine urban hospitals and no rural hospitals experience no change to their wage index.

These figures reflect changes in the ''pre-reclassified, occupational mix-adjusted wage index,'' that is, the wage index before the application of geographic reclassification, the rural and imputed floors, the out-migration adjustment, and other wage index exceptions and adjustments. (We refer readers to sections III.G. through III.L. of the preamble of this final rule for a complete discussion of the exceptions and adjustments to the wage index.) We note that the ''post-reclassified wage index'' or ''payment wage index,'' which is the wage index that includes all such exceptions and adjustments (as reflected in Tables 2 and 3 associated with this final rule, which are available via the Internet on the CMS Web site) is used to adjust the labor-related share of a hospital's standardized amount, either 68.3 percent or 62 percent, depending upon whether a hospital's wage index is greater than 1.0 or less than or equal to 1.0. Therefore, the pre-reclassified wage index figures in the following chart may illustrate a somewhat larger or smaller change than will occur in a hospital's payment wage index and total payment.

The following chart shows the projected impact of changes in the area wage index values for urban and rural hospitals.

FY 2018 percentage change in area wage index values	Number of hospitals	
	Urban	Rural
Increase 10 percent or more	4	0
Increase greater than or equal to 5 percent and less than 10 percent	50	0
Increase or decrease less than 5 percent	2,390	787
Decrease greater than or equal to 5 percent and less than 10 percent	49	2
Decrease 10 percent or more	4	3
Unchanged	9	0

d. Effects of MGCRB Reclassifications (Column 4)

Our impact analysis to this point has assumed acute care hospitals are paid on the basis of their actual geographic location (with the exception of ongoing policies that provide that certain hospitals receive payments on bases other than where they are geographically located). The changes in Column 4 reflect the per case payment impact of moving from this baseline to a simulation incorporating the MGCRB decisions for FY 2018.

By spring of each year, the MGCRB makes reclassification determinations that will be effective for the next fiscal year, which begins on October 1. The MGCRB may approve a hospital's reclassification request for the purpose of using another area's wage index value. Hospitals may appeal denials of MGCRB decisions to the CMS Administrator. Further, hospitals have 45 days from the date the IPPS proposed rule is issued in the **Federal Register** to decide whether to withdraw or terminate an approved geographic reclassification for the following year (we refer readers to the discussion of our clarification of this policy in section III.I.2. of the preamble to this final rule).

The overall effect of geographic reclassification is required by section 1886(d)(8)(D) of the Act to be budget neutral. Therefore, for purposes of this impact analysis, we are applying an adjustment of 0.988008 to ensure that the effects of the reclassifications under section 1886(d)(10) of the Act are budget neutral (section II.A. of the Addendum to this final rule). Geographic reclassification generally benefits hospitals in rural areas. We estimate that the geographic reclassification will increase payments to rural hospitals by an average of 1.4 percent. By region, all the rural hospital categories will experience increases in payments due to MGCRB reclassifications.

Table 2 listed in section VI. of the Addendum to this final rule and available via the Internet on the CMS Web site reflects the reclassifications for FY 2018.

e. Effects of the Rural Floor and Imputed Floor, Including Application of National Budget Neutrality (Column 5)

As discussed in section III.B. of the preamble of the FY 2009 IPPS final rule, the FY 2010 IPPS/RY 2010 LTCH PPS final rule, the FYs 2011, 2012, 2013, 2014, 2015, 2016, and 2017 IPPS/LTCH PPS final rules, and this FY 2018 final rule, section 4410 of Pub. L. 105–33 established the rural floor by requiring that the wage index for a hospital in any urban area cannot be less than the wage index received by rural hospitals in the same State. We would apply a uniform budget neutrality adjustment to the wage index.

The imputed floor, which is also included in the calculation of the budget neutrality adjustment to the wage index, was extended in FY 2012 for 2 additional years and in FY 2014 and FY 2015 for 1 additional year. Prior to FY 2013, only urban hospitals in New Jersey received the imputed floor. As discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53369), we established an alternative temporary methodology for the imputed floor, which resulted in an imputed floor for Rhode Island for FY 2013. For FY 2014 and FY 2015, we extended the imputed rural floor, as calculated under the original methodology and the alternative methodology. Due to the adoption of the new OMB labor market area delineations in FY 2015, the State of Delaware also became an all-urban State and thus eligible for an imputed floor. For FY 2016 and FY 2017, we extended the imputed floor for 1 year, as calculated under the original methodology and the alternative methodology, through September 30, 2016 and September 30, 2017, respectively. For FY 2018, we are extending the imputed rural floor for 1 year, as calculated under the original methodology and the alternative methodology, through September 30, 2018. As a result, New Jersey, Rhode Island, and Delaware will be able to receive an imputed floor through September 30, 2018. In New Jersey, 17 out of 64 hospitals will receive the imputed floor for FY 2018, 10 out of 11 hospitals in Rhode Island, and 6 out of 6 hospitals in Delaware.

The Affordable Care Act requires that we apply one rural floor budget neutrality factor to the wage index nationally, and we include the imputed floor in the calculation of this budget neutrality factor. We have calculated an FY 2018 rural floor and imputed floor budget neutrality factor to be applied to the wage index of 0.993348, which reduces wage indexes by 0.67 percent.

Column 5 shows the projected impact of the rural floor and imputed floor with the national rural floor and imputed floor budget neutrality factor applied to the wage index based on the OMB labor market area delineations. The column compares the post-reclassification FY 2018 wage index of providers before the rural floor and imputed floor adjustment and the post-reclassification FY 2018 wage index of providers with the rural floor and imputed floor adjustment based on the OMB labor market area delineations. Only urban hospitals can benefit from the rural and imputed floors. Because the provision is budget neutral, all other hospitals (that is, all rural hospitals and those urban hospitals to which the adjustment is not made) will experience a decrease in payments due to the budget neutrality adjustment that is applied nationally to their wage index.

We estimate that 400 hospitals will receive the rural and imputed floors in FY 2018. All IPPS hospitals in our model will have their wage index reduced by the rural floor budget neutrality adjustment of 0.993348. We project that, in aggregate, rural hospitals will experience a 0.67 percent decrease in payments as a result of the application of the rural floor budget neutrality because the rural hospitals do not benefit from the rural floor, but have their wage indexes downwardly

adjusted to ensure that the application of the rural floor is budget neutral overall. We project hospitals located in urban areas will experience no change in payments because increases in payments by hospitals benefitting from the rural floor offset decreases in payments by nonrural floor urban hospitals whose wage index is downwardly adjusted by the rural floor budget neutrality factor. Urban hospitals in the New England region will experience a 1.4 percent increase in payments primarily due to the application of the rural floor in Massachusetts and the imputed floor in Rhode Island. Thirty-six urban providers in Massachusetts are expected to receive the rural floor wage index value, including the rural floor budget neutrality adjustment, increasing payments overall to Massachusetts by an estimated $44 million. We estimate that Massachusetts hospitals will receive approximately a 1.3 percent increase in IPPS payments due to the application of the rural floor in FY 2018.

Urban Puerto Rico hospitals are expected to experience a 0.2 percent increase in payments as a result of the application of the rural floor.

There are 17 hospitals out of the 64 hospitals in New Jersey that will benefit from the extension of the imputed floor and will receive the imputed floor wage index value under the OMB labor market area delineations. Overall, New Jersey will receive a net decrease of $4 million in payments (to the nearest million) taking into account the 17 hospitals that will benefit from the imputed floor and the application of the national rural floor and imputed floor budget neutrality adjustment to all hospitals in the state. There are 10 hospitals out of the 11 hospitals in Rhode Island that will benefit from the extension of the imputed floor and will receive the imputed floor wage index value. Overall, Rhode Island will receive a net increase of $19 million in payments (to the nearest million) taking into account the 10 hospitals that will benefit from the imputed floor and the application of the national rural floor and imputed floor budget neutrality adjustment to all hospitals in the State. All 6 hospitals in Delaware will benefit from the extension of the imputed floor and will receive the imputed floor wage index value. Overall, Delaware will receive a net increase of $8 million in payments (to the nearest million) taking into account the 6 hospitals that will benefit from the imputed floor and the application of the national rural floor and imputed floor budget neutrality adjustment to all hospitals in the State.

In response to a public comment addressed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51593), we are providing the payment impact of the rural floor and imputed floor with budget neutrality at the State level. Column 1 of the following table displays the number of IPPS hospitals located in each State. Column 2 displays the number of hospitals in each State that will receive the rural or imputed floor wage index for FY 2018. Column 3 displays the percentage of total payments each State will receive or contribute to fund the rural floor and imputed floor with national budget neutrality. The column compares the post-reclassification FY 2018 wage index of providers before the rural floor and imputed floor adjustment and the post-reclassification FY 2018 wage index of providers with the rural and imputed floor adjustment. Column 4 displays the estimated payment amount that each State will gain or lose due to the application of the rural floor and imputed floor with national budget neutrality.

FY 2018 IPPS Estimated Payments Due to Rural and Imputed Floor With National Budget Neutrality

State	Number of hospitals (1)	Number of hospitals that will receive the rural or imputed floor (2)	Percent change in payments due to application of rural floor and imputed floor with budget neutrality (3)	Difference (in $ millions) (4)
Alabama	84	3	−0.3	−5
Alaska	6	4	1.4	3
Arizona	57	38	0.4	7
Arkansas	44	1	−0.3	−4
California	299	177	1.2	134
Colorado	47	4	0.4	5
Connecticut	30	7	0.1	2
Delaware	6	6	1.8	8
Washington, D.C.	7	0	−0.4	−2
Florida	171	17	−0.2	−15
Georgia	103	0	−0.3	−9
Hawaii	12	0	−0.3	−1
Idaho	14	0	−0.2	−1
Illinois	127	3	−0.4	−17
Indiana	85	0	−0.3	−8
Iowa	34	0	−0.3	−3
Kansas	53	0	−0.3	−3
Kentucky	66	0	−0.3	−5
Louisiana	94	2	−0.3	−5
Maine	17	0	−0.4	−2
Massachusetts	57	36	1.3	44
Michigan	94	0	−0.3	−14
Minnesota	49	0	−0.4	−8
Mississippi	60	0	−0.3	−4
Missouri	74	0	−0.2	−6
Montana	13	4	0	0
Nebraska	24	0	−0.3	−2
Nevada	23	0	−0.4	−3
New Hampshire	13	9	3.7	20
New Jersey	64	17	−0.1	−4
New Mexico	25	0	−0.2	−1
New York	154	11	−0.3	−23
North Carolina	84	0	−0.3	−10
North Dakota	6	0	−0.2	−1

FY 2018 IPPS ESTIMATED PAYMENTS DUE TO RURAL AND IMPUTED FLOOR WITH NATIONAL BUDGET NEUTRALITY—Continued

State	Number of hospitals (1)	Number of hospitals that will receive the rural or imputed floor (2)	Percent change in payments due to application of rural floor and imputed floor with budget neutrality (3)	Difference (in $ millions) (4)
Ohio	128	6	−0.3	−12
Oklahoma	84	4	−0.2	−3
Oregon	34	5	−0.3	−3
Pennsylvania	150	3	−0.4	−17
Puerto Rico	52	10	0.2	0
Rhode Island	11	10	5	19
South Carolina	56	0	−0.3	−5
South Dakota	17	0	−0.2	−1
Tennessee	91	3	−0.3	−8
Texas	310	4	−0.3	−21
Utah	31	1	−0.3	−2
Vermont	6	0	−0.2	0
Virginia	73	1	−0.3	−7
Washington	48	3	−0.2	−5
West Virginia	29	3	−0.1	−1
Wisconsin	66	8	−0.2	−3
Wyoming	10	0	−0.1	0

f. Effects of the Application of the Frontier State Wage Index and Out-Migration Adjustment (Column 6)

This column shows the combined effects of the application of section 10324(a) of the Affordable Care Act, which requires that we establish a minimum post-reclassified wage-index of 1.00 for all hospitals located in ''frontier States,'' and the effects of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, which provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index. These two wage index provisions are not budget neutral and increase payments overall by 0.1 percent compared to the provisions not being in effect.

The term ''frontier States'' is defined in the statute as States in which at least 50 percent of counties have a population density less than 6 persons per square mile. Based on these criteria, 5 States (Montana, Nevada, North Dakota, South Dakota, and Wyoming) are considered frontier States and 49 hospitals located in those States will receive a frontier wage index of 1.0000. Overall, this provision is not budget neutral and is estimated to increase IPPS operating payments by approximately $65 million. Rural and urban hospitals located in the West North Central region will experience an increase in payments by 0.3 and 0.7 percent, respectively, because many of the hospitals located in this region are frontier State hospitals.

In addition, section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index. Hospitals located in counties that qualify for the payment adjustment are to receive an increase in the wage index that is equal to a weighted average of the difference between the wage index of the resident county, post-reclassification and the higher wage index work area(s), weighted by the overall percentage of workers who are employed in an area with a higher wage index. There are an estimated 267 providers that will receive the out-migration wage adjustment in FY 2018. Rural hospitals generally qualify for the adjustment, resulting in a 0.2 percent increase in payments. This provision appears to benefit section 401 hospitals and RRCs in that they will each experience a 0.3 percent increase in payments. This out-migration wage adjustment also is not budget neutral, and we estimate the impact of these providers receiving the out-migration increase will be approximately $42 million.

g. Effects of the Expiration of MDH Special Payment Status (Column 7)

Column 7 shows our estimate of the changes in payments due to the expiration of MDH status, a nonbudget neutral payment provision. Section 205 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted on April 16, 2015) extended the MDH program (which, under previous law, was to be in effect for discharges on or before March 31, 2015 only) for discharges occurring on or after April 1, 2015, through FY 2017 (that is, for discharges occurring on or before September 30, 2017). Therefore, under current law, the MDH program will expire at the end of FY 2017. Hospitals that qualified to be MDHs receive the higher of payments made based on the Federal rate or the payments made based on the Federal rate amount plus 75 percent of the difference between payments based the Federal rate and payments based the hospital-specific rate (a hospital-specific cost-based rate). Because this provision was not budget neutral, the expiration of this payment provision results in a 0.1 percent decrease in payments overall. There are currently 159 MDHs, of which we estimate 96 would have been paid under the blended payment based on the Federal rate and hospital-specific rate if the MDH program had not expired. Because those 96 MDHs will no longer receive the blended payment and will be paid only under the Federal rate in FY 2018, it is estimated that those hospitals will experience an overall decrease in payments of approximately $119 million.

MDHs were generally rural hospitals, so the expiration of the MDH program will result in an overall decrease in payments to rural hospitals of 0.9 percent. Rural New England hospitals can expect a decrease in payments of 2.2 percent because 6 out of the 23 rural New England hospitals are MDHs that will lose this special payment status under the expiration of the program at the end of FY 2017. MDHs that would have been paid under the blended payment based on the Federal rate and hospital-specific rate can expect a decrease in payments of 12 percent.

h. Effects of All FY 2018 Changes (Column 8)

Column 8 shows our estimate of the changes in payments per discharge from FY 2017 and FY 2018, resulting from all changes reflected in this final rule for FY 2018. It

includes combined effects of the year to year change of the previous columns in the table.

The average increase in payments under the IPPS for all hospitals is approximately 1.3 percent for FY 2018 relative to FY 2017 and for this row is primarily driven by the changes reflected in Column 1. Column 8 includes the annual hospital update of 1.35 percent to the national standardized amount. This annual hospital update includes the 2.7 percent market basket update, the 0.6 percentage point reduction for the multifactor productivity adjustment, and the 0.75 percentage point reduction under section 3401 of the Affordable Care Act. As discussed in section II.D. of the preamble of this final rule, this column also includes the FY 2018 adjustment of 0.4588 percent on the national standardized amount. In addition, this column includes the adjustment factor of (1/1.006) to remove the 1.006 temporary one-time adjustment made in FY 2017 to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 related to the 2-midnight policy, which is discussed in section V.M. of the preamble of this final rule. Hospitals paid under the hospital-specific rate will receive a 0.75 percent hospital update. As described in Column 1, the annual hospital update with the adjustment of 0.4588 percent for hospitals paid under the national standardized amount, the adjustment of (1/1.006) to remove the 1.006 temporary one-time adjustment made in FY 2017 to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016, which is discussed in section V.M. of the preamble of this final rule, combined with the annual hospital update for hospitals paid under the hospital-specific rates will result in a 1.3 percent increase in payments in FY 2018 relative to FY 2017. There are also interactive effects among the various factors comprising the payment system that we are not able to isolate which contribute to our estimate of the changes in payments per discharge from FY 2017 and FY 2018 in Column 8.

Overall payments to hospitals paid under the IPPS due to the applicable percentage increase and changes to policies related to MS–DRGs, geographic adjustments, and outliers are estimated to increase by 1.3 percent for FY 2018. Hospitals in urban areas will experience a 1.4 percent increase in payments per discharge in FY 2018 compared to FY 2017. Hospital payments per discharge in rural areas are estimated to increase by 0.2 percent in FY 2018.

3. Impact Analysis of Table II

Table II presents the projected impact of the changes for FY 2018 for urban and rural hospitals and for the different categories of hospitals shown in Table I. It compares the estimated average payments per discharge for FY 2017 with the estimated average payments per discharge for FY 2018, as calculated under our models. Therefore, this table presents, in terms of the average dollar amounts paid per discharge, the combined effects of the changes presented in Table I. The estimated percentage changes shown in the last column of Table II equal the estimated percentage changes in average payments per discharge from Column 8 of Table I.

TABLE II—IMPACT ANALYSIS OF CHANGES FOR FY 2018 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM

[Payments per Discharge]

	Number of hospitals	Estimated average FY 2017 payment per discharge	Estimated average FY 2018 payment per discharge	FY 2018 changes
	(1)	(2)	(3)	(4)
All Hospitals	3,292	11,867	12,024	1.3
By Geographic Location:				
Urban hospitals	2,492	12,207	12,380	1.4
Large urban areas	1,340	12,881	13,059	1.4
Other urban areas	1,152	11,477	11,644	1.5
Rural hospitals	800	8,911	8,931	0.2
Bed Size (Urban):				
0–99 beds	648	9,730	9,814	0.9
100–199 beds	763	10,248	10,404	1.5
200–299 beds	441	11,079	11,244	1.5
300–499 beds	426	12,366	12,536	1.4
500 or more beds	214	15,011	15,228	1.5
Bed Size (Rural):				
0–49 beds	318	7,523	7,490	−0.4
50–99 beds	282	8,487	8,373	−1.4
100–149 beds	117	8,896	8,966	0.8
150–199 beds	44	9,292	9,410	1.3
200 or more beds	39	10,514	10,678	1.6
Urban by Region:				
New England	114	13,125	13,302	1.4
Middle Atlantic	315	13,819	13,965	1.1
South Atlantic	404	10,783	10,949	1.5
East North Central	385	11,537	11,727	1.7
East South Central	147	10,245	10,374	1.3
West North Central	160	11,915	12,131	1.8
West South Central	378	10,948	11,133	1.7
Mountain	162	12,824	12,896	0.6
Pacific	375	15,634	15,863	1.5
Puerto Rico	52	8,851	8,947	1.1
Rural by Region:				
New England	20	12,091	12,164	0.6
Middle Atlantic	53	8,891	8,812	−0.9
South Atlantic	125	8,274	8,269	−0.1
East North Central	115	9,224	9,144	−0.9
East South Central	154	7,900	7,987	1.1
West North Central	97	9,736	9,798	0.6
West South Central	154	7,539	7,588	0.6
Mountain	58	10,620	10,719	0.9

TABLE II—IMPACT ANALYSIS OF CHANGES FOR FY 2018 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM—Continued

[Payments per Discharge]

	Number of hospitals	Estimated average FY 2017 payment per discharge	Estimated average FY 2018 payment per discharge	FY 2018 changes
	(1)	(2)	(3)	(4)
Pacific	24	12,466	12,516	0.4
By Payment Classification:				
Urban hospitals	2,373	12,148	12,320	1.4
Large urban areas	1,354	12,867	13,046	1.4
Other urban areas	1,019	11,200	11,364	1.5
Rural areas	919	10,568	10,657	0.8
Teaching Status:				
Nonteaching	2,204	9,850	9,967	1.2
Fewer than 100 residents	839	11,372	11,534	1.4
100 or more residents	249	17,228	17,465	1.4
Urban DSH:				
Non-DSH	551	10,357	10,454	0.9
100 or more beds	1,543	12,512	12,690	1.4
Less than 100 beds	370	8,960	9,107	1.6
Rural DSH:				
SCH	257	9,526	9,579	0.6
RRC	293	11,384	11,569	1.6
100 or more beds	34	10,297	10,338	0.4
Less than 100 beds	244	7,035	6,765	−3.8
Urban teaching and DSH:				
Both teaching and DSH	863	13,579	13,767	1.4
Teaching and no DSH	92	11,410	11,520	1
No teaching and DSH	1,050	10,217	10,373	1.5
No teaching and no DSH	368	9,854	9,999	1.5
Special Hospital Types:				
RRC	263	11,165	11,361	1.8
SCH	316	10,774	10,861	0.8
SCH and RRC	131	11,265	11,362	0.9
Type of Ownership:				
Voluntary	1,914	12,058	12,213	1.3
Proprietary	863	10,392	10,553	1.6
Government	513	12,810	12,978	1.3
Medicare Utilization as a Percent of Inpatient Days:				
0–25	554	14,910	15,113	1.4
25–50	2,149	11,728	11,891	1.4
50–65	485	9,617	9,695	0.8
Over 65	103	7,591	7,444	−1.9
FY 2018 Reclassifications by the Medicare Geographic Classification Review Board:				
All Reclassified Hospitals	858	11,661	11,830	1.5
Non-Reclassified Hospitals	2,434	11,956	12,108	1.3
Urban Hospitals Reclassified	590	12,202	12,396	1.6
Urban Nonreclassified Hospitals	1,858	12,210	12,382	1.4
Rural Hospitals Reclassified	268	9,339	9,399	0.6
Rural Nonreclassified Hospitals	485	8,422	8,380	−0.5
All Section 401 Reclassified Hospitals:	166	12,504	12,679	1.4
Other Reclassified Hospitals (Section 1886(d)(8)(B))	47	8,122	8,173	0.6

H. Effects of Other Policy Changes

In addition to those policy changes discussed previously that we are able to model using our IPPS payment simulation model, we are making various other changes in this final rule. Generally, we have limited or no specific data available with which to estimate the impacts of these changes. Our estimates of the likely impacts associated with these other changes are discussed in this section.

1. Effects of Policy Relating to New Medical Service and Technology Add-On Payments

In section II.H. of the preamble to this final rule, we discuss three technologies for which we received applications for add-on payments for new medical services and technologies for FY 2018. We note that three applicants withdrew their applications prior to the issuance of the proposed rule, one applicant withdrew its application prior to the issuance of this final rule, and two applicants did not receive FDA approval for their technologies by the July 1 deadline. We also discuss the status of the new technologies that were approved to receive new technology add-on payments in FY 2017. As explained in the preamble to this final rule, add-on payments for new medical services and technologies under section 1886(d)(5)(K) of the Act are not required to be budget neutral.

As discussed in section II.H.6. of the preamble of this final rule, we are approving three applications (Bezlotoxumab (Zinplava™), EDWARDS INTUITY Elite™ Valve System (INTUITY) and Liva Nova Perceval Valve (Perceval), and Ustekinumab

(Stelara®)) for new technology add on payments for FY 2018. In addition, as we proposed, in this final rule, we are continuing to make new technology add-on payments for Defitelio® (Defibrotide), GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE), Idarucizumab and Vistogard™ (Uridine Triacetate) in FY 2018 because these four technologies are still considered new.

We note that new technology add-on payments for each case are limited to the lesser of (1) 50 percent of the costs of the new technology or (2) 50 percent of the amount by which the costs of the case exceed the standard MS–DRG payment for the case. Because it is difficult to predict the actual new technology add-on payment for each case, our estimates below are based on the increase in new technology add-on payments for FY 2018 as if every claim that would qualify for a new technology add-on payment would receive the maximum add-on payment. The following are estimates for FY 2018 for the four technologies that we are continuing to make new technology add-on payments in FY 2018.

- Based on the applicant's estimate from FY 2017, we currently estimate that new technology add-on payments for the Defitelio® will increase overall FY 2018 payments by $5,161,200 (maximum add-on payment of $75,900 * 68 patients).
- Based on the applicant's estimate for FY 2017, we currently estimate that new technology add-on payments for the GORE® EXCLUDER® IBE will increase overall FY 2018 payments by $5,685,750 (maximum add-on payment of $5,250 * 1,083 patients).
- Based on the applicant's estimate for FY 2017, we currently estimate that new technology add-on payments for Idarucizumab will increase overall FY 2018 payments by $14,766,500 (maximum add-on payment of $1,750 * 8,438 patients).
- Based on the applicant's estimate for FY 2017, we currently estimate that new technology add-on payments for Vistogard™ will increase overall FY 2018 payments by $3,009,750 (maximum add-on payment of $40,130 * 75 patients).

The following are estimates for FY 2018 for the three technologies that we are approving for new technology add-on payments beginning with FY 2018.

- Based on the applicant's estimate for FY 2018, we currently estimate that new technology add-on payments for Zinplava™ will increase overall FY 2018 payments by $2,857,600 (maximum add-on payment of $1,900 * 1,504 patients).
- Based on the estimates for INTUITY and Perceval for FY 2018 and using a weighted average, we currently estimate that new technology add-on payments for INTUITY and Perceval will increase overall FY 2018 payments by $14,841,749 (maximum add-on payment of $6,110.23 * 2,429 patients).
- Based on the applicant's estimate for FY 2018, we currently estimate that new technology add-on payments for Stelara® will increase overall FY 2018 payments by $400,800 (maximum add-on payment of $2,400 * 167 patients).

2. Effects of Changes to MS–DRGs Subject to the Postacute Care Transfer Policy and the MS–DRG Special Payment Policy

In section V.A. of the preamble of this final rule, we discuss our changes to the list of MS–DRGs subject to the postacute care transfer policy and the MS–DRG special payment policy. As reflected in Table 5 listed in section VI. of the Addendum to this final rule (which is available via the Internet on the CMS Web site), using criteria set forth in regulations at 42 CFR 412.4, we evaluated MS–DRG charge, discharge, and transfer data to determine which MS–DRGs qualify for the postacute care transfer and MS–DRG special payment policies. We note that we did not propose to make any changes in these payment policies in the FY 2018 IPPS/LTCH PPS proposed rule. As a result of finalization of our proposals to revise the MS–DRG classifications for FY 2018, which are discussed in section II.F. of the preamble of this final rule, we are adding three MS–DRGs to the list of MS–DRGs subject to the MS–DRG special payment policy. Column 4 of Table I in this Appendix A shows the effects of the changes to the MS–DRGs and the relative payment weights and the application of the recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate DRG classification changes in order to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. The analysis and methods for determining the changes due to the MS–DRGs and relative payment weights account for and include changes as a result of the changes to the MS–DRGs subject to the MS–DRG postacute care transfer and MS–DRG special payment policies. We refer readers to section I.G. of this Appendix A for a detailed discussion of payment impacts due to the MS–DRG reclassification policies for FY 2018.

3. Effects of the Changes to the Volume Decrease Adjustment for Sole Community Hospitals (SCHs)

In section V.C. of the preamble of this final rule, we discuss our proposed and finalized policies to modify the methodology used to calculate volume decrease adjustments for SCHs. We are prospectively requiring that the MACs compare Medicare revenue allocable to fixed costs from the cost reporting period when the hospital experienced the volume decrease to the hospital's fixed costs from that same cost reporting period when calculating a volume decrease adjustment. We also are providing that the cap will no longer be applied to the volume decrease adjustment calculation methodology in future periods. In addition, we are prospectively modifying the volume decrease adjustment process to no longer require that a hospital explicitly demonstrate that it appropriately adjusted the number of staff in inpatient areas of the hospital based on the decrease in the number of inpatient days and to no longer require the MACs to adjust the volume decrease adjustment payment amount for excess staffing. We estimate that these changes to the volume decrease adjustment will increase aggregate volume decrease adjustment payments by a total of approximately $15 million for cost reporting periods beginning in FY 2018. Given that the volume decrease adjustment is only available to SCHs and is predicated on the unanticipated nature of the volume decrease, it is difficult to predict how many hospitals will qualify for the adjustment in FY 2018. We assumed 20 hospitals will qualify for the adjustment in FY 2018 and that the additional amount of the volume decrease adjustment payment based on our methodology will be $750,000 per hospital.

4. Effects of Changes to Low-Volume Hospital Payment Adjustment Policy

In section V.E. of the preamble of this final rule, we discuss the expiration of the temporary changes to the low-volume hospital payment policy originally provided for by the Affordable Care Act and extended through FY 2017 by subsequent legislation. Effective for FY 2018 and subsequent years, qualifying hospitals must have less than 200 combined Medicare and non-Medicare discharges (instead of 1,600 Medicare discharges) and must be located more than 25 road miles from another subsection (d) hospital (instead of 15 road miles from another subsection (d) hospital). In this same section, we discuss our proposed and finalized parallel low-volume hospital payment adjustment regarding hospitals operated by the IHS or a Tribe. Under this finalized policy, an IHS hospital will be able to qualify for a low-volume hospital adjustment based on its distance to the nearest IHS hospital, and a non-IHS hospital will be able to qualify to receive a low-volume hospital adjustment based on its distance to the nearest non-IHS hospital. Based upon the best available data at this time, we estimate the expiration of the temporary changes to the low-volume hospital payment and the change to the low-volume payment adjustments will decrease aggregate low-volume payment adjustments from $316 million in FY 2017 to $4 million in FY 2018. This $312 million decrease in FY 2018 is based on an estimated $315 million decrease in payments from the expiration of the temporary changes to the low-volume hospital definition and payment adjustment methodology together with an estimated increase of $3 million in payments made to hospitals that are expected to qualify under our parallel low-volume hospital payment adjustment. These payment estimates were determined by identifying providers that, based on the best available data, are expected to qualify under the criteria that will apply in FY 2018 (that is, are located at least 25 miles from the nearest subsection (d) hospital and have less than 200 total discharges), and were determined from the same data used in developing the quantitative analyses of changes in payments per case discussed previously in section I.G. of this Appendix A.

5. Effects of the Changes to Medicare DSH and Uncompensated Care Payments for FY 2018

As discussed in section V.G. of the preamble of this final rule, under section 3133 of the Affordable Care Act, hospitals that are eligible to receive Medicare DSH payments will receive 25 percent of the

amount they previously would have received under the statutory formula for Medicare DSH payments under section 1886(d)(5)(F) of the Act. The remainder, equal to an estimate of 75 percent of what formerly would have been paid as Medicare DSH payments (Factor 1), reduced to reflect changes in the percentage of uninsured individuals and additional statutory adjustments (Factor 2), is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. Each hospital eligible for Medicare DSH payments will receive an additional payment based on its estimated share of the total amount of uncompensated care for all hospitals eligible for Medicare DSH payments. The uncompensated care payment methodology has redistributive effects based on the proportion of a hospital's uncompensated care relative to the uncompensated care for all hospitals eligible for Medicare DSH payments (Factor 3).

For FY 2018, we are establishing a Factor 2 of 58.01 percent determined using the uninsured estimates produced by CMS' Office of the Actuary (OACT) as part of the development of the National Health Expenditure Accounts (NHEA). Although we are continuing to use low-income insured patient days as a proxy for uncompensated care, for the first time, we are using these data in combination with data on uncompensated care costs from Worksheet S–10 in the calculation of Factor 3. The uncompensated care payment methodology has redistributive effects based on the proportion of a hospital's uncompensated care relative to the total uncompensated care for all hospitals eligible for Medicare DSH payments. The change to Medicare DSH payments under section 3133 of the Affordable Care Act is not budget neutral.

In this final rule, we are establishing the amount to be distributed as uncompensated care payments to DSH eligible hospitals, which for FY 2018 is $6,766,695,163.56. This figure represents 75 percent of the amount that otherwise would have been paid for Medicare DSH payment adjustments adjusted by a Factor 2 of 58.01 percent. For FY 2017, the amount available to be distributed for uncompensated care was $5,977,483,146.86, or 75 percent of the amount that otherwise would have been paid for Medicare DSH payment adjustments adjusted by a Factor 2 of 55.36 percent. To calculate Factor 3 for FY 2018, we used an average of data computed using Medicaid days from hospitals' 2012 and 2013 cost reports from the March 2017 update of the HCRIS database, uncompensated care costs from hospitals' 2014 cost reports from the same extract of HCRIS, Medicaid days from 2012 cost report data submitted to CMS by IHS hospitals, and SSI days from the FY 2014 and FY 2015 SSI ratios. For each eligible hospital, we calculated an individual Factor 3 for cost reporting years FYs 2012, 2013, and 2014. We then added the individual amounts and divided the sum by the number of cost reporting periods with data to calculate an average Factor 3 for FY 2018. For purposes of this final rule, as we proposed, we used the most recent data from the March 2017 update of the HCRIS database for the Medicaid days component of the Factor 3 calculation as well as for the Worksheet S–10 uncompensated care cost component.

The FY 2018 policy of using data from hospitals' FY 2012, FY 2013, and FY 2014 cost reporting years to determine Factor 3 is based on our FY 2017 final policy (81 FR 56943 through 56973), which is in contrast to the methodology used in FY 2016, when we used Medicaid days from the more recent of a hospital's full year 2012 *or* 2011 cost report from the March 2015 update of the HCRIS database, Medicaid days from 2012 cost report data submitted to CMS by IHS hospitals, and SSI days from the FY 2013 SSI ratios to calculate Factor 3. In addition, as explained in section V.G.4.c. of the preamble of this final rule, we are making several additional modifications to the Factor 3 methodology: (1) To annualize Medicaid data and uncompensated care data if a hospital's cost report does not equal 12 months of data; (2) to apply a scaling factor to the uncompensated care payment amount calculated for each DSH eligible hospital so that total uncompensated care payments are consistent with the estimated amount available to make uncompensated care payments for FY 2018; (3) to apply statistical trims to the CCRs on Worksheet S–10 that are considered anomalies to ensure reasonable CCRs are used to convert charges to costs for purposes of determining uncompensated care costs; (4) to calculate Factor 3 for Puerto Rico hospitals, all-inclusive rate providers, and Indian Health Service and Tribal hospitals by substituting data regarding low-income insured days for FY 2013 for the Worksheet S–10 data on uncompensated care costs from FY 2014 cost reports, and (5) to determine the ratio of uncompensated care costs relative to total operating costs on the hospital's 2014 cost report (as of March 2017), and in cases where the ratio of uncompensated care costs relative to total operating costs exceeds 50 percent, to determine the ratio of uncompensated care costs to total operating costs from the hospital's 2015 cost report (as of March 2017) and apply that ratio to the hospital's total operating costs from its 2014 cost report to determine uncompensated cast costs for FY 2014.

We also are continuing the policies that were finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50020 through 50022) to address several specific issues concerning the process and data to be employed in determining Factor 3 in the case of hospital mergers for FY 2018 and subsequent years, as well as continuing the policies finalized in the FY 2017 IPPS/LTCH PPS final rule concerning the methodology for calculating each hospital's relative share of uncompensated care, such as combining data from multiple cost reports beginning in the same fiscal year and calculating Factor 3 based on an average of the three individual Factor 3s for FYs 2012, 2013, and 2014, determined by adding the Factor 3 values for these years, and dividing by the number of cost reporting periods with data.

To estimate the impact of the combined effect of changes in Factors 1 and 2, as well as the changes to the data used in determining Factor 3, on the calculation of Medicare DSH payments, including both empirically justified Medicare DSH payments and uncompensated care payments, we compared total DSH payments estimated in the FY 2017 IPPS/LTCH PPS final rule to total DSH payments estimated in this FY 2018 IPPS/LTCH PPS final rule. For FY 2017, for each hospital, we calculated the sum of: (1) 25 percent of the estimated amount of what would have been paid as Medicare DSH in FY 2017 in the absence of section 3133 of the Affordable Care Act; and (2) 75 percent of the estimated amount of what would have been paid as Medicare DSH payments in the absence of section 3133 of the Affordable Care Act, adjusted by a Factor 2 of 55.36 percent and multiplied by a Factor 3 calculated as described in the FY 2017 IPPS/LTCH PPS final rule. For FY 2018, we calculated the sum of: (1) 25 percent of the estimated amount of what would be paid as Medicare DSH payments in FY 2018 absent section 3133 of the Affordable Care Act; and (2) 75 percent of the estimated amount of what would be paid as Medicare DSH payments absent section 3133 of the Affordable Care Act, adjusted by a Factor 2 of 58.01 percent and multiplied by a Factor 3 calculated using the methodology described above.

Our analysis included 2,427 hospitals that are projected to be eligible for DSH in FY 2018. It did not include hospitals that had terminated their participation in the Medicare program as of July 1, 2017, Maryland hospitals, and SCHs that are expected to be paid based on their hospital-specific rates. In addition, data from merged or acquired hospitals were combined under the surviving hospital's CCN, and the nonsurviving CCN was excluded from the analysis. The estimated impact of the changes to Factors 1, 2, and 3 across all hospitals projected to be eligible for DSH payments in FY 2018, by hospital characteristic, is presented in the following table.

MODELED DISPROPORTIONATE SHARE HOSPITAL PAYMENTS FOR ESTIMATED FY 2018 DSHS BY HOSPITAL TYPE: MODEL DSH $ (IN MILLIONS) FROM FY 2017 TO FY 2018

	Number of estimated DSHs	FY 2017 final rule estimated DSH $ (in millions)	FY 2018 final rule estimated DSH $ (in millions)	Dollar difference: FY 2017–FY 2018 (in millions)	Percent change **
	(1)	(2)	(3)	(4)	(5)
Total	2,427	$9,553	$10,626	$1,073	11.2
By Geographic Location:					
Urban Hospitals	1,930	9,113	10,111	997	10.9
Large Urban Areas	1,036	5,717	6,371	654	11.4
Other Urban Areas	894	3,396	3,739	343	10.1
Rural Hospitals	497	439	516	76	17.3
Bed Size (Urban):					
0 to 99 Beds	336	185	236	51	27.7
100 to 249 Beds	841	2,154	2,387	234	10.8
250+ Beds	753	6,775	7,487	712	10.5
Bed Size (Rural):					
0 to 99 Beds	369	190	235	44	23.3
100 to 249 Beds	114	193	220	27	14.1
250+ Beds	14	56	60	5	8.4
Urban by Region:					
New England	91	387	411	24	6.2
Middle Atlantic	241	1,570	1,644	74	4.7
South Atlantic	314	1,724	2,030	307	17.8
East North Central	322	1,252	1,374	123	9.8
East South Central	130	566	618	52	9.3
West North Central	104	439	495	56	12.7
West South Central	253	1,165	1,448	283	24.3
Mountain	121	448	498	50	11.2
Pacific	314	1,448	1,463	16	1.1
Puerto Rico	40	116	129	13	11.1
Rural by Region:					
New England	12	16	21	5	32.2
Middle Atlantic	25	33	32	−1	−3.8
South Atlantic	85	92	114	23	24.9
East North Central	68	44	58	13	30.2
East South Central	135	141	149	8	5.5
West North Central	30	19	23	4	22.4
West South Central	110	72	92	20	27.4
Mountain	27	15	21	5	32.5
Pacific	5	7	6	−1	−11.2
By Payment Classification:					
Urban Hospitals	1,920	9,106	10,101	995	10.9
Large Urban Areas	1,036	5,717	6,371	654	11.4
Other Urban Areas	884	3,389	3,730	341	10.1
Rural Hospitals	507	447	525	78	17.5
Teaching Status:					
Nonteaching	1,516	2,955	3,270	315	10.7
Fewer than 100 residents	667	3,213	3,496	282	8.8
100 or more residents	244	3,384	3,860	476	14.1
Type of Ownership:					
Voluntary	1,431	5,971	6,543	573	9.6
Proprietary	547	1,650	1,653	3	0.2
Government	449	1,932	2,430	498	25.8
Medicare Utilization Percent:					
Missing or Unknown	4	1	1	1	88.5
0 to 25	425	2,972	3,369	397	13.4
25 to 50	1,642	6,218	6,834	616	9.9
50 to 65	310	352	409	57	16.3
Greater than 65	46	11	13	2	17.7

Source: Dobson|DaVanzo analysis of 2012–2014 Hospital Cost Reports.

* Dollar DSH calculated by [0.25 * estimated section 1886(d)(5)(F) payments] + [0.75 * estimated section 1886(d)(5)(F) payments * Factor 2 * Factor 3]. When summed across all hospitals projected to receive DSH payments, DSH payments are estimated to be $9,553 million in FY 2017 and $10,626 million in FY 2018.

** Percentage change is determined as the difference between Medicare DSH payments modeled for the FY 2018 IPPS/LTCH PPS final rule (column 3) and Medicare DSH payments modeled for the FY 2017 IPPS/LTCH PPS final rule (column 2) divided by Medicare DSH payments modeled for the FY 2017 final rule (column 2) 1 times 100 percent.

Changes in projected FY 2018 DSH payments from DSH payments in FY 2017 are primarily driven by (1) changes to Factor 1, which increased from $10.797 billion to $11.665 billion; (2) changes to Factor 2, which increased from 55.36 percent to 58.01

percent; (3) changes to the data used to determine Factor 3; and (4) changes to the number of DSH-eligible hospitals within a given hospital type. The impact analysis found that, across all projected DSH eligible hospitals, FY 2018 DSH payments are estimated at approximately $10.626 billion, or an increase of approximately 11.2 percent from FY 2017 DSH payments (approximately $9.553 billion). While these changes result in a net increase in the amount available to be distributed in uncompensated care payments, DSH payments to select hospital types are expected to decrease. This redistribution of DSH payments is caused by changes in the data used to determine Factor 3 and changes in the number of DSH-eligible hospitals within a given hospital type.

As seen in the above table, percent changes in DSH payments of less than 11.2 percent indicate that hospitals within the specified category are projected to experience a smaller increase in DSH payments, on average, compared to the universe of projected FY 2018 DSH hospitals. Conversely, percent changes in DSH payments that are greater than 11.2 percent indicate a hospital type is projected to have a larger increase than the overall percent change on average. The variation in the distribution of DSH payments by hospital characteristic is largely dependent on the change in a given hospital's number of Medicaid days and SSI days for purposes of the low-income insured days proxy between FY 2017 and FY 2018, as well as on its uncompensated care costs as reported on its FY 2014 Worksheet S–10.

Many rural hospitals, grouped by geographic location, payment classification, and bed size, are projected to experience a larger increase in DSH payments than their urban counterparts. Overall, urban hospitals are projected to receive a 10.9 percent increase in DSH payments, and rural hospitals are projected to receive a 17.3 percent increase in DSH payments. However, only smaller and medium-sized rural hospitals are projected to receive increases in DSH payments that are, on average, higher than the 11.2 percent change across all hospitals that are projected to be eligible for DSH in FY 2018, with rural hospitals that have 0–99 beds projected to experience a 23.3 percent payment increase, those with 100–249 beds projected to receive a 14.1 percent increase, and larger rural hospitals with 250+ beds projected to experience an 8.4 percent payment increase. This trend is somewhat consistent with urban hospitals, in which the smallest urban hospitals (0– 99 beds) are projected to receive an increase in DSH payments of 27.7 percent. Medium-sized hospitals (100–250 beds) and larger hospitals (250+ beds) are projected to receive increases of 10.8 and 10.5 percent in DSH payments, respectively, which are relatively consistent with the overall average.

By region, projected DSH payment increases for urban hospitals are smallest in the New England, Middle Atlantic, East North Central, and East South Central, and Pacific regions. The South Atlantic, West North Central, and West South Central region hospitals are projected to receive increases in DSH payments that are, on average, larger than the 11.2 percent change across all hospitals projected to be eligible for DSH in FY 2018. Increases in remaining urban hospital regions are generally consistent with the overall average percent increase of 11.2 percent. Regionally, rural hospitals are projected to receive a wider range of increases. Rural hospitals in the Middle Atlantic and Pacific regions are expected to receive a decrease in DSH payments, while increases that are, on average, smaller than the 11.2 overall percent change are projected for the East South Central region. Increases are projected to be substantially larger than the overall average in many regions, including New England, South Atlantic, East North Central, West North Central, West South Central, and Mountain.

Teaching hospitals with 100 or more residents are projected to receive, on average, larger increases than the overall percent change of 11.2 percent, with a projected increase of 14.1 percent. Conversely, smaller teaching hospitals with fewer than 100 residents are projected to receive a smaller increase than the overall average, at 8.8 percent. Government hospitals are projected to receive a larger than average 25.8 percent increase, while voluntary hospitals are expected to receive increases somewhat smaller than the overall average (9.6 percent). Proprietary hospitals are expected to receive almost no change in DSH payments. Hospitals with 25 to 50 percent Medicare utilization are projected to receive increases in DSH payments slightly below the overall average at 9.9 percent, while all other hospitals are projected to receive larger increases.

6. Effects of Reduction Under the Hospital Readmissions Reduction Program

In section V.I. of the preamble of this final rule, we discuss our finalized proposals for the FY 2018 Hospital Readmissions Reduction Program (established under section 3025 of the Affordable Care Act), which requires a reduction to a hospital's base operating MS–DRG payments to account for excess readmissions. In this final rule, we estimate that 2,577 hospitals would have their base operating MS–DRG payments reduced by their proposed proxy FY 2018 hospital-specific readmissions adjustment. As a result, we estimate that the Hospital Readmissions Reduction Program would save approximately $556 million in FY 2018, an increase of $24 million over the estimated FY 2017 savings. This estimate is based on the same data used in developing the quantitative analyses of proposed changes in payments per case discussed previously in section I.G. of this Regulatory Impact Analysis, in conjunction with the FY 2017 hospital-specific readmissions adjustment factors and the proxy FY 2018 hospital-specific readmissions adjustment factors found in Table 15 of this final rule (available only through the Internet as described in section VI. of the Addendum to this final rule).

The table and analysis below illustrate the estimate of the financial impact of the implementation methodology for the provisions of the 21st Century Cures Act, as outlined in this final rule. We are presenting the estimated impact of the finalized methodology on hospitals by hospital characteristic.

The table presents results of hospitals stratified into quintiles based on the proportion of dual-eligible beneficiaries among Medicare FFS and managed care patients discharged between July 1, 2013 and June 30, 2016. Hospital excess readmission ratios (ERRs) are assessed relative to their peer group median and a neutrality modifier is applied to the payment reduction to maintain budget neutrality. The table includes three penalty metrics: Average payment reduction, total Medicare savings, and share of payment adjustments as a percentage of total payments. The average payment reduction is the average reduction in Medicare DRG payments of hospitals with a specified characteristic. The total Medicare savings column shows the total estimated penalties borne by hospitals with that characteristic. The share of payment adjustments is total Medicare savings for all hospitals with that characteristic as a percentage of all DRG payments for FY 2016 (October 1, 2015 to September 30, 2016). Because the payment reduction is applied to hospitals' base DRG payments, hospitals with more discharges will contribute a larger amount of Medicare savings to the group total of Medicare savings. For example, under the finalized methodology, the share of payment adjustments as a percentage of all DRG payments for urban hospitals is 0.63 percent. This means that total penalties for all urban hospitals are 0.63 percent of total payments for urban hospitals (that is, the ratio of total penalties to total DRG payments is 0.63 percent). The metric allows us to compare the financial impact of the method for assessing penalties between hospitals with different numbers of beds even though larger hospitals tend to generate higher total Medicare savings since their payment reduction is applied to more DRG payments. Measuring the financial impact on hospitals as a proportion of total DRG payments allows us to account for differences in the amount of DRG payments for hospitals within the group when comparing the financial impact of the program on different groups of hospitals.

THE IMPACT OF THE FINALIZED CHANGES TO THE HOSPITAL READMISSIONS REDUCTION PROGRAM PAYMENT ADJUSTMENT FORMULA BY HOSPITAL CHARACTERISTIC

Hospital characteristic	Number of hospitals	Penalty reduction (%)	Total medicare savings	Share of payment adjustments as a percentage of all base operating DRG payments (%)
All Hospitals	3,074	0.60	$565,847,690	0.63
By Geographic Location:				
Urban	2,295	0.63	523,183,133	0.63
Rural	779	0.53	42,664,557	0.61
By Bed Size:				
1–99 beds	1,099	0.51	40,264,581	0.58
100–199 beds	881	0.68	123,751,723	0.71
200–299 beds	452	0.71	122,943,199	0.71
300–399 beds	279	0.61	89,688,666	0.63
400–499 beds	152	0.53	54,484,491	0.53
500 or more beds	211	0.55	134,715,029	0.57
By Teaching Status:				
Non-teaching	2,038	0.60	246,681,611	0.70
Teaching	1,036	0.60	319,166,078	0.59
Fewer than 100 residents	787	0.62	208,876,515	0.63
100 or more residents	249	0.51	110,289,563	0.51
By Ownership Type:				
Government	482	0.49	58,536,682	0.54
Proprietary	751	0.72	122,880,821	0.87
Voluntary	1,820	0.59	384,262,881	0.59
By Safety-net Status:				
Safety net hospitals	621	0.49	94,429,377	0.54
Non-safety net hospitals	2,453	0.63	471,418,312	0.65
By DSH Payment Eligibility:				
Not eligible	460	0.64	59,681,863	0.65
DSH payment eligible	2,614	0.60	506,165,827	0.63
By DSH Patient Percentage Quintile:				
First Quintile	560	0.64	79,746,089	0.65
Second Quintile	632	0.66	132,231,066	0.72
Third Quintile	633	0.60	126,404,719	0.62
Fourth Quintile	628	0.63	133,036,439	0.63
Fifth Quintile	621	0.49	94,429,377	0.54
By Medicare Cost Report (MCR) Percent:				
0–24	401	0.38	45,026,649	0.42
25–49	2,071	0.62	433,616,692	0.64
50 and over	592	0.69	87,133,066	0.80
By Region:				
New England	129	0.63	41,123,715	0.74
Middle Atlantic	352	0.78	108,046,217	0.81
South Atlantic	511	0.78	132,626,599	0.78
East North Central	480	0.58	85,657,162	0.60
East South Central	288	0.74	52,465,078	0.84
West North Central	250	0.44	26,564,022	0.39
West South Central	481	0.55	54,135,151	0.57
Mountain	219	0.47	22,147,627	0.44
Pacific	364	0.35	43,082,119	0.36

Notes: Results based on July 1, 2013 through June 30, 2016 discharges among subsection (d) and Maryland hospitals only. Although data from all subsection (d) and Maryland hospitals are used in calculations of each hospital's ERR, this table does not include results for Maryland hospitals. This table only includes results for hospitals who are eligible for a penalty under the program on the basis of having at least 25 eligible discharges for at least one measure. Hospitals are stratified into quintiles based on the proportion of dual-eligible beneficiaries for the 3-year FY 2018 performance period. Hospital penalties are scaled by a neutrality modifier of 0.9481 to maintain budget neutrality. To calculate the payment adjustment as a proportion of total base operating DRG payments this analysis used MedPAR data to calculate the total base operating DRG payments from October 1, 2015 through September 30, 2016 (FY 2016). The group average share of payment adjustments as a percentage of all DRG payments is calculated as the sum of all Medicare savings for the group of hospitals divided by total FY 2016 base operating DRG payments for all hospitals in that group. Hospital characteristics from the FY 2018 Hospital Inpatient Prospective Payment System (IPPS) proposed rule impact file. Data on SSI ratio comes from FY 2014 SSI data file. The total number of hospitals with hospital characteristics data do not add up to the total number of hospitals included in the FY 2018 Hospital Readmissions Reduction Program because not all hospitals have data for all characteristics. A hospital is considered a teaching hospital if it has an IME adjustment factor for Operation PPS (TCHOP) greater than zero and is considered a DSH hospital if it has a DSH patient percentage greater than zero. A hospital is a safety-net hospital if they are in the top DSH quintile. MCR percent is the percentage of total inpatient stays from Medicare patients.

The estimated impact of the finalized stratified methodology for the FY 2019 Hospital Readmissions Reduction Program compared to the current methodology according to this metric is shown in the table below. The table is based on results when

hospitals are stratified into quintiles based on the proportion of dual-eligible beneficiaries among Medicare fee-for-service and managed care patients discharged between July 1, 2013 through June 30, 2016. The table shows the share of payment adjustments as a percentage of all DRG payments for each group of hospitals. The group share is calculated as the sum of penalties for all hospitals with that characteristic over the sum of all DRG payments for those hospitals between October 1, 2015 and September 30, 2016 (FY 2016).

PENALTY AS SHARE OF PAYMENT WHEN HOSPITALS ARE STRATIFIED INTO QUINTILES USING THE 3-YEAR DUAL PROPORTION AMONG FFS AND MANAGED CARE PATIENTS, BY HOSPITAL CHARACTERISTIC FOR THE CURRENT AND FINALIZED PAYMENT ADJUSTMENT FACTOR METHODOLOGIES

Hospital characteristic	Current methodology: FY 2018 hospital readmissions reduction program (%)	Finalized FY 2019 methodology: median plus neutrality modifier (NM = 0.9481) (%)
All Hospitals	0.63	0.63
Urban Status:		
Urban	0.63	0.63
Rural	0.64	0.61
Bed Size:		
1–99 beds	0.57	0.58
100–199 beds	0.72	0.71
200–299 beds	0.71	0.71
300–399 beds	0.64	0.63
400–499 beds	0.52	0.53
500 or more beds	0.57	0.57
Teaching Status:		
Non-teaching	0.69	0.70
Teaching	0.59	0.59
Fewer than 100 residents	0.62	0.63
100 or more residents	0.54	0.51
Ownership:		
Government	0.55	0.54
Proprietary	0.88	0.87
Voluntary	0.59	0.59
Safety-net Status:		
Safety-net hospitals	0.63	0.54
Nonsafety-net hospitals	0.63	0.65
DSH Payment Eligible:		
Not eligible	0.59	0.65
DSH payment eligible	0.63	0.63
DSH Patient Percentage Quintile:		
First Quintile	0.59	0.65
Second Quintile	0.68	0.72
Third Quintile	0.61	0.62
Fourth Quintile	0.64	0.63
Fifth Quintile	0.63	0.54
MCR percentage:		
0–24	0.45	0.42
25–49	0.63	0.64
50 or more	0.79	0.80
Region:		
New England	0.76	0.74
Middle Atlantic	0.84	0.81
South Atlantic	0.76	0.78
East North Central	0.60	0.60
East South Central	0.81	0.84
West North Central	0.37	0.39
West South Central	0.55	0.57
Mountain	0.41	0.44

PENALTY AS SHARE OF PAYMENT WHEN HOSPITALS ARE STRATIFIED INTO QUINTILES USING THE 3-YEAR DUAL PROPORTION AMONG FFS AND MANAGED CARE PATIENTS, BY HOSPITAL CHARACTERISTIC FOR THE CURRENT AND FINALIZED PAYMENT ADJUSTMENT FACTOR METHODOLOGIES—Continued

Hospital characteristic	Current methodology: FY 2018 hospital readmissions reduction program (%)	Finalized FY 2019 methodology: median plus neutrality modifier (NM = 0.9481) (%)
Pacific	0.41	0.36

Notes: Results based on July 1, 2013 through June 30, 2016 discharges among subsection (d) and Maryland hospitals only. Although data from all subsection (d) and Maryland hospitals are used in calculations of each hospital's ERR, this table does not include results for Maryland hospitals. This table only includes results for hospitals who are eligible for a penalty under the program on the basis of having at least 25 eligible discharges for at least one measure. Under the finalized methodology, hospitals are stratified into quintiles based on the proportion of FFS and managed care dual-eligible beneficiaries for the 3-year FY 2018 performance period. To calculate the payment adjustment as a proportion of total FY 2016 base operating DRG payments this analysis used MedPAR data to calculate the total base operating DRG payments from October 1, 2015 through September 30, 2016 (FY 2016). The group average share of payment adjustments as a percentage of all DRG payments is calculated as the sum of all Medicare savings for the group of hospitals divided by total base operating DRG payments for all hospitals in that group. Hospital characteristics from the FY 2018 Hospital Inpatient Prospective Payment System (IPPS) proposed rule impact file. Data on SSI ratio comes from FY 2014 SSI data file. The total number of hospitals with hospital characteristics data do not add up to the total number of hospitals included in the FY 2018 Hospital Readmissions Reduction Program because not all hospitals have data for all characteristics. A hospital is considered a teaching hospital if it has an IME adjustment factor for Operation PPS (TCHOP) greater than zero and is considered a DSH hospital if it has a DSH patient percentage greater than zero. A hospital is a safety-net hospitals if they are in the top DSH quintile. MCR percent is the percentage of total inpatient stays from Medicare patients.

7. Effects of Changes Under the FY 2018 Hospital Value-Based Purchasing (VBP) Program

In section V.J. of the preamble of this final rule, we discuss the Hospital VBP Program under which the Secretary makes value-based incentive payments to hospitals based on their performance on measures during the performance period with respect to a fiscal year. These incentive payments will be funded for FY 2018 through a reduction to the FY 2018 base operating DRG payment amounts for all discharges for participating hospitals for such fiscal year, as required by section 1886(o)(7)(B) of the Act. The applicable percentage for FY 2018 and subsequent years is 2 percent. The total amount available for value-based incentive payments must be equal to the total amount of reduced payments for all hospitals for the fiscal year, as estimated by the Secretary.

In section V.J.1.b. of the preamble of this final rule, we estimate the available pool of funds for value-based incentive payments in the FY 2018 program year, which, in accordance with section 1886(o)(7)(C)(v) of the Act, will be 2.00 percent of base operating DRG payments, or a total of approximately $1.9 billion. This estimated available pool for FY 2018 is based on the historical pool of hospitals that were eligible to participate in the FY 2017 program year and the payment information from the March 2017 update of the FY 2016 MedPAR file.

The estimated impacts of the FY 2018 program year by hospital characteristic, found in the table below, are based on historical TPSs. We used the FY 2017 program year's TPSs to calculate the proxy adjustment factors used for this impact analysis. These are the most recently available scores that hospitals were given an opportunity to review and correct. The proxy adjustment factors use estimated annual base operating DRG payment amounts derived from the March 2017 update to the FY 2016 MedPAR file. The proxy adjustment factors can be found in Table 16A associated with this final rule (available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-For-Service-Payment/AcuteInpatientPPS/index.html*).

The impact analysis shows that, for the FY 2018 program year, the number of hospitals that would receive an increase in their base operating DRG payment amounts is higher than the number of hospitals that would receive a decrease. Among urban hospitals, those in the New England, South Atlantic, East North Central, East South Central, West North Central, West South Central, Mountain, and Pacific regions would have an increase, on average, in their base operating DRG payment amounts. Urban hospitals in the Middle Atlantic region would receive an average decrease in their base operating DRG payment amounts. Among rural hospitals, those in all geographic regions would have an increase, on average, in their base operating DRG payment amounts.

On average, hospitals that receive a higher (over 65) percent of DSH payments would receive decreases in base operating DRG payment amounts. With respect to hospitals' Medicare utilization as a percent of inpatient days (MCR), those hospitals with an MCR above 65 percent would have the largest average increase in base operating DRG payment amounts.

Non-teaching hospitals would have an average increase, and teaching hospitals would experience an average decrease in base operating DRG payment amounts.

IMPACT ANALYSIS OF BASE OPERATING DRG PAYMENT AMOUNT CHANGES RESULTING FROM THE FY 2018 HOSPITAL VBP PROGRAM

	Number of hospitals	Average percentage change
By Geographic Location:		
All Hospitals	2,955	0.183
Large Urban	1,215	0.092
Other Urban	1,060	0.154
Rural Area	680	0.392
Urban hospitals	*2,275*	*0.121*
0–99 beds	487	0.689
100–199 beds	720	0.079
200–299 beds	434	−0.038
300–499 beds	423	−0.160
500 or more beds	211	−0.160

IMPACT ANALYSIS OF BASE OPERATING DRG PAYMENT AMOUNT CHANGES RESULTING FROM THE FY 2018 HOSPITAL VBP PROGRAM—Continued

	Number of hospitals	Average percentage change
Rural hospitals	*680*	*0.392*
0–49 beds	209	0.608
50–99 beds	275	0.400
100–149 beds	112	0.243
150–199 beds	45	0.054
200 or more beds	39	−0.009
By Region:		
Urban By Region	2,275	0.121
New England	110	0.072
Middle Atlantic	297	−0.119
South Atlantic	387	0.026
East North Central	364	0.217
East South Central	135	0.010
West North Central	152	0.451
West South Central	320	0.194
Mountain	156	0.058
Pacific	354	0.203
Rural By Region	680	0.392
New England	19	0.539
Middle Atlantic	52	0.196
South Atlantic	111	0.540
East North Central	106	0.420
East South Central	126	0.172
West North Central	85	0.502
West South Central	107	0.257
Mountain	52	0.740
Pacific	22	0.504
By MCR Percent:		
0–25	420	0.121
25–50	2,022	0.167
50–65	468	0.279
Over 65	41	0.440
Missing	4	0.789
By DSH Percent:		
0–25	1,221	0.359
25–50	1,389	0.083
50–65	189	0.025
Over 65	156	−0.118
By Teaching Status:		
Non-Teaching	1,905	0.316
Teaching	1,050	−0.059

Actual FY 2018 program year's TPSs will not be reviewed and corrected by hospitals until after the FY 2018 IPPS/LTCH PPS final rule has been published. Therefore, the same historical universe of eligible hospitals and corresponding TPSs from the FY 2017 program year are used for the updated impact analysis in this final rule.

8. Effects of Proposed Changes to the HAC Reduction Program for FY 2018

The table and analysis below illustrate the estimated cumulative effect of the measures and scoring system for the Hospital-Acquired Condition (HAC) Reduction Program, as outlined in section V.K. of the preamble of this FY 2018 IPPS/LTCH PPS final rule. We are presenting the estimated impact of the FY 2018 HAC Reduction Program on hospitals by hospital characteristic.

These FY 2018 HAC Reduction Program results were calculated using the Winsorized z-score methodology finalized in the FY 2017 IPPS/LTCH PPS final rule (80 FR 57022 through 57025). Each hospital's Total HAC Score was calculated as the weighted average of the hospital's Domain 1 score (15 percent) and Domain 2 score (85 percent). Non-Maryland hospitals with a Total HAC Score above the 75th percentile Total HAC Score were identified as being in the worst-performing quartile. The table below presents the estimated proportion of hospitals in the worst-performing quartile of the Total HAC Scores by hospital characteristic. We are not providing hospital-level data or payment impact in conjunction with this final rule because scores will undergo a 30-day review and correction period that will not conclude until after the publication of this final rule.

We used the modified Recalibrated Patient Safety Indicator (PSI) 90 Composite measure results based on Medicare fee-for-service (FFS) discharges from July 1, 2014 through September 30, 2015 and recalibrated version 6.0.2 of the PSI software to estimate the impact of the FY 2018 HAC Reduction Program. For the CDC Central Line-Associated Bloodstream Infection (CLABSI), Catheter-Associated Urinary Tract Infection (CAUTI), Colon and Abdominal Hysterectomy Surgical Site Infection (SSI), Methicillin-resistant *Staphylococcus aureus* (MRSA) bacteremia, and *Clostridium difficile* Infection (CDI) measure results, we used standardized infection ratios (SIRs) calculated with hospital surveillance data reported to the National Healthcare Safety Network (NHSN) for infections occurring between January 1, 2015 and December 31, 2016.

To analyze the results by hospital characteristic, we used the FY 2018 Proposed Rule Impact File. This table includes 3,233 non-Maryland hospitals with a FY 2018 Total HAC Score. Of these, 3,215 hospitals had information for geographic location, region, bed size, disproportionate share hospital (DSH) percent, and teaching status; 3,184 had information for ownership; and 3,190 had information for Medicare utilization as a percent of inpatient days, which is also known as the Medicare Cost Report (MCR) percent. Maryland hospitals and hospitals

without a Total HAC Score are not included in the table below.

The second column in the table indicates the total number of non-Maryland hospitals with available data for each characteristic that have a Total HAC Score for the FY 2018 HAC Reduction Program. For example, with regard to teaching status, 2,151 hospitals are characterized as non-teaching hospitals, 815 are characterized as teaching hospitals with fewer than 100 residents, and 249 are characterized as teaching hospitals with at least 100 residents. This only represents a total of 3,215 hospitals because the other 18 hospitals have missing data for teaching status.

The third column in the table indicates the number of hospitals for each characteristic that would be in the worst-performing quartile of Total HAC Scores. These hospitals would receive a payment reduction under the FY 2018 HAC Reduction Program. For example, with regard to teaching status, 500 hospitals out of 2,151 hospitals characterized as non-teaching hospitals would be subject to a payment reduction. Among teaching hospitals, 189 out of 815 hospitals with fewer than 100 residents and 103 out of 249 hospitals with 100 or more residents would be subject to a payment reduction.

The fourth column in the table indicates the proportion of hospitals for each characteristic that would be in the worst-performing quartile of Total HAC Scores and would receive a payment reduction under the FY 2018 HAC Reduction Program. For example, 23.2 percent of the 2,151 hospitals characterized as non-teaching hospitals, 23.2 percent of the 815 teaching hospitals with fewer than 100 residents, and 41.4 percent of the 249 teaching hospitals with 100 or more residents would be subject to a payment reduction.

ESTIMATED PROPORTION OF HOSPITALS IN THE WORST-PERFORMING QUARTILE (>75TH PERCENTILE) OF THE TOTAL HAC SCORES FOR THE FY 2018 HAC REDUCTION PROGRAM (BY HOSPITAL CHARACTERISTIC)

Hospital characteristic	Number of hospitals	Number of hospitals in the worst-performing quartile [a]	Percent of hospitals in the worst-performing quartile [b]
Total [c]	3,233	808	25.0
By Geographic Location: (n = 3,215) [d]			
Urban hospitals	2,417	618	25.6
1–99 beds	612	156	25.5
100–199 beds	732	175	23.9
200–299 beds	435	98	22.5
300–399 beds	276	74	26.8
400–499 beds	151	48	31.8
500 or more beds	211	67	31.8
Rural hospitals	798	174	21.8
1–49 beds	309	69	22.3
50–99 beds	287	59	20.6
100–149 beds	116	26	22.4
150–199 beds	46	11	23.9
200 or more beds	40	9	22.5
By Region:			
New England	133	35	26.3
Mid-Atlantic	362	122	33.7
South Atlantic	519	142	27.4
East North Central	497	97	19.5
East South Central	299	80	26.8
West North Central	260	45	17.3
West South Central	517	109	21.1
Mountain	229	56	24.5
Pacific	399	106	26.6
By DSH Percent [e] (n = 3,215):			
0–24	1,362	315	23.1
25–49	1,465	342	23.3
50–64	207	66	31.9
65 and over	181	69	38.1
By Teaching Status [f] (n = 3,215):			
Non-teaching	2,151	500	23.2
Fewer than 100			
Residents	815	189	23.2
100 or more residents	249	103	41.4
By Ownership [g] (n = 3,184):			
Voluntary	1,875	446	23.8
Proprietary	811	191	23.6
Government	498	145	29.1
By MCR Percent [h] (n =3,190):			
0–24	475	139	29.3
25–49	2,103	482	22.9
50–64	524	138	26.3
65 and over	88	19	21.6

Source: FY 2018 HAC Reduction Program Final Rule Results are based on Recalibrated PSI 90 Composite data from July 2014 through September 2015 and CDC CLABSI, CAUTI, SSI, CDI, and MRSA results from January 2015 through December 2016. Hospital Characteristics are based on the FY 2018 Proposed Rule Impact File.

[a] This column is the number of non-Maryland hospitals with a Total HAC Score within the corresponding characteristic that are estimated to be in the worst-performing quartile.

[b] This column is the percent of non-Maryland hospitals within each characteristic that are estimated to be in the worst-performing quartile. The percentages are calculated by dividing the number of non-Maryland hospitals with a Total HAC Score in the worst-performing quartile by the total number of non-Maryland hospitals with a Total HAC Score within that characteristic.

[c] The number of non-Maryland hospitals with a FY 2018 Total HAC Score (N = 3,233). Note that not all hospitals have data for all hospital characteristics.
[d] The number of hospitals that had information for: geographic location including urban/rural, bed size, and region; Disproportionate Share Hospital (DSH); and teaching status (n = 3,215).
[e] A hospital is considered a DSH hospital if it has a DSH patient percentage greater than zero.
[f] A hospital is considered a teaching hospital if it has an IME adjustment factor for Operation PPS (TCHOP) greater than zero.
[g] Not all hospitals had data for type of ownership (n = 3,184).
[h] Not all hospitals had data for MCR percent (n = 3,190).

9. Effects of Implementation of the Additional 5-Year Extension of the Rural Community Hospital Demonstration Program

In section V.L. of the preamble of this final rule, we discuss our implementation of section 410A of Public Law 108–173, as amended by sections 3123 and 10313 of Public Law 111–148, and more recently, by section 15003 of Public Law 114–255, which requires the Secretary to conduct a demonstration that tests the feasibility and advisability of establishing ''rural community'' hospitals to furnish covered inpatient hospital services to Medicare beneficiaries. The demonstration makes payments under a reasonable cost methodology for covered inpatient hospital services furnished to Medicare beneficiaries by up to 30 rural hospitals. Section 15003 of Public Law 114–255, enacted December 13, 2016, requires a 10-year extension period (in place of the 5-year extension required by Public Law 111–148) for the demonstration. Therefore, the Secretary is required to conduct the demonstration for an additional 5-year period. Section 15003 of Public Law 114–255 also requires that, no later than 120 days after enactment of Public Law 114–255, the Secretary issue a solicitation for applications to select additional hospitals to participate in the demonstration program for the second 5 years of the 10-year extension period so long as the maximum number of 30 hospitals stipulated by Public Law 111–148 is not exceeded. Section 410A(c)(2) of Public Law 108–173 requires that, in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented (budget neutrality).

In this FY 2018 IPPS/LTCH PPS final rule, we describe our proposed and finalized policies for implementation of the extension under section 15003 of Public Law 114–255, the budget neutrality methodology for the extension period authorized by the legislation, and the reconciliation of actual and estimated costs of the demonstration for previous years (2011, 2012, and 2013). Our proposal and final policy for budget neutrality adopted the general methodology used in previous years for the demonstration. As discussed in section V.L. of the preamble of the proposed rule, in the IPPS final rules from FYs 2005 through 2016, we estimated the additional payments made by the program for each of the participating hospitals as a result of the demonstration. In order to achieve budget neutrality, we adjusted the national IPPS rates by an amount sufficient to account for the added costs of this demonstration. In other words, we have applied budget neutrality across the payment system as a whole rather than across the participants of this demonstration. The language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. The statutory language requires that aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration was not implemented, but does not identify the range across which aggregate payments must be held equal.

Section 15003 of Public Law 114–255 requires the Secretary to conduct the Rural Community Hospital Demonstration for a 10-year extension period (in place of the 5-year extension period required by the Affordable Care Act), beginning on the date immediately following the last day of the initial 5-year period under section 410A(a)(5) of Public Law 108–173. Specifically, section 15003 of Public Law 114–255 amended section 410A(g)(4) of Public Law 108–173 to require that, for hospitals participating in the demonstration as of the last day of the initial 5-year period, the Secretary shall provide for continued participation of such rural community hospitals in the demonstration during the 10-year extension period, unless the hospital makes an election to discontinue participation. Furthermore, section 15003 of Public Law 114–255 requires that, during the second 5 years of the 10-year extension period, the Secretary shall provide for participation under the demonstration during the second 5 years of the 10 year extension period for hospitals that are not described in subsection 410A(g)(4).

In the FY 2018 IPPS/LTCH PPS proposed rule, we proposed to implement the second 5 years of the 10-year extension period in a way that recognizes a gap in participation for the previously participating hospitals between the end of the first 5 years and the start of the second 5 years of the extension period, and that provides for alignment of the periods of performance under the extension among all participating hospitals. Thus, for each previously participating hospital that decides to participate in the second 5 years of the 10-year extension period, we proposed that the start date for the period of performance under the second 5-year extension period would be the start of the first cost reporting period on or after October 1, 2017 following upon the announcement of the selection of the additional hospitals for the demonstration. Our goal was to finalize this selection by June 2017, in time to include in the FY 2018 IPPS final rule an estimate of the costs of the demonstration during FY 2018 and the resulting budget neutrality offset amount for these newly participating hospitals, as well as for those hospitals among the previously participating hospitals that decide to participate in the extension period.

In the proposed rule, we proposed that if the selection of the additional hospitals under the solicitation were not to be announced by June 2017, we would include the estimated costs of the demonstration for all participating hospitals for FY 2018 in the budget neutrality offset amount to be calculated in the FY 2019 IPPS/LTCH PPS proposed and final rules.

In the preamble in section V.L. of the proposed rule, we also described an alternative implementation approach, according to which each previously participating hospital would begin the second 5 years of the 10-year extension period on the date immediately after the date the period of performance under the first 5-year extension period ended. We also described the methodology that we considered for calculating the budget neutrality offset amount under this alternative approach.

In response to public comments that indicated that our proposed implementation approach would cause financial hardship for some of the previously participating hospitals, we are adopting this alternative implementation approach in this FY 2018 IPPS/LTCH PPS final rule. We describe the method for calculating budget neutrality under this approach. Because we were unable to announce the selections of additional hospitals by June 2017, in time for including the estimates of the cost of the demonstration for both previously and newly participated hospitals in FY 2018 in this FY 2018 final rule, we will include this estimate in the FY 2019 IPPS/LTCH PPS proposed and final rules. In addition, we will determine the costs of the demonstration for the previously participating hospitals for the period from when their period of performance ended for the first 5-year extension period and the start of the cost report year in FY 2018 when finalized cost reports for this period are available. We will include these costs for the demonstration in future rulemaking.

In previous years, we have incorporated a second component into the budget neutrality offset amounts identified in the final IPPS rules. As finalized cost reports became available, we determined the amount by which the actual costs of the demonstration for an earlier, given year differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year, and we incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. We have calculated this difference for FYs 2005 through 2010 between the actual costs of the demonstration as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.

With the extension of the demonstration for another 5-year period, as authorized by section 15003 of Public Law 114–255, we

will continue this general procedure. Specifically, when finalized cost reports for FYs 2011, 2012, and 2013 are available, we will include this difference for these years in the budget neutrality offset adjustment to be applied to the national IPPS rates in a future final rule. We expect that this will occur in FY 2019. Also, when finalized cost reports for FYs 2014 through 2016 are available, we will include the difference between the actual costs as reflected on these cost reports and the amounts included in the budget neutrality offset amounts for these fiscal years in a future final rule.

10. Effects of Changes Relating to Provider-Based Status of Indian Health Service and Tribal Facilities and Organizations

In section V.N. of the preamble of this final rule, we discuss our proposals and finalized policies relating to provider-based status of Indian Health Service (IHS) and tribal facilities and organizations. Regulations at § 413.65(m) currently grandfather facilities from provider-based regulations if they meet certain criteria, including on or before April 7, 2000, having furnished only services that were billed as if they had been furnished by a department of a hospital operated by the IHS or a Tribe. We have also issued subregulatory guidance on circumstances that would or would not result in a facility or organization losing its grandfathered status. After consideration of the special and legally recognized relationship between Indian Tribes and the U.S. Government, as well as current IHS policies and procedures, as we proposed, we remove the date limitation in § 413.65(m) that restricted the grandfathering provision to IHS or Tribal facilities and organizations furnishing services on or before April 7, 2000. We also made a technical change to make the regulation text more consistent with our current rules that require these facilities to comply with all applicable Medicare conditions of participation that apply to the main provider. We do not expect any significant payment impact because these finalized policies are in line with current guidance, and we believe that IHS policies and procedures regarding the planning, operation, and funding of such facilities are resulting in appropriate Medicare payments.

11. Effects of Changes Relating to Hospital-within-Hospital (HwH) Policy

In section VII.B. of the preamble of this final rule, we discuss our proposal and finalized policy to revise the regulations applicable to HwHs so that the separateness and control requirements would only apply to IPPS-excluded HwHs that are co-located with IPPS hospitals beginning in FY 2018. This policy change is premised on the belief that the policy concerns that underlie our existing HwH regulations (that is, inappropriate patient shifting and hospitals acting as illegal de facto units) are sufficiently moderated in situations where IPPS-excluded hospitals are co-located with each other but not IPPS hospitals, in large part due to the payment system changes that have occurred over the intervening years for IPPS-excluded hospitals. In addition, we are revising the HwH requirements to no longer require the provisions that outline performance of basic hospital functions in order to maintain IPPS-exclusion beginning in FY 2018. This revision will not result in a practical change to how HwHs are currently operated because the performance of basic hospital functions that are required under the HwH regulations are currently addressed under CMS' interpretative guidelines for the hospital conditions of participation. We do not expect any significant payment impact because these policies are primarily administrative in nature or in line with current guidance.

12. Effects of Continued Implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57064 through 57065) we finalized, and in section VII.D.2. of the preamble of this final rule we discuss, the implementation of the FCHIP demonstration, which allows eligible entities to develop and test new models for the delivery of health care services in eligible counties in order to improve access to and better integrate the delivery of acute care, extended care, and other health care services to Medicare beneficiaries in no more than four States. Budget neutrality estimates for CAHs selected for the demonstration will be based on the demonstration period, August 1, 2016 through July 31, 2019. The demonstration includes three intervention prongs, under which specific waivers of Medicare payment rules will allow for enhanced payment: telehealth, skilled nursing facility/nursing facility, and ambulance services. These waivers are being implemented with the goal of increasing access to care with no net increase in costs.

We have specified the payment enhancements for the demonstration with the goal of maintaining the budget neutrality of the demonstration on its own terms (that is, the demonstration will produce savings from reduced transfers and admissions to other health care providers, thus offsetting any increase in payments resulting from the demonstration). However, because of the small size of this demonstration program and uncertainty associated with projected Medicare utilization and costs, we adopted a contingency plan (81 FR 57064 through 57065) to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met. Accordingly, if analysis of claims data for the Medicare beneficiaries receiving services at each of the participating CAHs, as well as of other data sources, including cost reports, show that increases in Medicare payments under the demonstration during the 3-year period are not sufficiently offset by reductions elsewhere, we will recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide. The demonstration is projected to impact payments to participating CAHs under both Medicare Part A and Part B. Thus, in the event that we determine that aggregate payments under the demonstration exceed the payments that would otherwise have been made, CMS will recoup payments through reductions of Medicare payments to all CAHs under both Medicare Part A and Part B. Because of the small scale of the demonstration, it would not be feasible to implement budget neutrality by reducing payments only to the participating CAH providers. Therefore we will make the reduction to payments to all CAHs, not just those participating in the demonstration, because the FCHIP program is specifically designed to test innovations that affect delivery of services by this provider category. We explained our belief that the language of the statutory budget neutrality requirement at section 123(g)(1)(B) of the Act permits the agency to implement the budget neutrality provision in this manner. The statutory language merely refers to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not implemented, and does not identify the range across which aggregate payments must be held equal.

Given the 3-year period of performance of the FCHIP demonstration and the time needed to conduct the budget neutrality analysis, in the event the demonstration is found not to have been budget neutral, any excess costs will be recouped over a period of three cost reporting periods, beginning in CY 2020. Therefore, this policy will have no impact for any national payment system for FY 2018.

I. Effects of Changes in the Capital IPPS

1. General Considerations

For the impact analysis presented below, we used data from the March 2017 update of the FY 2016 MedPAR file and the March 2017 update of the Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the changes to the capital prospective payment system do not incorporate cost data, we used the March 2017 update of the most recently available hospital cost report data (FYs 2014 and 2015) to categorize hospitals. Our analysis has several qualifications. We use the best data available and make assumptions about case-mix and beneficiary enrollment as described later in this section.

Due to the interdependent nature of the IPPS, it is very difficult to precisely quantify the impact associated with each change. In addition, we draw upon various sources for the data used to categorize hospitals in the tables. In some cases (for instance, the number of beds), there is a fair degree of variation in the data from different sources. We have attempted to construct these variables with the best available sources overall. However, it is possible that some individual hospitals are placed in the wrong category.

Using cases from the March 2017 update of the FY 2016 MedPAR file, we simulated payments under the capital IPPS for FY 2017 and payments for FY 2018 for a comparison of total payments per case. Any short-term, acute care hospitals not paid under the general IPPS (for example, hospitals in Maryland) are excluded from the simulations.

The methodology for determining a capital IPPS payment is set forth at § 412.312. The basic methodology for calculating the capital IPPS payments in FY 2018 is as follows:

(Standard Federal Rate) × (DRG weight) × (GAF) × (COLA for hospitals located in

Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME adjustment factor, if applicable).

In addition to the other adjustments, hospitals may receive outlier payments for those cases that qualify under the threshold established for each fiscal year. We modeled payments for each hospital by multiplying the capital Federal rate by the GAF and the hospital's case-mix. We then added estimated payments for indirect medical education, disproportionate share, and outliers, if applicable. For purposes of this impact analysis, the model includes the following assumptions:

- We estimate that the Medicare case-mix index will increase by 0.5 percent in both FYs 2017 and 2018.
- We estimate that Medicare discharges will be approximately 11.0 million in FY 2017 and 11.1 million in FY 2018.
- The capital Federal rate was updated beginning in FY 1996 by an analytical framework that considers changes in the prices associated with capital-related costs and adjustments to account for forecast error, changes in the case-mix index, allowable changes in intensity, and other factors. As discussed in section III.A.1.a. of the Addendum to this rule, the update is 1.3 percent for FY 2018.
- In addition to the FY 2018 update factor, the FY 2018 capital Federal rate was calculated based on a GAF/DRG budget neutrality adjustment factor of 0.9986, an outlier adjustment factor of 0.9484, and an adjustment to remove the one-time prospective adjustment of 1.006 made in FY 2017 to address the effect of the 0.2 percent reduction to the national capital Federal rates in effect for FY 2014, FY 2015, and FY 2016 relating to the 2-midnight policy. The 2-midnight adjustment that was finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57294) is discussed in section V.C. of the preamble of this final rule as it relates to the capital Federal rate. As also discussed in section V.C. of the preamble of this final rule, we are not making an additional MS–DRG documentation and coding adjustment to the capital IPPS Federal rate for FY 2018.

2. Results

We used the actuarial model previously described in section I.I. of Appendix A of this final rule to estimate the potential impact of our changes for FY 2018 on total capital payments per case, using a universe of 3,292 hospitals. As previously described, the individual hospital payment parameters are taken from the best available data, including the March 2017 update of the FY 2016 MedPAR file, the March 2017 update to the PSF, and the most recent cost report data from the March 2017 update of HCRIS. In Table III, we present a comparison of estimated total payments per case for FY 2017 and estimated total payments per case for FY 2018 based on the FY 2018 payment policies. Column 2 shows estimates of payments per case under our model for FY 2017. Column 3 shows estimates of payments per case under our model for FY 2018. Column 4 shows the total percentage change in payments from FY 2017 to FY 2018. The change represented in Column 4 includes the 1.3 percent update to the capital Federal rate and other changes in the adjustments to the capital Federal rate. The comparisons are provided by: (1) Geographic location; (2) region; and (3) payment classification.

The simulation results show that, on average, capital payments per case in FY 2018 are expected to increase as compared to capital payments per case in FY 2017. This expected increase overall is due to the approximately 1.3 percent update to the capital Federal rate for FY 2018, as well as the outlier adjustment of 0.9484 which is a 1.04 percent change from the FY 2017 outlier adjustment of 0.9386. The change in the outlier adjustment is expected to increase capital payments per case for most hospitals to a lesser or greater extent. (For a discussion of the determination of the capital Federal rate and adjustments, we refer readers to section III.A. of the Addendum to this final rule.) Hospitals within both rural and urban regions may experience an increase or a decrease in capital payments per case due to changes in the GAFs. These regional effects of the changes to the GAFs on capital payments are consistent with the projected changes in payments due to changes in the wage index (and policies affecting the wage index) as shown in Table I in section I.G. of this Appendix A.

The net impact of these changes is an estimated 2.5 percent change in capital payments per case from FY 2017 to FY 2018 for all hospitals (as shown in Table III).

The geographic comparison shows that, on average, most hospitals in all classifications (urban and rural) will experience an increase in capital IPPS payments per case in FY 2018 as compared to FY 2017. Capital IPPS payments per case for hospitals in large urban areas as well as hospitals in rural areas, would increase by an estimated 2.9 percent, from FY 2017 to FY 2018. Capital IPPS payments per case for other urban hospitals are estimated to increase 2.0 percent.

The comparisons by region show that the estimated increases in capital payments per case from FY 2017 to FY 2018 in urban areas range from a 3.7 percent increase for the West South Central urban region to a 0.8 percent increase for the Mountain urban region. For rural regions, the New England rural region is projected to experience the largest increase in capital IPPS payments per case of 5.2 percent, while the South Atlantic rural region is projected to experience an increase in capital IPPS payments per case of 1.9 percent.

Hospitals of all types of ownership (that is, voluntary hospitals, government hospitals, and proprietary hospitals) are expected to experience an increase in capital payments per case from FY 2017 to FY 2018. The increase in capital payments for voluntary hospitals is estimated to be 2.3 percent. Government hospitals and proprietary hospitals, are expected to experience an increase in capital IPPS payments of 3.2 percent.

Section 1886(d)(10) of the Act established the MGCRB. Hospitals may apply for reclassification for purposes of the wage index for FY 2018. Reclassification for wage index purposes also affects the GAFs because that factor is constructed from the hospital wage index. To present the effects of the hospitals being reclassified as of the publication of this rule for FY 2018, we show the average capital payments per case for reclassified hospitals for FY 2018. Urban reclassified hospitals are expected to experience an increase in capital payments of 1.6 percent; urban nonreclassified hospitals are expected to experience an increase in capital payments of 2.9 percent. The estimated percentage increase for rural reclassified hospitals as well as for rural nonreclassified hospitals is 2.8 percent. Hospitals reclassified under section 401 are among the few groups of hospitals not expected to experience an increase in capital payments—it is expected that these hospitals would experience a decrease in capital payments of 1.6 percent, while capital payments for other reclassified hospitals are expected to increase an estimated 6.6 percent.

TABLE III—COMPARISON OF TOTAL PAYMENTS PER CASE

[FY 2017 payments compared to FY 2018 payments]

	Number of hospitals	Average FY 2017 payments/case	Average FY 2018 payments/case	Change
By Geographic Location:				
All hospitals	3,292	920	943	2.5
Large urban areas (populations over 1 million)	1,340	1,007	1,036	2.9
Other urban areas (populations of 1 million of fewer)	1,152	896	913	2.0
Rural areas	800	625	644	2.9
Urban hospitals	2,492	953	977	2.5
0–99 beds	648	768	798	3.9
100–199 beds	763	825	850	3.0
200–299 beds	441	877	897	2.2

TABLE III—COMPARISON OF TOTAL PAYMENTS PER CASE—Continued

[FY 2017 payments compared to FY 2018 payments]

	Number of hospitals	Average FY 2017 payments/case	Average FY 2018 payments/case	Change
300–499 beds	426	965	988	2.4
500 or more beds	214	1,142	1,168	2.3
Rural hospitals	800	625	644	2.9
0–49 beds	318	523	544	3.9
50–99 beds	282	584	599	2.5
100–149 beds	117	625	642	2.7
150–199 beds	44	663	687	3.6
200 or more beds	39	749	771	2.9
By Region:				
Urban by Region	2,492	953	977	2.5
New England	114	1,038	1,056	1.8
Middle Atlantic	315	1,054	1,074	1.9
South Atlantic	404	849	869	2.3
East North Central	385	918	941	2.5
East South Central	147	800	815	1.8
West North Central	160	933	964	3.3
West South Central	378	863	896	3.7
Mountain	162	1,005	1,013	0.8
Pacific	375	1,209	1,249	3.3
Puerto Rico	52	437	451	3.1
Rural by Region	800	625	644	2.9
New England	20	860	905	5.2
Middle Atlantic	53	603	616	2.2
South Atlantic	125	584	595	1.9
East North Central	115	645	661	2.5
East South Central	154	574	591	3.0
West North Central	97	667	690	3.4
West South Central	154	555	574	3.4
Mountain	58	695	716	3.1
Pacific	24	805	836	3.7
By Payment Classification:				
All hospitals	3,292	920	943	2.5
Large urban areas (populations over 1 million)	1,354	1,005	1,035	2.9
Other urban areas (populations of 1 million of fewer)	1,019	883	908	2.9
Rural areas	919	768	771	0.3
Teaching Status:				
Non-teaching	2,204	779	802	2.9
Fewer than 100 Residents	839	890	910	2.3
100 or more Residents	249	1,283	1,315	2.5
Urban DSH:				
100 or more beds	1,543	975	1,003	2.9
Less than 100 beds	370	697	727	4.2
Rural DSH:				
Sole Community (SCH/EACH)	257	622	632	1.6
Referral Center (RRC/EACH)	293	833	834	0.1
Other Rural:				
100 or more beds	34	820	791	−3.5
Less than 100 beds	244	511	522	2.2
Urban teaching and DSH:				
Both teaching and DSH	863	1,043	1,073	2.8
Teaching and no DSH	92	921	937	1.8
No teaching and DSH	1,050	823	847	3.0
No teaching and no DSH	368	832	863	3.7
Rural Hospital Types:				
Nonspecial status hospitals	2,580	946	973	2.8
RRC/EACH	263	861	862	0.2
SCH/EACH	316	716	743	3.7
SCH, RRC and EACH	131	763	782	2.5
Hospitals Reclassified by the Medicare Geographic Classification Review Board:				
FY2018 Reclassifications:.				
All Urban Reclassified	590	948	964	1.6
All Urban Non-Reclassified	1,858	956	985	2.9
All Rural Reclassified	268	660	679	2.8
All Rural Non-Reclassified	485	580	596	2.8
All Section 401 Reclassified Hospitals	166	937	922	−1.6
Other Reclassified Hospitals (Section 1886(d)(8)(B))	41	604	644	6.6
Type of Ownership:				
Voluntary	1,914	938	959	2.3

TABLE III—COMPARISON OF TOTAL PAYMENTS PER CASE—Continued

[FY 2017 payments compared to FY 2018 payments]

	Number of hospitals	Average FY 2017 payments/case	Average FY 2018 payments/case	Change
Proprietary	863	823	850	3.2
Government	513	952	982	3.2
Medicare Utilization as a Percent of Inpatient Days:				
0–25	554	1,072	1,100	2.6
25–50	2,149	921	944	2.5
50–65	485	754	774	2.7
Over 65	103	589	656	11.4

J. Effects of Payment Rate Changes and Policy Changes Under the LTCH PPS

1. Introduction and General Considerations

In section VIII. of the preamble of this final rule and section V. of the Addendum to this final rule, we set forth the annual update to the payment rates for the LTCH PPS for FY 2018. In the preamble of this final rule, we specify the statutory authority for the provisions that are presented, identify the proposed and finalized policies, and present rationales for our decisions as well as alternatives that were considered. In this section of Appendix A to this final rule, we discuss the impact of the changes to the payment rate, factors, and other payment rate policies related to the LTCH PPS that are presented in the preamble of this final rule in terms of their estimated fiscal impact on the Medicare budget and on LTCHs.

There are 415 LTCHs included in this impacts analysis. We note that, although there are currently approximately 428 LTCHs, for purposes of this impact analysis, we excluded the data of all-inclusive rate providers consistent with the development of the FY 2018 MS–LTC–DRG relative weights (discussed in section VIII.B.3.c. of the preamble of this final rule. Moreover, in the claims data use for this final rule, two of these 415 LTCHs only have claims for site neutral payment rate cases and are thus not included in our impact analysis for LTCH PPS standard Federal payment rate cases.) In the impact analysis, we used the payment rate, factors, and policies presented in this final rule, which include the rolling end to transition to the site neutral payment rate required by section 1886(m)(6)(A) of the Act (as described below), the 1.0 percent annual update to the LTCH PPS standard Federal payment rate required by section 411 of Pub. L. 114–10, the update to the MS–LTC–DRG classifications and relative weights, the update to the wage index values and labor-related share, the change to the SSO payment methodology (discussed in VIII.E. of the preamble of this final rule), our finalized policy to adopt a 1-year regulatory delay of the full implementation of the 25-percent threshold policy for FY 2018, and our finalized policies to implement certain provisions of the 21st Century Cures Act, and the best available claims and CCR data to estimate the change in payments for FY 2018.

Under the dual rate LTCH PPS payment structure, payment for LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) is based on the LTCH PPS standard Federal payment rate. Consistent with the statute, the site neutral payment rate is the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), including any applicable outlier payments as specified in § 412.525(a); or 100 percent of the estimated cost of the case as determined under existing § 412.529(d)(2). In addition, there are two separate HCO targets—one for LTCH PPS standard Federal payment rate cases and one for site neutral payment rate cases. The statute also establishes a transitional payment method for cases that are paid the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 and FY 2017. For FY 2018, the applicability of this transitional payment method for site neutral payment rate cases is dependent upon both the discharge date and the start date of the LTCH's FY 2018 cost reporting period. Specifically, the transitional payment method only applies to those site neutral payment rate cases that occur in cost reporting periods that begin *before* October 1, 2017. The transitional payment amount for site neutral payment rate cases is a blended payment rate, which is calculated as 50 percent of the applicable site neutral payment rate amount for the discharge as determined under § 412.522(c)(1) and 50 percent of the applicable LTCH PPS standard Federal payment rate for the discharge determined under § 412.523, while site neutral payment rate cases in cost reporting periods beginning on or *after* October 1, 2017 are paid the site neutral payment rate amount determined under § 412.522(c)(1).

Comment: Several commenters requested that we extend the transition period to the site neutral payment rate under the LTCH PPS' dual payment rate structure.

Response: Under Section 1886(m)(6)(B)(i)(II) of the Act, we are required to pay for discharges that do not to meet the statutory criteria for exclusion from the site neutral payment rate at the site neutral payment rate for discharges in cost reporting periods beginning in FY 2018 or later. The statute only provides for payments at the blended payment rate for discharges that do not to meet the statutory criteria for exclusion from the site neutral payment rate for those discharges that occur in cost reporting periods beginning during FY 2016 or FY 2017. Therefore, under Section 1886(m)(6)(B)(i)(II) of the Act, we lack the statutory authority to do as these commenters request.

Comment: Several commenters objected to our expectation that the site neutral payment rate would not affect access to or quality of care for patients based on what they assert are incorrect actuarial assumptions. In support of this objection, some commenters analyzed FY 2016 claims data which they believe shows that site neutral payment rate cases have not matched our actuarial assumptions that the costs and resource use for cases paid at the site neutral payment rate will likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG. These commenters believe CMS' statements could mislead LTCHs and Medicare beneficiaries about the projected impact of the site neutral payment rate on access to or quality of care.

Response: While we understand and share commenters' concerns about access to and quality of care for Medicare beneficiaries, we disagree that our stated expectation that the site neutral payment rate will not affect these is incorrect or misleading. To the extent that the data from FY 2016 appears to rebut our actuarial assumptions on the costs and resource of site neutral payment rate cases, we remind commenters that given the rolling nature of the start of the transition to the site neutral payment rate (discharges in cost reporting periods beginning on or after October 1, 2015), many LTCH claims from FY 2016 were not subject to the site neutral payment rate at all as many LTCHs did not begin their FY 2016 cost reporting period until the fourth quarter of that fiscal year. In addition, no LTCH is fully subject to the site neutral payment rate until its cost reporting period beginning in FY 2018 due to the 2-year transition period provided by the statute (meaning that all claims which were subject to the site neutral payment rate in FY 2016 were paid under the blended payment rate which included a payment based on 50 percent of the LTCH PPS standard Federal payment rate). Therefore, the analysis presented by commenters, based on FY 2016 data, does not invalidate our assumptions about the costs and resource use for site neutral payment rate cases as the FY 2016 claims appear to not yet reflect the expected change in cost and resources once the payment for site neutral payment rate cases is fully based on the site neutral payment rate. We will continue to monitor the data and review the assumptions as appropriate. However, we continue to believe that the

assumptions underlying our conclusion that the site neutral payment system will not negatively impact access to or quality of care are valid, as is the conclusion. As demonstrated in areas where there is little or no LTCH presence, general short-term acute care hospitals are effectively providing treatment for the same types of patients that are treated in LTCHs in areas where there is one or more LTCH present.

Based on the best available data for the 415 LTCHs in our database that were considered in the analyses used for this final rule, we estimate that overall LTCH PPS payments in FY 2018 will decrease by approximately 4.2 percent (or approximately $195 million) based on the rates and factors presented in section VIII. of the preamble and section V. of the Addendum to this final rule. (We note that this estimate does not reflect our finalized policy to adopt a 1-year regulatory delay of the full implementation of the 25-percent threshold policy for FY 2018 and, with the exception of changes to the HCO payment policy, does not reflect our finalized policies regarding the implementation of certain provisions of the 21st Century Cures Act. As discussed in greater detail below, our actuaries estimate these finalized policies will increase spending by approximately $85 million in FY 2018.) This projection takes into account estimated payments for LTCH cases in our database that met or would have met the patient-level criteria and been paid the LTCH PPS standard Federal payment rate if those criteria had been in effect at the time of the discharge, and estimated payments for LTCH cases that did not meet or would not have met the patient-level criteria and been paid under the site neutral payment rate if that rate had been in effect at the time of the discharge, as described in the following paragraph.

The statutory transitional payment method for cases that are paid the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 or FY 2017 uses a blended payment rate, which is determined as 50 percent of the site neutral payment rate amount for the discharge and 50 percent of the standard Federal prospective payment rate amount for the discharge (§ 412.522(c)(3)). The transitional blended payment rate uses the same blend percentages (that is, 50 percent) for both years of the 2-year transition period. Therefore, when estimating FY 2017 LTCH PPS payments for site neutral payment rate cases for this impact analysis, the transitional blended payment rate was applied to all such cases because all discharges in FY 2017 are either in the hospital's cost reporting period that began during FY 2016 or in the hospital's cost reporting period that will begin during FY 2017. However, when estimating FY 2018 LTCH PPS payments for site neutral payment rate cases for this impact analysis, because the statute specifies that the site neutral payment rate effective date (and 2-year transitional period) for a given LTCH is based on the date that LTCH's cost reporting period begins during FY 2018, we included an adjustment to account for this rolling effective date, consistent with the general approach used for the LTCH PPS impact analysis presented in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49831). This approach accounts for the fact that site neutral payment rate cases in FY 2018 that are in a LTCH's cost reporting period that begin *before* October 1, 2017 continue to be paid under the transitional payment method until the start of the LTCH's first cost reporting period beginning on or *after* October 1, 2017. Site neutral payment rate cases in a LTCH's cost reporting period beginning on or after October 1, 2017 will no longer be paid under the transitional payment method and will instead be paid the site neutral payment rate amount as determined by § 412.522(c)(1).

For purposes of this impact analysis, to estimate total FY 2018 LTCH PPS payments for site neutral payment rate cases, we used the same general approach as was used in the FY 2016 IPPS/LTCH PPS final rule with modifications to account for the rolling end date to the transitional site neutral payment rate in FY 2018 instead of the rolling effective date for implementation of the transitional site neutral payment rate in FY 2016. In summary, under this approach, we grouped LTCHs based on the quarter their cost reporting periods will begin during FY 2018. For example, LTCHs with cost reporting periods that begin during October through December 2017 begin during the first quarter of FY 2018. For LTCHs grouped in each quarter of FY 2018, we modeled those LTCHs' estimated FY 2018 site neutral payment rate payments under the transitional blended payment rate based on the quarter in which the LTCHs in each group would continue to be paid the transitional payment method for the site neutral payment rate cases.

For purposes of this estimate, then, we assume the cost reporting period is the same for all LTCHs in each of the quarterly groups and that this cost reporting period begins on the first day of that quarter. (For example, our first group consists of 42 LTCHs whose cost reporting period will begin in the first quarter of FY 2018 so that, for purposes of this estimate, we assume all 42 LTCHs will begin their FY 2018 cost reporting period on October 1, 2017.) Second, we estimated the proportion of FY 2018 site neutral payment rate cases in each of the quarterly groups, and we then assume this proportion is applicable for all four quarters of FY 2018. (For example, as discussed in more detail below, we estimate the first quarter group will discharge 6.6 percent of all FY 2018 site neutral payment rate cases and therefore, we estimate that group of LTCHs will discharge 6.6 percent of all FY 2018 site neutral payment rate cases in each quarter of FY 2018.) Then, we modeled estimated FY 2018 payments on a quarterly basis under the LTCH PPS standard Federal payment rate based on the assumptions described above. We continue to believe that this approach is a reasonable means of taking the rolling effective date into account when estimating FY 2018 payments.

Based on the fiscal year begin date information in the March 2017 update of the PSF and the LTCH claims from the March 2017 update of the FY 2016 MedPAR files for the 415 LTCHs in our database used for this final rule, we found the following: 6.6 percent of site neutral payment rate cases are from 42 LTCHs whose cost reporting periods will begin during the first quarter of FY 2018; 21.2 percent of site neutral payment rate cases are from 97 LTCHs whose cost reporting periods will begin in the second quarter of FY 2018; 10.2 percent of site neutral payment rate cases are from 57 LTCHs whose cost reporting periods will begin in the third quarter of FY 2018; and 62.1 percent of site neutral payment rate cases are from 219 LTCHs whose cost reporting periods will begin in the fourth quarter of FY 2018. Therefore, the following percentages apply in the approach described above:

- First Quarter FY 2018: 6.6 percent of site neutral payment rate cases (that is, the percentage of discharges from LTCHs whose FY 2018 cost reporting will begin in the first quarter of FY 2018) are no longer eligible for the transitional payment method, while the remaining 93.4 percent of site neutral payment rate discharges are eligible to be paid under the transitional payment method.
- Second Quarter FY 2018: 27.7 percent of site neutral payment rate second quarter discharges (that is, the percentage of discharges from LTCHs whose FY 2018 cost reporting will begin in the first or second quarter of FY 2018) are no longer eligible for the transitional payment method while the remaining 72.3 percent of site neutral payment rate second quarter discharges are eligible to be paid under the transitional payment method.
- Third Quarter FY 2018: 37.9 percent of site neutral payment rate third quarter discharges (that is, the percentage of discharges from LTCHs whose FY 2018 cost reporting will begin in the first, second, or third quarter of FY 2018) are no longer eligible for the transitional payment method while the remaining 62.1 percent of site neutral payment rate third quarter discharges are eligible to be paid under the transitional payment method.
- Fourth Quarter FY 2018: 100.0 percent of site neutral payment rate fourth quarter discharges (that is, the percentage of discharges from LTCHs whose FY 2018 cost reporting will begin in the first, second, third, or fourth quarter of FY 2018) are no longer eligible for the transitional payment method so that no site neutral payment rate case discharges are eligible be paid under the transitional payment method.

Based on the FY 2016 LTCH cases that were used for the analyses in this final rule, approximately 42 percent of those cases were or would have been classified as site neutral payment rate cases if the site neutral payment rate had been in effect at the time of the discharge (that is, 42 percent of LTCH cases did not or would not have met the patient-level criteria for exclusion from the site neutral payment rate). Our Office of the Actuary estimates that the percent of LTCH PPS cases that will be paid at the site neutral payment rate in FY 2018 will not change significantly from the historical data. Taking into account the transitional blended payment rate and other changes that will apply to the site neutral payment rate cases in FY 2018, we estimate that aggregate LTCH PPS payments for these site neutral payment

rate cases will decrease by approximately 20 percent (or approximately $230 million).

Approximately 58 percent of LTCH cases are expected to meet the patient-level criteria for exclusion from the site neutral payment rate in FY 2018, and will be paid based on the LTCH PPS standard Federal payment rate for the full year. We estimate that total LTCH PPS payments for these LTCH PPS standard Federal payment rate cases in FY 2018 will increase approximately 1.0 percent (or approximately $35 million). This estimated increase in LTCH PPS payments for LTCH PPS standard Federal payment rate cases in FY 2018 is primarily due to the 1.0 percent annual update to the LTCH PPS standard Federal payment rate for FY 2018 required by section 411 of Public Law 114–10 (discussed in section V.A. of the Addendum to this final rule). (We note that because our SSO payment methodology discussed in VIII.E. of the preamble of this final rule incorporates a budget neutrality adjustment, this policy does not increase or decrease aggregate payments, and therefore does not factor into the 1.0 percent increase in aggregate payments.)

Based on the 415 LTCHs that were represented in the FY 2016 LTCH cases that were used for the analyses in this final rule presented in this Appendix, we estimate that aggregate FY 2018 LTCH PPS payments will be approximately $4.418 billion, as compared to estimated aggregate FY 2017 LTCH PPS payments of approximately $4.612 billion, resulting in an estimated overall decrease in LTCH PPS payments of approximately $195 million. Furthermore, as discussed in more detail below, our Office of the Actuary is estimating an additional increase in aggregate FY 2018 LTCH PPS payments of approximately $85 million with $70 million resulting from our finalized policy to delay full implementation of the 25-percent threshold policy for FY 2018 and another $15 million coming from our implementation of certain provisions of the 21st Century Cures Act. Therefore, in total, we project an overall decrease in LTCH PPS payments of approximately $110 million (−$195 million + $85 million) or approximately a 2.4 percent decrease in LTCH PPS payments in FY 2018 as compared to FY 2017. Because the combined distributional effects and estimated payment changes exceed $100 million, this final rule is a major economic rule. We note that the estimated $195 million decrease in LTCH PPS payments in FY 2018 (which includes estimated payments for LTCH PPS standard Federal payment rate cases and site neutral payment rate cases, but does not include estimated payments for our finalized policy to delay full implementation of the 25-percent threshold policy for FY 2018 or the certain provisions of the 21st Century Cures Act) does not reflect changes in LTCH admissions or case-mix intensity, which will also affect the overall payment effects of the policies in this final rule.

The LTCH PPS standard Federal payment rate for FY 2017 is $42,476.41. For FY 2018, we are establishing an LTCH PPS standard Federal payment rate of $41,430.56 which reflects the 1.0 percent annual update to the LTCH PPS standard Federal payment rate, the area wage budget neutrality factor of 1.0006434 to ensure that the changes in the wage indexes and labor-related share do not influence aggregate payments, and the budget neutrality adjustment of 0.9651 to ensure that our changes to the SSO payment methodology (discussed in VIII.E. of the preamble of this final rule) do not influence aggregate payments. For LTCHs that fail to submit data for the LTCH QRP, in accordance with section 1886(m)(5)(C) of the Act, we are establishing an LTCH PPS standard Federal payment rate of $40,610.16. This reduced LTCH PPS standard Federal payment rate reflects the updates and factors previously described as well as the required 2.0 percentage point reduction to the annual update for failure to submit data under the LTCH QRP. We note that the factors previously described to determine the FY 2018 LTCH PPS standard Federal payment rate are applied to the FY 2017 LTCH PPS standard Federal rate set forth under § 412.523(c)(3)(xiv) (that is, $42,476.41).

Table IV shows the estimated impact for LTCH PPS standard Federal payment rate cases. The estimated change attributable solely to the annual update of 1.0 percent to the LTCH PPS standard Federal payment rate is projected to result in an increase of 0.9 percent in payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2017 to FY 2018, on average, for all LTCHs (Column 6). In addition to the annual update to the LTCH PPS standard Federal payment rate for FY 2018, the estimated increase of 0.9 percent shown in Column 6 of Table IV also includes estimated payments for SSO cases that will be paid using special methodologies that are not affected by the annual update to the LTCH PPS standard Federal payment rate (without incorporating our SSO payment methodology as discussed in discussed in VIII.E. of the preamble of this final rule), as well as the reduction that is applied to the annual update of LTCHs that do not submit the required LTCH QRP data. Therefore, for all hospital categories, the projected increase in payments based on the proposed LTCH PPS standard Federal payment rate to LTCH PPS standard Federal payment rate cases is somewhat less than the 1.0 percent annual update for FY 2018 required under section 411 of Pub. L. 114–10.

For FY 2018, we are updating the wage index values based on the most recent available data, and we are continuing to use labor market areas based on the OMB CBSA delineations (as discussed in section V.B. of the Addendum to this final rule). In addition, we reduced the labor-related share from 66.5 percent to 66.2 percent under the LTCH PPS for FY 2018, based on the most recent available data on the relative importance of the labor-related share of operating and capital costs of the 2013-based LTCH market basket. We also applied an area wage level budget neutrality factor of 1.0006434 to ensure that the changes to the wage data and labor-related share do not result in a change in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases.

As we discuss in VIII.E. of the preamble of this final rule, we are simplifying our SSO payment methodology in order to alleviate potential incentives to improperly hold patients beyond the SSO threshold. We also note we do not believe aggregate payments to LTCHs should increase or decrease as a result of our policy, and thus, we applied a budget neutrality factor of 0.9651 to ensure the changes to the SSO payment methodology does not result in a change in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases.

We currently estimate total HCO payments for LTCH PPS standard Federal payment rate cases will decrease from FY 2017 to FY 2018. Based on the FY 2016 LTCH cases that were used for the analyses in this final rule, we estimate that the FY 2017 HCO threshold of $21,943 (as established in the FY 2017 IPPS/LTCH PPS final rule) will result in estimated HCO payments for LTCH PPS standard Federal payment rate cases in FY 2017 that are above the estimated 8 percent target. Specifically, we currently estimate that HCO payments for LTCH PPS standard Federal payment rate cases will be approximately 8.1 percent of the estimated total LTCH PPS standard Federal payment rate payments in FY 2017. Combined with our estimate that FY 2018 HCO payments for LTCH PPS standard Federal payment rate cases will be 7.975 percent of estimated total LTCH PPS standard Federal payment rate payments in FY 2018 as required by section 15004 of the 21st Century Cures Act, this will result in the estimated decrease in HCO payments of approximately 0.1 percent between FY 2017 and FY 2018.

In calculating these estimated HCO payments, we increased estimated costs by our actuaries' projected market basket percentage increase factor. Without the change to our SSO payment methodology, this increase in estimated costs will result in a projected increase in SSO payments in FY 2018 (because 100 percent of the estimated cost of the case is an option in the SSO payment formula (§ 412.529)). We estimate that those increased SSO payments in FY 2018 will increase total payments for LTCH PPS standard Federal payment rate cases by approximately 0.2 percent.

Table IV shows the estimated impact of the payment rate and policy changes on LTCH PPS payments for LTCH PPS standard Federal payment rate cases for FY 2018 by comparing estimated FY 2017 LTCH PPS payments to estimated FY 2018 LTCH PPS payments. (As noted earlier, our analysis does not reflect changes in LTCH admissions or case-mix intensity.) The projected increase in payments from FY 2017 to FY 2018 for LTCH PPS standard Federal payment rate cases of 1.0 percent is attributable to the impacts of the change to the LTCH PPS standard Federal payment rate (0.9 percent in Column 6) and the effect of the estimated decrease in HCO payments for LTCH PPS standard Federal payment cases (0.1 percent), and the estimated increase in payments for SSO cases (0.2 percent) prior to incorporation of our SSO payment methodology. We note that these impacts do not include LTCH PPS site neutral payment rate cases for the reasons discussed in section I.J.4. of this Appendix.

As we discuss in detail throughout this final rule, based on the most recent available

data, we believe that the provisions of this final rule relating to the LTCH PPS, which are projected to result in an overall decrease in estimated aggregate LTCH PPS payments, and the resulting LTCH PPS payment amounts will result in appropriate Medicare payments that are consistent with the statute.

2. Impact on Rural Hospitals

For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. As shown in Table IV, we are projecting a 0.1 percent decrease in estimated payments for LTCH PPS standard Federal payment rate cases. This estimated impact is based on the FY 2016 data for the 21 rural LTCHs (out of 415 LTCHs) that were used for the impact analyses shown in Table IV.

3. Impact of Other Changes Under the LTCH PPS for FY 2018

Overall, our actuaries estimate the provisions of the 21st Century Cures Act that affect LTCH PPS payments will increase aggregate spending to LTCHs by approximately $15 million in FY 2018. Specifically, they estimate the provisions in section 15004, which provide for certain exceptions to the moratorium on an increase in beds in LTCH or LTCH satellite locations (discussed in section VIII.H of the preamble of this final rule) and a change in the treatment of HCO payments to LTCH PPS standard rate cases (discussed in section V.D. of the Addendum of this final rule) to result in an aggregate increase in Medicare spending of $10 million. The remaining estimated increase of $5 million in Medicare spending comes from the temporary exception to the site neutral payment rate for certain spinal cord hospitals provided for under section 15009 (as discussed in section VIII.E. of the preamble of this final rule). Our actuaries estimate the remaining provisions of the 21st Century Cures Act applicable to LTCHs (that is, sections 15007, 15008, and 15010, discussed in sections VIII.I., VIII.J., and VIII.F., respectively, of the preamble of this final rule) will have negligible impact on aggregate Medicare spending in FY 2018. (We note that section 15006, which provides for an additional delay in the full implementation of the 25-percent threshold policy (discussed in VIII.G. of the preamble of this final rule), does not impact FY 2018 LTCH PPS payments.) In addition, our actuaries estimate that our implementation of a further delay the full implementation of the 25-percent threshold policy for FY 2018 will increase aggregate Medicare spending by $70 million, up from our estimate of $50 million in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20218). This increase is due to updating the estimate for consistency with the assumptions used to develop the Midsession Review of the President's Budget, in addition to refinements in modeling LTCH PPS payments under the new dual rate payment system.

As discussed in section VIII.E. of the preamble of this final rule, section 15009 of the 21st Century Cures Act provides for a temporary exception to the site neutral payment rate for certain spinal cord specialty hospitals for discharges occurring in cost reporting periods beginning during FY 2018 and FY 2019. To qualify for this temporary exception, an LTCH must, among other things, meet the ''significant out-of-state admissions criterion'' at section 1886(m)(6)(F)(iii) of the Act. The statute further provides authority for the Secretary to implement the significant out-of-state admissions criterion at section 1886(m)(6)(F)(iii) of the Act by program instruction or otherwise, and exempts the policy initiatives from any information collection requirements under the Paperwork Reduction Act. Although exempt from these information collection requirements, we estimate that each application will require 2.5 hours of work from each LTCH (to review the billing addresses of the hospital's Medicare and non-Medicare inpatients). This information will be collected on a one-time basis. Based on the best information available to CMS, we estimate that only two hospitals meet the other requirements for this exception. Therefore, we estimate that the total number of hours associated with this request will be 5 (2.5 hours per hospital for 2 hospitals). We estimate a current, average salary of $29 per hour plus 100 percent for fringe benefits ($58 per hour). Therefore, we estimate the total costs associated with this information collection will be $290 (5 hours at $58 per hour).

4. Anticipated Effects of LTCH PPS Payment Rate Changes and Policy Changes

a. Budgetary Impact

Section 123(a)(1) of the BBRA requires that the PPS developed for LTCHs ''maintain budget neutrality.'' We believe that the statute's mandate for budget neutrality applies only to the first year of the implementation of the LTCH PPS (that is, FY 2003). Therefore, in calculating the FY 2003 standard Federal payment rate under § 412.523(d)(2), we set total estimated payments for FY 2003 under the LTCH PPS so that estimated aggregate payments under the LTCH PPS were estimated to equal the amount that would have been paid if the LTCH PPS had not been implemented.

Section 1886(m)(6)(A) of the Act establishes a dual rate LTCH PPS payment structure with two distinct payment rates for LTCH discharges beginning in FY 2016. Under this statutory change, LTCH discharges that meet the patient-level criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid based on the LTCH PPS standard Federal payment rate. LTCH discharges paid at the site neutral payment rate are generally paid the lower of the IPPS comparable per diem amount, including any applicable HCO payments, or 100 percent of the estimated cost of the case. The statute also establishes a transitional payment method for cases that are paid at the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 or FY 2017, under which the site neutral payment rate cases are paid based on a blended payment rate calculated as 50 percent of the applicable site neutral payment rate amount for the discharge and 50 percent of the applicable LTCH PPS standard Federal payment rate for the discharge. As discussed in more detail in section I.J. of this Appendix, some LTCH discharges in FY 2018 will still be eligible to be paid based on the blended payment rate.

As discussed in section I.J. of this Appendix, we project a decrease in aggregate LTCH PPS payments in FY 2018 of approximately $195 million. This estimated decrease in payments reflects the projected increase in payments to LTCH PPS standard Federal payment rate cases of approximately $35 million and the projected decrease in payments to site neutral payment rate cases of approximately $230 million under the dual rate LTCH PPS payment rate structure required by the statute beginning in FY 2016. (As stated previously, this estimate does not include the estimated increase in aggregate FY 2018 LTCH PPS payments for our finalized policy to delay full implementation of the 25-percent threshold policy or certain provisions of the 21st Century Cures Act, which are discussed in section I.J.3. of this Appendix.)

As discussed in section V.D. of the Addendum of this final rule, our actuaries project cost and resource changes for site neutral payment rate cases due to the site neutral payment rates required under the statute. Specifically, our actuaries project that the costs and resource use for cases paid at the site neutral payment rate will likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate, and will likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG. While we are able to incorporate this projection at an aggregate level into our payment modeling, because the historical claims data that we are using in this final rule to project estimated FY 2018 LTCH PPS payments (that is, FY 2016 LTCH claims data) do not reflect this actuarial projection, we are unable to model the impact of the change in LTCH PPS payments for site neutral payment rate cases at the same level of detail with which we are able to model the impacts of the proposed changes to LTCH PPS payments for LTCH PPS standard Federal payment rate cases. Therefore, Table IV only reflects changes in LTCH PPS payments for LTCH PPS standard Federal payment rate cases and, unless otherwise noted, the remaining discussion in section I.J.4. of this Appendix refers only to the impact on LTCH PPS payments for LTCH PPS standard Federal payment rate cases. In the following section, we present our provider impact analysis for the changes that affect LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

b. Impact on Providers

Under the dual rate LTCH PPS payment structure, there are two distinct payment rates for LTCH discharges occurring in cost reporting periods beginning on or after October 1, 2016. Under that statute, any discharges that occur on or after October 1, 2015, but prior to the start of the LTCH's FY 2016 cost reporting period, will be paid at the LTCH PPS standard Federal payment rate. On or after the start of an LTCH's FY 2017 cost reporting period, discharges are paid based on whether or not the discharge meets

the patient-level criteria to be excluded from the site neutral payment rate. That is, LTCH PPS standard Federal payment rate cases are defined as LTCH discharges that meet the patient-level criteria to be excluded from the typically lower site neutral payment rate, and site neutral payment rate cases are defined as LTCH discharges that do not meet the patient-level criteria and generally will be paid the lower site neutral payment rate. However, for discharges occurring in cost reporting periods beginning in FY 2016 or 2017, the statute specifies that site neutral payment rate cases are paid based on a transitional payment method that is calculated as 50 percent of the applicable site neutral payment rate amount and 50 percent of the applicable LTCH PPS standard Federal payment rate (which, as discussed earlier, will continue to apply to certain discharges occurring during FY 2018).

The basic methodology for determining a per discharge payment for LTCH PPS standard Federal payment rate cases is currently set forth under §§ 412.515 through 412.538. In addition to adjusting the LTCH PPS standard Federal payment rate by the MS–LTC–DRG relative weight, we make adjustments to account for area wage levels and SSOs (including our proposed SSO payment methodology). LTCHs located in Alaska and Hawaii also have their payments adjusted by a COLA. Under our application of the dual rate LTCH PPS payment structure, the LTCH PPS standard Federal payment rate is generally only used to determine payments for LTCH PPS standard Federal payment rate cases (that is, those LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate). LTCH discharges that do not meet the patient-level criteria for exclusion are paid the site neutral payment rate, which we are calculating as the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), including any applicable outlier payments, or 100 percent of the estimated cost of the case as determined under existing § 412.529(d)(2). In addition, when certain thresholds are met, LTCHs also receive HCO payments for both LTCH PPS standard Federal payment rate cases and site neutral payment rate cases that are paid at the IPPS comparable per diem amount.

To understand the impact of the changes to the LTCH PPS payments for LTCH PPS standard Federal payment rate cases presented in this final rule on different categories of LTCHs for FY 2018, it is necessary to estimate payments per discharge for FY 2017 using the rates, factors, and the policies established in the FY 2017 IPPS/LTCH PPS final rule and estimate payments per discharge for FY 2018 using the rates, factors, and the policies in this FY 2018 IPPS/LTCH PPS final rule (as discussed in section VIII. of the preamble of this final rule and section V. of the Addendum to this final rule). As discussed elsewhere in this final rule, these estimates are based on the best available LTCH claims data and other factors, such as the application of inflation factors to estimate costs for HCO cases in each year. The resulting analyses can then be used to compare how our policies applicable to LTCH PPS standard Federal payment rate cases affect different groups of LTCHs.

For the following analysis, we group hospitals based on characteristics provided in the OSCAR data, cost report data in HCRIS, and PSF data. Hospital groups included the following:

- Location: large urban/other urban/rural.
- Participation date.
- Ownership control.
- Census region.
- Bed size.

c. Calculation of LTCH PPS Payments for LTCH PPS Standard Federal Payment Rate Cases

For purposes of this impact analysis, to estimate the per discharge payment effects of our finalized policies on payments for LTCH PPS standard Federal payment rate cases, we simulated FY 2017 and FY 2018 payments on a case-by-case basis using historical LTCH claims from the FY 2016 MedPAR files that met or would have met the criteria to be paid at the LTCH PPS standard Federal payment rate if the statutory patient-level criteria had been in effect at the time of discharge for all cases in the FY 2016 MedPAR files. For modeling FY 2017 LTCH PPS payments, we used the FY 2017 standard Federal payment rate of $42,476.41 (or $41,641.49 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP). Similarly, for modeling payments based on the FY 2018 LTCH PPS standard Federal payment rate, we used the FY 2018 standard Federal payment rate of $41,430.56 (or $40,610.16 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP). In each case, we applied the applicable adjustments for area wage levels and the COLA for LTCHs located in Alaska and Hawaii. Specifically, for modeling FY 2017 LTCH PPS payments, we used the current FY 2017 labor-related share (66.5 percent); the wage index values established in the Tables 12A and 12B listed in the Addendum to the FY 2017 IPPS/LTCH PPS final rule (which are available via the Internet on the CMS Web site); the FY 2017 HCO fixed-loss amount for LTCH PPS standard Federal payment rate cases of $21,943 (as discussed in section V.D. of the Addendum to that final rule) and the FY 2017 COLA factors (shown in the table in section V.C. of the Addendum to that final rule) to adjust the FY 2017 nonlabor-related share (33.5 percent) for LTCHs located in Alaska and Hawaii. Similarly, for modeling FY 2018 LTCH PPS payments, we used the FY 2018 LTCH PPS labor-related share (66.2 percent), the FY 2018 wage index values from Tables 12A and 12B listed in section VI. of the Addendum to this final rule (which are available via the Internet on the CMS Web site), the FY 2018 fixed-loss amount for LTCH PPS standard Federal payment rate cases of $27,382 (as discussed in section V.D.3. of the Addendum to this final rule), and the FY 2018 COLA factors (shown in the table in section V.C. of the Addendum to this final rule) to adjust the FY 2018 nonlabor-related share (33.8 percent) for LTCHs located in Alaska and Hawaii.

As previously discussed, our impact analysis reflects an estimated change in payments for SSO cases (including our changes to the SSO payment methodology), as well as an estimated decrease in HCO payments for LTCH PPS standard Federal payment rate cases (as described previously in section I.J.1. of this Appendix). In modeling payments for SSO cases prior to accounting for our SSO payment methodology and for HCO cases for LTCH PPS standard Federal payment rate cases, we applied an inflation factor of 5.5 percent (determined by the Office of the Actuary) to update the 2016 costs of each case.

The impacts that follow reflect the estimated ''losses'' or ''gains'' among the various classifications of LTCHs from FY 2017 to FY 2018 based on the payment rates and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this final rule. Table IV illustrates the estimated aggregate impact of the change in LTCH PPS payments for LTCH PPS standard Federal payment rate cases among various classifications of LTCHs. (As discussed previously, these impacts do not include LTCH PPS site neutral payment rate cases.)

- The first column, LTCH Classification, identifies the type of LTCH.
- The second column lists the number of LTCHs of each classification type.
- The third column identifies the number of LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria.
- The fourth column shows the estimated FY 2017 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described previously).
- The fifth column shows the estimated FY 2018 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described previously).
- The sixth column shows the percentage change in estimated payments per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria from FY 2017 to FY 2018 due to the annual update to the standard Federal rate (as discussed in section V.A.2. of the Addendum to this final rule).
- The seventh column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2017 to FY 2018 for changes to the area wage level adjustment (that is, the wage indexes and the labor-related share), including the application of the area wage level budget neutrality factor (as discussed in section V.B. of the Addendum to this final rule).
- The eighth column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases for changes resulting from our SSO payment methodology and associated budget neutral adjustment to the LTCH PPS standard Federal payment rate (column 7).
- The ninth column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2017 (Column 4) to FY 2018 (Column 5) for all changes (and includes the effect of estimated changes to HCO and SSO payments).

TABLE IV—IMPACT OF PAYMENT RATE AND POLICY CHANGES TO LTCH PPS PAYMENTS FOR STANDARD PAYMENT RATE CASES FOR FY 2018

[Estimated FY 2017 payments compared to estimated FY 2018 payments]

LTCH classification	Number of LTCHS	Number of LTCH PPS standard payment rate cases	Average FY 2017 LTCH PPS payment per standard payment rate	Average FY 2018 LTCH PPS payment per standard payment rate [1]	Percent change due to change to the annual update to the standard federal rate [2]	Percent change due to changes to area wage adjustment with wage budget neutrality [3]	Proposed percent change due to change to the short stay outlier payment methodology change [4]	Percent change due to all standard payment rate changes [5]
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
All Providers	415	73,915	$46,637	$47,108	0.9	0.0	0.0	1.0
By Location:								
Rural	21	2,223	38,004	37,971	0.9	−0.3	−0.3	−0.1
Urban	394	71,692	46,905	47,392	0.9	0.0	0.0	1.0
Large	199	41,253	49,568	50,142	0.9	0.1	0.1	1.2
Other	195	30,439	43,294	43,665	0.9	−0.1	−0.2	0.9
By Participation Date:								
Before Oct. 1983	11	1,832	43,730	44,550	0.9	−0.6	0.7	1.9
Oct. 1983–Sept. 1993	42	9,202	52,289	52,672	0.8	−0.1	−0.2	0.7
Oct. 1993–Sept. 2002	167	27,657	46,363	46,846	0.9	0.1	0.1	1.0
After October 2002	195	35,224	45,527	45,994	0.9	0.0	−0.1	1.0
By Ownership Type:								
Voluntary	72	9,636	48,980	49,288	0.9	−0.1	−0.3	0.6
Proprietary	329	62,783	46,105	46,619	0.9	0.0	0.1	1.1
Government	14	1,496	53,851	53,603	0.9	−0.2	−1.1	−0.5
By Region:								
New England	12	2,757	43,309	44,407	0.9	−0.3	0.7	2.5
Middle Atlantic	25	5,896	51,862	52,196	0.9	−0.1	0.2	0.6
South Atlantic	66	13,333	46,700	47,211	0.9	−0.1	0.2	1.1
East North Central	68	11,540	46,371	46,732	0.9	0.0	−0.1	0.8
East South Central	34	5,276	43,787	44,299	0.9	0.0	0.5	1.2
West North Central	28	4,402	45,291	45,233	0.9	0.1	−1.3	−0.1
West South Central	126	18,529	41,578	41,922	0.9	0.01	−0.4	0.8
Mountain	31	4,279	48,360	48,775	0.9	−0.2	−0.1	0.9
Pacific	25	7,903	57,760	58,809	0.8	0.0	0.5	1.8
By Bed Size:								
Beds: 0–24	26	1,770	46,206	46,346	0.9	0.5	−0.7	0.3
Beds: 25–49	195	26,171	43,608	43,970	0.9	−0.1	0.0	0.8
Beds: 50–74	117	20,276	48,220	48,530	0.9	−0.1	−0.2	0.6
Beds: 75–124	45	12,708	49,890	50,560	0.9	0.2	0.1	1.3
Beds: 125–199	23	8,079	47,633	48,228	0.9	0.0	0.0	1.2
Beds: 200+	9	4,911	46,341	47,462	0.8	0.0	0.8	2.4

[1] Estimated FY 2018 LTCH PPS payments for LTCH PPS standard Federal payment rate criteria based on the payment rate and factor changes applicable to such cases presented in the preamble of and the Addendum to this final rule.

[2] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2017 to FY 2018 for the annual update to the LTCH PPS standard Federal payment rate.

[3] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2017 to FY 2018 for changes to the area wage level adjustment under § 412.525(c) (as discussed in section V.B. of the Addendum to this final rule).

[4] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2017 to FY 2018 for change to the SSO payment methodology.

[5] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2017 (shown in Column 4) to FY 2018 (shown in Column 5), including all of the changes to the rates and factors applicable to such cases presented in the preamble and the Addendum to this final rule. We note that this column, which shows the percent change in estimated payments per discharge for all changes, does not equal the sum of the percent changes in estimated payments per discharge for the annual update to the LTCH PPS standard Federal payment rate (Column 6) and the changes to the area wage level adjustment with budget neutrality (Column 7) due to the effect of estimated changes in both estimated payments to SSO cases (prior to accounting for the change to the SSO payment methodology) and aggregate HCO payments for LTCH PPS standard Federal payment rate cases (as discussed in this impact analysis), as well as other interactive effects that cannot be isolated.

d. Results

Based on the FY 2016 LTCH cases (from 415 LTCHs) that were used for the analyses in this final rule, we have prepared the following summary of the impact (as shown in Table IV) of the LTCH PPS payment rate and policy changes for LTCH PPS standard Federal payment rate cases presented in this final rule. The impact analysis in Table IV shows that estimated payments per discharge for LTCH PPS standard Federal payment rate cases are projected to increase 1.0 percent, on average, for all LTCHs from FY 2017 to FY 2018 as a result of the payment rate and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this final rule. This estimated 1.0 percent increase in LTCH PPS payments per discharge was determined by comparing estimated FY 2018 LTCH PPS payments (using the payment rates and factors discussed in this final rule) to estimated FY 2017 LTCH PPS payments for LTCH discharges which will be LTCH PPS standard Federal payment rate cases if the dual rate LTCH PPS payment structure was or had been in effect at the time of the discharge (as described in section I.J.4. of this Appendix).

As stated previously, we are updating the LTCH PPS standard Federal payment rate for FY 2018 by 1.0 percent as required by statute. For LTCHs that fail to submit quality data under the requirements of the LTCH QRP, as required by section 1886(m)(5)(C) of the Act, a 2.0 percentage point reduction is applied to the annual update to the LTCH PPS standard Federal payment rate. Consistent with § 412.523(d)(4), we also are applying an area wage level budget neutrality factor to the FY 2018 LTCH PPS standard Federal payment rate of 1.0006434, based on the best available data at this time, to ensure that any changes to the area wage level adjustment (that is, the annual update of the wage index values and labor-related share) will not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard Federal payment rate payments. Finally, we are making a budget neutrality adjustment of 0.9651 for our changes to the SSO payment methodology (discussed in VIII.E.2.d. of the preamble of this final rule). As we also explained earlier in this section, for most categories of LTCHs (as shown in Table IV,

Column 6), the estimated payment increase due to the 1.0 percent annual update to the LTCH PPS standard Federal payment rate is projected to result in approximately a 0.9 percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases for all LTCHs from FY 2017 to FY 2018. This is because our estimate of the changes in payments due to the update to the LTCH PPS standard Federal payment rate also reflects estimated payments for SSO cases that are paid using special methodologies that are not affected by the update to the LTCH PPS standard Federal payment rate (prior to accounting for the change to the SSO payment methodology). Consequently, for certain hospital categories, we estimate that payments to LTCH PPS standard Federal payment rate cases may increase by less than 1.0 percent due to the annual update to the LTCH PPS standard Federal payment rate for FY 2018.

(1) Location

Based on the most recent available data, the vast majority of LTCHs are located in urban areas. Only approximately 5 percent of the LTCHs are identified as being located in a rural area, and approximately 3 percent of all LTCH PPS standard Federal payment rate cases are expected to be treated in these rural hospitals. The impact analysis presented in Table IV shows that the overall average percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2017 to FY 2018 for all hospitals is 1.0 percent. However, for rural LTCHs, the overall percent change for LTCH PPS standard Federal payment rate cases is estimated to be a 0.1 percent decrease. This projected decrease is primarily driven by a projected decrease resulting from changes to the changes to the area wage index adjustment. For urban LTCHs, we estimate an increase of 1.0 percent from FY 2017 to FY 2018. Among the urban LTCHs, large urban LTCHs are projected to experience an increase of 1.2 percent in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2017 to FY 2018, and the remaining urban LTCHs are projected to experience an increase of 0.9 percent in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2017 to FY 2018, as shown in Table IV.

(2) Participation Date

LTCHs are grouped by participation date into four categories: (1) Before October 1983; (2) between October 1983 and September 1993; (3) between October 1993 and September 2002; and (4) October 2002 and after. Based on the most recent available data, the categories of LTCHs with the largest expected percentage of LTCH PPS standard Federal payment rate cases (approximately 48 percent) are in LTCHs that began participating in the Medicare program after October 2002, and they are projected to experience a 1.0 percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2017 to FY 2018, as shown in Table IV.

Approximately 2.7 percent of LTCHs began participating in the Medicare program before October 1983, and these LTCHs are projected to experience an average percent increase of 1.9 percent in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2017 to FY 2018, as shown in Table IV with a large portion of this increase among this small group of LTCHs to be a projected 0.7 percent increase resulting from our SSO payment methodology. Approximately 10 percent of LTCHs began participating in the Medicare program between October 1983 and September 1993, and these LTCHs are projected to experience an increase of 0.7 percent in estimated payments for LTCH PPS standard Federal payment rate cases from FY 2017 to FY 2018. LTCHs that began participating in the Medicare program between October 1993 and October 1, 2002, which treat approximately 37 percent of all LTCH PPS standard Federal payment rate cases, are projected to experience a 1.0 percent increase in estimated payments from FY 2017 to FY 2018.

(3) Ownership Control

LTCHs are grouped into four categories based on ownership control type: voluntary, proprietary, government and unknown. Based on the most recent available data, approximately 17 percent of LTCHs are identified as voluntary (Table IV). The majority (approximately 80 percent) of LTCHs are identified as proprietary, while government owned and operated LTCHs represent approximately 3 percent of LTCHs. Based on ownership type, voluntary LTCHs are expected to experience a 0.6 percent increase in payments to LTCH PPS standard Federal payment rate cases, while proprietary LTCHs are expected to experience an average increase of 1.1 percent in payments to LTCH PPS standard Federal payment rate cases. Government owned and operated LTCHs, meanwhile, are expected to experience a 0.5 percent decrease in payments to LTCH PPS standard Federal payment rate cases from FY 2017 to FY 2018.

(4) Census Region

Estimated payments per discharge for LTCH PPS standard Federal payment rate cases for FY 2017 are projected to increase across 8 of the 9 census regions. LTCHs located in the West North Central region are projected to experience a slight decrease of 0.1 percent, while LTCHs located in all other regions are projected to experience an increase in estimated payments per discharge in comparison to FY 2017. Of the 9 census regions, we project that the increase in estimated payments per discharge to LTCH PPS standard Federal payment rate cases will have the largest positive impact on LTCHs in the New England regions (2.5 percent, as shown in Table IV), which is largely attributable to changes to the SSO payment methodology. In contrast, LTCHs located in the Middle Atlantic region are projected to experience the smallest increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2017 to FY 2018 (0.6 percent).

(5) Bed Size

LTCHs are grouped into six categories based on bed size: 0–24 beds; 25–49 beds; 50–74 beds; 75–124 beds; 125–199 beds; and greater than 200 beds. We project that LTCHs with 0–24 beds will experience an increase in payments for LTCH PPS standard Federal payment rate cases of 0.3 percent, and LTCHs with 25–49 beds will experience an increase in payments for LTCH PPS standard Federal payment rate cases of 0.8 percent. LTCHs with 50–74 beds will experience an increase in payments for LTCH PPS standard Federal payment rate cases of 0.6 percent. We project the largest increases in payments to occur in LTCHs with at least 75 beds. In particular, we project LTCHs with 75–124 beds will experience an increase in payments for LTCH PPS standard Federal payment rate cases of 1.3 percent while LTCHs with 125–199 beds will experience an increase in payments for LTCH PPS standard Federal payment rate cases of 1.2 percent. Finally, LTCHs with 200 or more beds will experience the largest increase in payments for LTCH PPS standard Federal payment rate cases of 2.4 percent mostly due to estimated increase in payments from changes to our SSO payment methodology.

4. Effect on the Medicare Program

As stated previously, we project that the provisions of this final rule will result in an increase in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases in FY 2018 relative to FY 2017 of approximately 35 million (or approximately 1.0 percent) for the 415 LTCHs in our database. Although, as stated previously, the hospital-level impacts do not include LTCH PPS site neutral payment rate cases, we estimate that the provisions of this final rule will result in a decrease in estimated aggregate LTCH PPS payments to site neutral payment rate cases in FY 2018 relative to FY 2017 of approximately $230 million (or approximately 20 percent) for the 415 LTCHs in our database. Therefore, we project that the provisions of this final rule will result in a decrease in estimated aggregate LTCH PPS payments to all LTCH cases in FY 2018 relative to FY 2017 of approximately $195 million (or approximately 4.2 percent) for the 415 LTCHs in our database. Furthermore, as stated previously, our Office of the Actuary estimates an additional estimated increase in aggregate FY 2018 LTCH PPS payments of approximately $85 million for our finalized policy to delay full implementation of the 25-percent threshold policy for FY 2018 and our implementation of certain provisions of the 21st Century Cures Act. Therefore, in total, we project an overall decrease in LTCH PPS payments of approximately $110 million ($195 million decrease + $85 million increase) or approximately a 2.4 percent decrease in LTCH PPS payments in FY 2018 as compared to FY 2017.

5. Effect on Medicare Beneficiaries

Under the LTCH PPS, hospitals receive payment based on the average resources consumed by patients for each diagnosis. We do not expect any changes in the quality of care or access to services for Medicare beneficiaries as a result of this final rule, but we continue to expect that paying prospectively for LTCH services will enhance the efficiency of the Medicare program. As

discussed above, we do not expect the continued implementation of the site neutral payment system to have a negative impact access to or quality of care, as demonstrated in areas where there is little or no LTCH presence, general short-term acute care hospitals are effectively providing treatment for the same types of patients that are treated in LTCHs.

K. Effects of Requirements for the Hospital Inpatient Quality Reporting (IQR) Program

1. Background

In section IX.A. of the preambles of the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20031 through 20075) and this final rule, we discuss our requirements for hospitals to report quality data under the Hospital IQR Program in order to receive the full annual percentage increase for the FY 2020 payment determination.

In this final rule, we are finalizing our policies to: (1) modify the previously finalized the electronic clinical quality measure (eCQM) reporting requirements for the FY 2019 and FY 2020 payment determinations, such that hospitals submit one, self-selected calendar quarter of data for 4 eCQMs; (2) update the eCQM certification requirements for the FY 2019 and FY 2020 payment determinations; (3) modify the previously finalized eCQM data validation process, whereby hospitals selected for eCQM data validation will be required to submit a reduced number of cases for eCQM data validation for the FY 2020 and FY 2021 payment determinations; (4) allow hospitals to use an educational review process to correct incorrect validation results for the first three quarters of validation for chart-abstracted measures beginning with the FY 2020 payment determination and for subsequent years; (5) begin voluntary reporting on the Hybrid Hospital-Wide 30-Day Readmission (HWR) measure for the CY 2018 reporting period; (6) refine the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey measure to replace the questions on Pain Management for the FY 2020 payment determination and subsequent years; (7) refine the Hospital 30-Day Mortality Following Acute Ischemic Stroke Hospitalization measure to include the use of NIH Stroke Scale claims data for the FY 2023 payment determination and subsequent years; and (8) update the terminology used to refer to the Extraordinary Circumstances Exceptions (ECE) policy for the FY 2020 payment determination and subsequent years.

As further explained in section XIII.B.3. of the preamble of this final rule, we believe that there will be an overall decrease in burden for hospitals due to the finalized policies discussed above. We refer readers to section XIII.B.3. of the preamble of this final rule for a summary of our burden estimates.

2. Impact of the Updates to the eCQM Reporting Requirements for the CY 2017 Reporting Period/FY 2019 and CY 2018 Reporting Period/FY 2020 Payment Determinations

In the FY 2017 IPPS/LTCH PPS final rule, we finalized policies to require hospitals to submit a full year (four quarters) of data (81 FR 57159) for at least eight eCQMs (81 FR 57157) for both the FY 2019 and FY 2020 payment determinations. In section IX.A.8. of the preamble of this final rule, we are finalizing modifications to the eCQM reporting requirements we proposed in the FY 2018 IPPS/LTCH PPS proposed rule, such that, for the CY 2017 reporting period/FY 2019 payment determination and CY 2018 reporting period/FY 2020 payment determination, hospitals must submit one, self-selected, calendar quarter of data for 4 eCQMs. As discussed in section XIII.B.3.b. of the preamble of this final rule, we believe the reduced number of eCQMs required for the CY 2017 and CY 2018 reporting periods will result in a reduction of 15,400 hours (−280 minutes per hospital per year/60 minutes per hours × 3,300 hospitals) and $563,332 (15,400 hours × $36.58 per hour) for each of the FY 2019 and FY 2020 payment determinations.

3. Impact of the Modifications to the Existing Data Validation Processes for the FY 2020 Payment Determination and Subsequent Years

In section IX.A.11. of the preamble of this final rule, we discuss our finalized policy to modify the existing eCQM data validation process for the Hospital IQR Program data beginning with validation for the FY 2020 payment determination. First, we are finalizing with modifications our proposal to require hospitals selected for eCQM data validation to submit eight cases per quarter for the FY 2020 payment determination and subsequent years.[519] We are also finalizing our proposals to: (1) Add additional exclusion criteria to our hospital and case selection process for eCQM data validation for the FY 2020 payment determination and subsequent years; and (2) extend our previously finalized medical record submission requirements the accuracy of eCQM data submitted for validation will not affect a hospital's validation score for the FY 2021 payment determination and subsequent years. As discussed in section XIII.B.3.d.(1) of the preamble of this final rule, we estimate our proposal to reduce the number of cases submitted by hospitals submitted by hospitals selected for eCQM data validation will result in an annual burden reduction of approximately 6,400 hours (8,533 hours estimated in the FY 2017 IPPS/LTCH PPS final rule −2,133 hours estimated in this final rule) and $234,112 (6,400 hours × $36.58 per hour) across the 200 hospitals selected for eCQM validation.

4. Impact of the Voluntary Reporting on the Hybrid Hospital-Wide 30-Day Readmission Measure for the CY 2018 Reporting Period

In section IX.A.7.b. of the preamble of this final rule, we are finalizing our proposal that hospitals may voluntarily submit the 13 core clinical data elements and the 6 data elements required for linking with claims data for this measure using the same submission process required for eCQM reporting, specifically, that these data be reported using QRDA I files submitted to the CMS data receiving system. As discussed in section XIII.B.3.e., we expect the burden associated with voluntary reporting of this measure to be approximately 67 hours (40 minutes per hospital/60 minutes per hour × 100 hospitals = 67 hours) and $2,451 ($36.58 per hour × 67 hours annually) across up to 100 hospitals voluntarily participating in reporting for the Hybrid HWR measure.

5. Summary of Effects

Historically, 100 hospitals, on average, that participate in the Hospital IQR Program do not receive the full annual percentage increase in any fiscal year due to the requirements of this program. We anticipate that, because of the modified, reduced requirements for eCQM reporting that we are finalizing for the FY 2019 and FY 2020 payment determinations, the number of hospitals not receiving the full annual percentage increase will not substantially increase due to this requirement of the program. If the number of hospitals failing to receive the full annual percentage increase does increase because of our modified requirements, we anticipate that, over the long run, this number will decline as hospitals gain more experience with these requirements.

In implementing the Hospital IQR Program and other quality reporting programs, we have focused on measures that have high impact and support CMS and HHS priorities for improving the quality of care and value for Medicare beneficiaries.

L. Effects of Requirements for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

In section IX.B. of the preambles of the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20075 through 20086) and this final rule, we discuss our policies for the quality data reporting program for PPS-exempt cancer hospitals (PCHs), which we refer to as the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. The PCHQR Program is authorized under section 1866(k) of the Act, which was added by section 3005 of the Affordable Care Act. There is no financial impact to PCH Medicare reimbursement if a PCH does not submit data.

In section IX.B.4. of the preamble of this final rule, we are finalizing our proposals to adopt four claims-based measures beginning with the FY 2020 program: (1) Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (NQF #0210); (2) Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life (NQF #0213); (3) Proportion of Patients Who Died from Cancer Not Admitted to Hospice (NQF #0215); and (4) Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days (NQF #0216)). In conjunction with our finalized proposal in section IX.B.3.b. of the preamble of this final rule to

[519] We are finalizing this requirement in conjunction with our finalized policy to require hospitals to report one, self-selected quarter of data for 4 eCQMs for each of the CY 2017 and CY 2018 eCQM reporting periods, as described above. Accordingly, we are finalizing our modified policy and will require the number of required case files for validation will be 8 records (eight cases for one quarter) for each of the FY 2020 and FY 2021 payment determinations.

remove three existing chart-abstracted measures beginning with the FY 2020 program—(1) Adjuvant Chemotherapy is Considered or Administered Within 4 Months (120 Days) of Diagnosis to Patients Under the Age of 80 with AJCC III (Lymph Node Positive) Colon Cancer (PCH–01/NQF #0223); (2) Combination Chemotherapy is Considered or Administered Within 4 Months (120 Days) of Diagnosis for Women Under 70 with AJCC T1c, or Stage II or III Hormone Receptor Negative Breast Cancer (PCH–02/NQF #0559); and (3) Adjuvant Hormonal Therapy (PCH–03/NQF #0220)—the PCHQR Program measure set will consist of 18 measures for the FY 2020 program.

As further explained in section XIII.B.4. of the preamble of this final rule, we anticipate that these new requirements will reduce overall burden on participating PCHs. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53667), we estimated a burden of 30 minutes for a PCH to perform chart abstraction of a single patient record and submit it to CMS. Using estimates from the FY 2013 IPPS/LTCH PPS final rule (77 FR 53667), we estimate the total annual hourly burden for each PCH for the collection and submission of measure information and the training of personnel for submitting quality measure data applicable to one (1) chart-abstracted measure is approximately 1,258.7 hours per year, or 104.9 hours per month (1,258.7 hours per year/12 months). We multiply this number by three (3) to obtain our estimated reduction in burden for collecting measure information, submitting measure information, and training personnel provided by the finalized removal of the three measures, which is approximately 3,776 hours per year for each PCH, or an average reduction in burden of 315 hours per month per PCH and a total of 41,536 hours across all 11 PCHs. Our finalized removal of three chart-abstracted measures will reduce the burden associated with quality data reporting on PCHs by reducing quality measure chart abstraction by approximately 16,364 cases across all 11 PCHs.

We do not anticipate any increase in burden on the PCHs corresponding to our finalized adoption of four claims-based measures into the PCHQR Program beginning with the FY 2020 program year. These measures are claims-based and therefore do not require facilities to report any additional data. Because these measures do not require facilities to submit any additional data, we do not believe that there is any associated burden with this finalized policy.

M. Effects of Requirements for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In section IX.C.1. of the preambles of the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20086 through 20121) and this final rule, we discuss the implementation of the LTCH QRP. At the time that this analysis was prepared, 41, or approximately 9.7 percent, of 424 eligible LTCHs were determined to be noncompliant and therefore received a 2 percentage point reduction to their FY 2017 annual payment update. We anticipate that fewer LTCHs will receive the reduction for FY 2018 as LTCHs become more familiar with the requirements as we believe that continued trainings, as well as utilization of new reports for LTCHs, will help LTCHs comply with the LTCH QRP requirements. Thus, we estimate that the proposals that we are finalizing in this final rule will have a negligible impact on overall LTCH payments for FY 2018.

In section IX.C.7. of the preamble of this final rule, we are finalizing our proposal to replace the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), with a new modified version of the measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, beginning with the FY 2020 LTCH QRP. We are also finalizing our proposals to adopt two additional measures: Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay; and Ventilator Liberation Rate, beginning with the FY 2020 LTCH QRP. In addition, we are finalizing our proposals that data for these measures will be collected and reported using the LTCH CARE Data Set (LTCH CARE Data Set Version 4.00, which will be effective July 1, 2018). For more information regarding the LTCH CARE Data Set Version 4.00 implementation date, we refer readers to section IX.C.11. of the preamble of this final rule.

We also are finalizing our proposal to remove the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512). Because LTCHs will still be required to report data on this measure for payment purposes, we believe that the removal of this measure will not affect the burden estimate for the LTCH QRP.

In addition, adoption of the pressure ulcer measure, Change in Skin Integrity Post-Acute Care: Pressure Ulcer Injury which will replace the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), will result in the removal of some data elements related to pressure ulcer assessment that we believe are duplicative or no longer necessary. As a result, the estimated burden and cost for LTCHs to report the newly finalized measure will be reduced from the burden and cost to report the current measure.

We also are finalizing our proposals to remove the program interruption items from the LTCH CARE Data Set. Specifically, we are finalizing our proposals to remove the following items: A2500, Program Interruption(s); A2510, Number of Program Interruptions During This Stay in This Facility; and A2525, Program Interruption Dates, because we do not currently utilize this information and do not have plans to utilize this information for the LTCH QRP. As a result, the estimated burden and cost for LTCHs will be reduced.

In section IX.C.10. of the preamble of this final rule, we are finalizing standardized patient assessment data proposals with respect to the Functional Status and Medical Condition and Comorbidity categories. All of the data elements are already included on the LTCH CARE Data Set and therefore our finalized policy to characterize those data elements as standardized patient assessment data will not result in an additional reporting burden for LTCHs.

We are not finalizing our proposals to require LTCHs to report 25 new standardized patient assessment data elements with respect to LTCH admissions and 17 new standardized patient assessment data elements with respect to LTCH discharges. This results in a burden reduction from what we proposed. We refer readers to the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20225 through 20226), for a discussion of our burden estimates for these proposals.

As described in section XIII.B.6. of the preamble of this final rule, the 4.5-minute increase in burden for the two finalized ventilator weaning quality measures is offset by the 3 minute reduction in burden for the finalized pressure ulcer quality measure and the 3.6 minute reduction in burden for the program interruption items. This results in a net reduction in burden of 2.1 minutes. Overall, this results in a net decrease in cost associated with the finalized changes to the LTCH QRP, which we estimate to be reduced by estimated at a reduction of $893.14 per LTCH annually, or $380,480 for all LTCHs annually.

For additional discussion of information collection requirements related to our finalized proposals, we refer readers to section XIII.B.6 of the preamble of this final rule. We received public comments about the effects of requirements for the LTCH QRP, which we summarize and respond to below.

Comment: Several commenters expressed views regarding the burden imposed by the proposed LTCH CARE Data Set Version 4.00. One commenter commended CMS for ensuring robust and accurate quality reporting, but noted that the absence of EHRs in the LTCH setting contributes to this burden and requires extra staff to collect, process, and transmit the necessary data. Another commenter noted the importance of assessing the value of new quality measures, and ensuring that they are not prematurely implemented.

Response: We always considers provider burden, and we take this into account when developing quality measures or standardized patient assessment data elements for inclusion into our quality reporting programs. We assess the value of adopting new quality measures into the LTCH QRP and we consider overall clinical relevance and usability to support clinical decision-making, care transitions, and resource utilization.

In response to the commenter's concern regarding EHRs, while we support the use of EHRs, we do not require that providers use EHRs to populate assessment data in the LCDS. We also disagree with the commenter's suggestion that we do not provide a mechanism for collecting, processing, and transmitting data, and we note that with each assessment release, we offer free software for LTCHs (LASER), allowing LTCHs to record and transmit the required LTCH CARE Data Set assessment based data. This free software, including instructions for installing and using the software, is located at: *https://www.qtso.com/laser.html*.

We intend to continue to closely monitor the effects of the LTCH QRP on LTCHs and help facilitate successful reporting outcomes through ongoing stakeholder education, national trainings, LTCH announcements, Web site postings, CMS Open Door Forums, and general and technical help desks.

As discussed in section IX.C.11.d. of the preamble of this final rule, after consideration of the public comments we received, we are moving the release date for the LTCH CARE Data Set Version 4.00 from April 1, 2018 to July 1, 2018. The LTCH CARE Data Set Version 4.00, which will be effective July 1, 2018, will contain additional data elements needed to calculate the Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP quality measure, which was finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57219 through 57223), as well as the data elements needed to calculate the measures we are adopting in this final rule.

Comment: A few commenters stated that CMS' burden estimates were inaccurate, pointing out the need for additional staff, training, and expenses when items are added to the LTCH CARE Data Set.

Response: Our burden estimates only capture the time needed to complete LTCH CARE Data Set data elements and do not include clinical time spent assessing the patient as this activity is already part of the healthcare providers standard of care.

N. Effects of Updates to the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program

As discussed in section IX.D. of the preambles of the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20120 through 20130) and this final rule, and in accordance with section 1886(s)(4)(A) of the Act, we will implement a 2 percentage point reduction in the FY 2020 market basket update for IPFs that have failed to comply with the IPFQR Program requirements for the FY 2020 payment determination. In section IX.D. of the preamble of this final rule, we discuss how the 2 percentage point reduction will be applied. For the FY 2017, payment determination (that is, data collected during CY 2015 and submitted in CY 2016) of the 1,647 IPFs eligible for the IPFQR Program, 49 did not receive the full market basket update due to reasons specific to the IPFQR Program; 22 of these IPFs chose not to participate and 27 did not meet the requirements of the Program. We anticipate that even fewer IPFs will receive the reduction for FY 2018 as IPFs become more familiar with the requirements. Thus, we estimate that the IPFQR Program will have a negligible impact on overall IPF payments for FY 2018.

We intend to closely monitor the effects of this quality reporting program on IPFs and to help facilitate successful reporting outcomes through ongoing stakeholder education, national trainings, and a technical help desk.

We are finalizing our proposals, without change, that impact the FY 2018 procedural requirements and subsequent years. We are not finalizing our proposal to adopt one claims-based measure for the FY 2020 payment determinations and subsequent years. We refer readers to section XIII.B.7. of the preamble of this final rule for details discussing information collection requirements for the IPFQR Program.

O. Effects of Requirements Regarding the Electronic Health Record (EHR) Incentive Programs and Meaningful Use

In section IX.E of the preambles of the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20130 through 20133) and this final rule, we discuss proposed and newly finalized policies for eligible hospitals and CAHs reporting CQMs electronically under the Medicare and Medicaid EHR Incentive Programs in 2017 and 2018. As outlined in this final rule, we are finalizing modifications to our proposals and making the following modifications to the CY 2017 final CQM policies: (1) Revising the CY 2017 reporting period for eligible hospitals and CAHs reporting CQMs electronically to require the submission of one, self-selected calendar quarter of data; and (2) revising the number of CQMs eligible hospitals and CAHs are required to report electronically for CY 2017 to 4 (self-selected) available CQMs.

In addition, we are finalizing modifications to our proposals that adopt the following CQM reporting requirements for CY 2018: (1) For eligible hospitals and CAHs reporting CQMs electronically that demonstrate meaningful use for the first time in 2018 or that have demonstrated meaningful use in any year prior to 2018, the reporting period will be one, self-selected quarter of data from CY 2018 with a submission period (Medicare EHR Incentive Program only) consisting of the 2 months following the close of the calendar year, ending on February 28, 2019; (2) eligible hospitals and CAHs reporting CQMs electronically will be required to report at least 4 (self-selected) of the available CQMs; (3) eligible hospitals and CAHs that report CQMs by attestation under the Medicare EHR Incentive Program because electronic reporting is not feasible, and eligible hospitals and CAHs that report CQMs by attestation under their State's Medicaid EHR Incentive Program, will be required to report on all 16 available CQMs; and (4) eligible hospitals and CAHs reporting CQMs by attestation under the Medicare EHR Incentive Program will have a submission period that will be the 2 months following the close of the CY 2018 CQM reporting period, ending February 28, 2019.

Because the finalized reporting requirements for data collection regarding the reporting of CQMs electronically under the Medicare and Medicaid EHR Incentive Programs will align with the reporting requirements under the Hospital IQR Program, we do not believe that there is any additional burden for the collection of such information. We did not propose modifications for the CQMs reporting requirements by attestation in this section. Therefore, no change in burden associated with attestation of CQMs will result from this section.

In section IX.F of the preambles of the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20134 through 20135) and this final rule, we discuss proposed and newly finalized policies regarding clinical quality measurement for EPs participating in the Medicaid EHR Incentive Program. We note that there may be costs incurred by States associated with systems development as a result of the newly finalized policies. State attestation systems will likely require minor updates, which may be eligible for support through enhanced Federal funding, subject to CMS prior approval, if outlined in an updated Implementation Advance Planning Document (IAPD). We anticipate that eligible professionals (EPs) may also face minor burden and incremental capital cost for updating clinical quality measures and reporting capabilities in the EHR. However, we intend to reduce EP burden and simplify the program through these newly finalized policies, which are intended to better align CQM reporting periods and CQM reporting for the Medicaid EHR Incentive Program with policies under MIPS. Overall, we believe the finalized CQM alignment at the State attestation system and EP levels will both reduce burden associated with reporting on multiple CMS programs and enhance State and CMS operational efficiency.

In section IX.G.1. of the preamble of the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20135 through 20136) and section IX.G.2. of the preamble of this final rule, we discuss our proposed and newly finalized policies to change the EHR reporting period in 2018 from the full CY 2018 to any continuous 90-day period within CY 2018 for all new and returning EPs, eligible hospitals and CAHs attesting to meaningful use in the Medicare and Medicaid EHR Incentive Programs. We do not believe that modifying the EHR reporting period for attestation will cause an increase in cost because the reporting requirements for a 90-day EHR reporting period are virtually the same as for a full calendar year EHR reporting period because the requirements for a full calendar year EHR reporting period and 90-day EHR reporting period require the same number of objectives and measures to be met.

In section IX.G.2. of the preamble of the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20136 through 20138) and section IX.G.3. of the preamble of this final rule, as required by the 21st Century Cures Act (Pub. L. 114–255), we discuss and finalize our proposal for an exemption from the payment adjustments under sections 1848(a)(7)(A), 1886(b)(3)(B)(ix)(I), and 1814(l)(4) of the Act for EPs, eligible hospitals and CAHs, respectively, that demonstrate through an application process that compliance with the requirements for being a meaningful EHR user is not possible because their certified EHR technology has been decertified under ONC's Health IT Certification Program. The application process involves participants completing an application form for an exception. While the form is standardized, we believe it is exempt from the PRA. The form is structured as an attestation. Therefore, we believe it is exempt under 5 CFR 1320.3(h)(1) of the implementing regulations of the PRA. The form is an attestation that imposes no burden beyond what is required to provide identifying information and to attest to the applicable information.

In section IX.G.3. of the preamble of the FY 2018 IPPS/LTCH PPS proposed rule (82 FR

20138 through 20139) and IX.G.4. of the preamble of this final rule, as required by the 21st Century Cures Act, we discuss and finalize our proposal to exempt ambulatory surgical center-based EPs from the 2017 and 2018 payment adjustments under section 1848(a)(7)(A) of the Act if they furnish substantially all of their covered professional services in an ambulatory surgical center. We do not believe this requirement will cause an increase in burden as CMS will identify the EPs who might meet this requirement.

For the information collection requirements relating to the above finalized proposals, we refer readers to section XIII.B.8. of the preamble of this final rule.

P. Effects of Electronic Signature and Electronic Submission of the Certification and Settlement Summary Page of Medicare Cost Reports

In section X.A. of the preambles of the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20139 through 20142) and this final rule, we discuss and finalize our proposal to allow providers to use an electronic signature on the certification statement of the Certification and Settlement Summary page of the Medicare cost report and submit it electronically. This final policy will result in savings to providers.

Using the most current data from Medicare's System for Tracking Audit and Reimbursement, approximately 51,000 providers file a Medicare cost report and, therefore, must currently mail the Certification and Settlement Summary page. Because most providers mail the Certification and Settlement Summary page via certified mail with return receipt (which includes delivery confirmation), at the current U.S. Postal Service price of $7.10, if all of these providers elect to electronically submit the Certification and Settlement Summary page with an electronic signature, this final policy will collectively save these providers approximately $362,000 in postage costs. This is an underestimate as it does not include mailing costs when providers choose to mail the Certification and Settlement Summary page to their contractors via overnight mail at a significantly higher expense.

Q. Effects of Changes Relating to Survey and Certification Requirements

In section XI.B. of the preambles of the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20145 through 20146) and this final rule, we discuss and finalize our proposal to eliminate the term ''newspaper'' from the requirement to publish public notice upon a provider's involuntary termination for RHCs, FQHCs, ASCs, and OPOs. Eliminating the term ''newspaper'' will allow greater flexibility for the CMS Regional Offices in publishing public notices and will also reduce burden on the CMS Regional Offices.

The print newspaper advertisements for an involuntary termination are required to be purchased by the CMS Regional Office assigned to that provider or supplier. The advertisement is placed under the legal advertisement section of the local newspaper outlet. A single CMS Regional Office may incur an average annual cost of approximately $3,000 to $5,000 for the purchase of involuntary termination notices for the providers or suppliers assigned to its region. For example, from 2014 to 2016, the Dallas Regional Office spent $14,331.89 on the publication of termination notices in local newspapers, with costs of $3,949.45 in 2014, costs of $5,386.67 in 2015, and costs of $4,998.77 in 2016. In same timeframe of 2014 to 2016, the Philadelphia Regional Office spent a total of $7,114.75 and the Kansas Regional Office spent a total of $11,121.40. The table below depicts the actual FY 2016 costs for all 10 CMS Regional Offices.

Regional office	2016 costs
Boston	$4,766
New York	645
Philadelphia	3,570
Atlanta	6,712
Chicago	10.853
Dallas	4,252
Kansas City	3,098
Denver	910
San Francisco	1,507
Seattle	707
Total Cost	37,020.00

If one CMS Regional Office spends approximately $5,000 annually, and there are 10 CMS Regional Offices, the average cost nationwide per annum for termination notices could be as high as $50,000.

The cost associated with the involuntary termination notice is assessed only to the CMS Regional Offices. The provider or supplier is not required to post a notice for an involuntary termination. Therefore, there will be no associated costs for the provider or supplier.

All CMS Regional Offices have Web sites available to the public, which are regularly maintained and updated. Creation of a subsite to reflect termination notices for providers will be at no cost to CMS. In addition, the use of Regional Press Officers to convey termination of a provider will be a minimal cost to CMS and absorbed through the Survey & Certification budget.

R. Effects of Clarification of Limitations on the Valuation of Depreciable Assets Disposed of on or after December 1, 1997

In section X.B. of the preambles of the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20142 through 20143) and this final rule, we discuss and finalize our proposal to revise the Medicare provider reimbursement regulations to clarify our longstanding policy pertaining to allowable costs and the limits on the valuation of a depreciable asset that may be recognized in establishing an appropriate allowance for depreciation for assets disposed of on or after December 1, 1997. Specifically, we are clarifying that the elimination of the gain or loss for depreciable assets applies to assets a provider disposes of by sale or scrapping on or after December 1, 1997, regardless of whether the asset is scrapped, sold as an individual asset of a Medicare participating provider, or sold incident to a provider change of ownership. Because we are not making any change in policy, but rather are restating longstanding Medicare policy, there is no economic impact on providers resulting from this policy clarification.

S. Alternatives Considered

This final rule contains a range of policies. It also provides descriptions of the statutory provisions that are addressed, identifies the finalized policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

As discussed in section III.H. of the preamble of this final rule, we are extending the imputed floor policy for developing the hospital wage index for 1 additional year. We note that if the imputed floor policy had expired at the end of FY 2017, we estimate that IPPS payments would have decreased by approximately $12 million in New Jersey, $22 million in Rhode Island, and $12 million in Delaware. Because the imputed floor policy is budget neutral nationally, had the policy expired, these payments would have been redistributed to all IPPS hospitals nationally.

T. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled ''Reducing Regulation and Controlling Regulatory Costs,'' was issued on January 30, 2017. This final rule is considered an Executive Order 13771 regulatory action. In the table below, we provide a summation of the savings/costs delineated in the sections XIII.B of the preamble and section I. of Appendix A of this final rule. Additional details on the estimated costs of this rule can be found in the preceding and subsequent analyses.

Section of the final rule	Description	Amount of costs or savings
Section XII.B.3. of the preamble	ICRs for the Hospital IQR Programs	($1,592,437)
Section XII.B.4. of the preamble	ICRs for the PCHQR Program	(1,519,427)
Section I.M.of Appendix A	Effects of Requirements for the LTCH QRP	(380,480)

Section of the final rule	Description	Amount of costs or savings
Section I.P.of Appendix A	Effects of Electronic Signature and Electronic Submission of the Certification and Settlement Summary Page of Medicare Cost Reports for FY 2018.	(362,000)
Total		(3,854,344)

U. Overall Conclusion

1. Acute Care Hospitals

Table I of section I.G. of this Appendix demonstrates the estimated distributional impact of the IPPS budget neutrality requirements for the MS–DRG and wage index changes, and for the wage index reclassifications under the MGCRB. Table I also shows a projected overall increase of 1.3 percent in operating payments before accounting for the impact of the changes in Medicare DSH payments and uncompensated care payments. When combined with the impact of those changes, consistent with our policy discussed in section V.G. of the preamble of this final rule, we estimate that operating payments will increase by approximately 2.3 percent in FY 2018, or approximately $2.5 billion. We also currently estimate that the changes in new technology add-on payments for FY 2018 will decrease spending by approximately $34 million and the changes to the volume decrease adjustment will increase spending by approximately $15 million. In addition, we estimate the change in low-volume hospital payments, including the statutory expiration of the temporary increase in the low-volume hospital payment adjustment in FY 2018 will decrease spending by approximately $312 million in FY 2018. These estimates, combined with our estimated increase in FY 2018 operating payment of $2.5 billion, will result in an estimated increase of approximately $2.2 billion for FY 2018. We estimate that hospitals will experience a 2.7 percent increase in capital payments per case, as shown in Table III of section I.I. of this Appendix. We project that there will be a $226 million increase in capital payments in FY 2018 compared to FY 2017. The cumulative operating and capital payments will result in a net increase of approximately $2.4 billion to IPPS providers. The discussions presented in the previous pages, in combination with the rest of this final rule, constitute a regulatory impact analysis.

2. LTCHs

Overall, LTCHs are projected to experience a decrease in estimated payments per discharge in FY 2018. In the impact analysis, we are using the rates, factors, and policies presented in this final rule based on the best available claims and CCR data to estimate the change in payments under the LTCH PPS for FY 2018. Accordingly, based on the best available data for the 415 LTCHs in our database, we estimate that FY 2018 LTCH PPS payments will decrease approximately $110 million relative to FY 2017 as a result of the payment rates and factors presented in this final rule.

V. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret a rule, we should estimate the cost associated with regulatory review. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20228), due to the uncertainty involved with accurately quantifying the number of entities that would review the proposed rule, we assumed that the total number of timely pieces of correspondence on last year's proposed rule would be the number of reviewers of the proposed rule. We acknowledged that this assumption may understate or overstate the costs of reviewing the rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For those reasons, we decided that the number of past commenters would be a fair estimate of the number of reviewers of the proposed rule. We welcomed any public comments on the approach in estimating the number of entities that would review the proposed rule. We did not receive any public comments specific to our solicitation.

We also recognized that different types of entities are in many cases affected by mutually exclusive sections of the proposed rule. Therefore, for the purposes of our estimate, we assumed that each reviewer read approximately 50 percent of the proposed rule. We sought public comments on this assumption. We did not receive any public comments specific to our solicitation.

We have used the number of timely pieces of correspondence on the FY 2018 proposed rule as our estimate for the number of reviewers of this final rule. We continue to acknowledge the uncertainty involved with using this number, but we believe it is a fair estimate due to the variety of entities affected and the likelihood that some of them choose to rely (in full or in part) on press releases, newsletters, fact sheets, or other sources rather than the comprehensive review of preamble and regulatory text. Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing the final rule is $105.16 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it will take approximately 21 hours for the staff to review half of the final rule. For each IPPS hospital or LTCH that reviews the final rule, the estimated cost is $2,208.36 (21 hours x $105.16). Therefore, we estimate that the total cost of reviewing the final rule is $9,707,951 ($2,208.36 x 4,396 reviewers).

II. Accounting Statements and Tables

A. Acute Care Hospitals

As required by OMB Circular A–4 (available at *https://obamawhitehouse.archives.gov/omb/circulars_a-004_a-4/* and *https://georgewbush-whitehouse.archives.gov/omb/circulars/a004/a-4.html*), in the following Table V., we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule as they relate to acute care hospitals. This table provides our best estimate of the change in Medicare payments to providers as a result of the changes to the IPPS presented in this final rule. All expenditures are classified as transfers to Medicare providers.

As shown below in Table V., the net costs to the Federal Government associated with the policies in this final rule are estimated at $2.4 billion.

TABLE V—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES UNDER THE IPPS FROM FY 2017 TO FY 2018

Category	Transfers
Annualized Monetized Transfers	$2.4 billion.
From Whom to Whom	Federal Government to IPPS Medicare Providers.

B. LTCHs

As discussed in section I.J. of this Appendix, the impact analysis of the payment rates and factors presented in this final rule under the LTCH PPS is projected to result in a decrease in estimated aggregate LTCH PPS payments in FY 2018 relative to FY 2017 of approximately $110 million based on the data for 415 LTCHs in our database that are subject to payment under the LTCH PPS. Therefore, as required by OMB Circular A–4 (available at *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/* and *https://georgewbush-whitehouse.archives.gov/omb/circulars/a004/a-4.html*), in Table VI., we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule as they relate to the changes to the LTCH PPS. Table VI. provides our best estimate of the estimated change in Medicare payments under the LTCH PPS as a result of the payment rates and factors and other provisions presented in this final rule based on the data for the 415 LTCHs in our database.

As shown in Table VI. below, the net savings to the Federal Government associated with the policies for LTCHs in this final rule are estimated at $110 million.

TABLE VI—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FROM THE FY 2017 LTCH PPS TO THE FY 2018 LTCH PPS

Category	Transfers
Annualized Monetized Transfers	−$110 million
From Whom to Whom	Federal Government to LTCH Medicare Providers

C. Information Collection Requirements, Regulatory Impact Analyses, and Regulatory Familiarization Costs

As noted in section I.T. of Appendix A of this final rule, the savings and costs reflected in the information collection requirements and regulatory impact analyses of this final rule is a savings of $3,854,344. Also, as noted in section I.V. of Appendix A of this final rule, the regulatory review cost for this final rule is $9,707,951.

TABLE VII—ACCOUNTING STATEMENT: SAVINGS FROM THE HOSPITAL IQR PROGRAM AND COST OF REGULATION FAMILIARIZATION

Category	Cost *
Cost (in millions)	$5.853607

* Familiarization cost is one time and some of the savings associated with the Hospital IQR Program are annually.

III. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $7.5 million to $38.5 million in any 1 year). (For details on the latest standards for health care providers, we refer readers to page 36 of the Table of Small Business Size Standards for NAIC 622 found on the SBA Web site at: *http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf*.)

For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. Individuals and States are not included in the definition of a small entity. We believe that the provisions of this final rule relating to acute care hospitals will have a significant impact on small entities as explained in this Appendix. For example, because all hospitals are considered to be small entities for purposes of the RFA, the hospital impacts described in this final rule are impacts on small entities. For example, we refer readers to ''Table I—Impact Analysis of Changes to the IPPS for Operating Costs for FY 2018.'' Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary LTCHs. Therefore, we are assuming that all LTCHs are considered small entities for the purpose of the analysis in section I.J. of this Appendix. MACs are not considered to be small entities because they do not meet the SBA definition of a small business. Because we acknowledge that many of the affected entities are small entities, the analysis discussed throughout the preamble of this final rule constitutes our regulatory flexibility analysis. This final rule contains a range of policies. It provides descriptions of the statutory provisions that are addressed, identifies the finalized policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20229), we solicited public comments on our estimates and analysis of the impact of our proposals on those small entities. Any public comments that we received and our responses are presented throughout this final rule.

IV. Impact on Small Rural Hospitals

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis for any proposed or final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent urban area. Thus, for purposes of the IPPS and the LTCH PPS, we continue to classify these hospitals as urban hospitals. (We refer readers to Table I in section I.G. of this Appendix for the quantitative effects of the policy changes under the IPPS for operating costs.)

V. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2017, that threshold level is approximately $146 million. This final rule will not mandate any requirements for State, local, or tribal governments, nor will it affect private sector costs.

VI. Executive Order 13175

Executive Order 13175 directs agencies to consult with Tribal officials prior to the formal promulgation of regulations having tribal implications. This final rule contains provisions applicable to hospitals and facilities operated by the Indian Health Service or Tribes or Tribal organizations under the Indian Self-Determination and Education Assistance Act and, thus, has tribal implications. Therefore, in accordance with Executive Order 13175 and the CMS Tribal Consultation Policy (December 2015),

CMS has consulted with Tribal officials on these Indian-specific provisions of the proposed rule prior to the formal promulgation of this final rule.

VII. Executive Order 12866

In accordance with the provisions of Executive Order 12866, the Executive Office of Management and Budget reviewed this final rule.

Appendix B: Recommendation of Update Factors for Operating Cost Rates of Payment for Inpatient Hospital Services

I. Background

Section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Under section 1886(e)(5) of the Act, we are required to publish update factors recommended by the Secretary in the proposed and final IPPS rules, respectively. Accordingly, this Appendix provides the recommendations for the update factors for the IPPS national standardized amount, the hospital-specific rate for SCHs, and the rate-of-increase limits for certain hospitals excluded from the IPPS, as well as LTCHs. In prior years, we have made a recommendation in the IPPS proposed rule and final rule for the update factors for the payment rates for IRFs and IPFs. However, for FY 2018, consistent with approach for FY 2017, we are including the Secretary's recommendation for the update factors for IRFs and IPFs in separate **Federal Register** documents at the time that we announce the annual updates for IRFs and IPFs. We also discuss our response to MedPAC's recommended update factors for inpatient hospital services.

II. Inpatient Hospital Update for FY 2018

A. FY 2018 Inpatient Hospital Update

As discussed in section V.B. of the preamble to this final rule, for FY 2018, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. Specifically, the applicable percentage increase under the IPPS is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to a reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act and a reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful electronic health record (EHR) users in accordance with section 1886(b)(3)(B)(ix) of the Act, and then subject to an adjustment based on changes in economy-wide productivity (the multifactor productivity (MFP) adjustment), and an additional reduction of 0.75 percentage point as required by section 1886(b)(3)(B)(xii) of the Act. Sections 1886(b)(3)(B)(xi) and (b)(3)(B)(xii) of the Act, as added by section 3401(a) of the Affordable Care Act, state that application of the MFP adjustment and the additional FY 2018 adjustment of 0.75 percentage point may result in the applicable percentage increase being less than zero.

We note that, in compliance with section 404 of the MMA, in this final rule, we are replacing the FY 2010-based IPPS operating and capital market baskets with the rebased and revised 2014-based IPPS operating and capital market baskets for FY 2018.

In the FY 2018 IPPS/LTCH PPS proposed rule, based on the most recent data available at that time, in accordance with section 1886(b)(3)(B) of the Act, we proposed to establish the FY 2018 market basket update used to determine the applicable percentage increase for the IPPS on the IGI's fourth quarter 2016 forecast of the proposed 2014-based IPPS market basket rate-of-increase with historical data through third quarter 2016, which was estimated to be 2.9 percent. Based on the most recent data available for this FY 2018 IPPS/LTCH PPS final rule, in accordance with section 1886(b)(3)(B) of the Act, we are establishing the FY 2018 market basket update used to determine the applicable percentage increase for the IPPS on IGI's second quarter 2017 forecast of the 2014-based IPPS market basket rate-of-increase with historical data through first quarter 2017, which is estimated to be 2.7 percent.

In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in section V.B. of the preamble of the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19932), we proposed an MFP adjustment of 0.4 percent for FY 2018. Therefore, based on IGI's fourth quarter 2016 forecast of the proposed 2014-based IPPS market basket, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), we presented in the proposed rule four possible applicable percentage increases that could be applied to the standardized amount. Based on the most recent data available for this FY 2018 IPPS/LTCH PPS final rule, in accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in section V.B. of the preamble of this final rule, we are establishing a MFP adjustment (the 10-year moving average percent change of MFP for the period ending FY 2018) of 0.6 percent.

In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in section V.B. of the preamble of this final rule, we are establishing the applicable percentages increases for the FY 2018 updates based on IGI's second quarter 2017 forecast of the 2014-based IPPS market basket, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act as outlined in the table below.

FY 2018	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Market Basket Rate-of-Increase	2.7	2.7	2.7	2.7
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.675	−0.675
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−2.025	0.0	−2.025
MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.6	−0.6	−0.6	−0.6
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.75	−0.75	−0.75	−0.75
Applicable Percentage Increase Applied to Standardized Amount	1.35	−0.675	0.675	−1.35

B. Update for SCHs for FY 2018

Section 1886(b)(3)(B)(iv) of the Act provides that the FY 2018 applicable percentage increase in the hospital-specific rate for SCHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS).

(We note that, as discussed in section V.H. of the preamble of this final rule, section 205 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted on April 16, 2015) extended the MDH program (which, under previous law, was to be in effect for discharges on or before March 31, 2015 only) for discharges occurring on or after April 1, 2015, through FY 2017 (that is, for discharges occurring on or before September 30, 2017). Therefore, under current law, the MDH program will expire at the end of FY 2017. However, as discussed in section V.H. of the preamble of this final rule, MDHs have the opportunity to apply for SCH status in advance of the expiration of the MDH program and be paid as such under certain conditions, as specified in the regulations at 42 CFR 412.92(b)(2)(i) and (b)(2)(v).)

As previously mentioned, the update to the hospital specific rate for SCHs is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, depending on whether a hospital submits quality data and is a meaningful EHR user, we are establishing the same four possible applicable percentage increases in the table above for the hospital-specific rate applicable to SCHs.

C. FY 2018 Puerto Rico Hospital Update

As discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56939), prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. Section 601 of Public Law 114–113 amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount under the amendments to section 1886(d)(9)(E) of the Act, there is no longer a need for us to make an update to the Puerto Rico standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the same update to the national standardized amount discussed under section V.B.1. of the preamble of this final rule. Accordingly, for FY 2018, we are establishing an applicable percentage increase of 1.35 percent to the standardized amount for hospitals located in Puerto Rico.

D. Update for Hospitals Excluded from the IPPS for FY 2018

Section 1886(b)(3)(B)(ii) of the Act is used for purposes of determining the percentage increase in the rate-of-increase limits for children's hospitals, cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and America Samoa). Section 1886(b)(3)(B)(ii) of the Act sets the percentage increase in the rate-of-increase limits equal to the market basket percentage increase. In accordance with § 403.752(a) of the regulations, RNHCIs are paid under the provisions of § 413.40, which also use section 1886(b)(3)(B)(ii) of the Act to update the percentage increase in the rate-of-increase limits.

Currently, children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa are among the remaining types of hospitals still paid under the reasonable cost methodology, subject to the rate-of-increase limits. As discussed in section VII. of the preamble of this final rule, we are using the percentage increase in the 2014-based IPPS operating market basket to update the target amounts for children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa for FY 2018 and subsequent fiscal years. Accordingly, for FY 2018, the rate-of-increase percentage to be applied to the target amount for these children's hospitals, cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa would be the FY 2018 percentage increase in the 2014-based IPPS operating market basket. For this final rule, the current estimate of the IPPS operating market basket percentage increase for FY 2018 is 2.7 percent.

E. Update for LTCHs for FY 2018

Section 123 of Public Law 106–113, as amended by section 307(b) of Public Law 106–554 (and codified at section 1886(m)(1) of the Act), provides the statutory authority for updating payment rates under the LTCH PPS.

As discussed in section V.A. of the Addendum to this final rule, we are establishing an update the LTCH PPS standard Federal payment rate by 1.0 percent for FY 2018, consistent with the amendments to section 1886(m)(3) of the Act provided by section 411 of MACRA. In accordance with the LTCHQR Program under section 1886(m)(5) of the Act, we are reducing the annual update to the LTCH PPS standard Federal rate by 2.0 percentage points for failure of a LTCH to submit the required quality data. Accordingly, we are establishing an update factor of 1.01 in determining the LTCH PPS standard Federal rate for FY 2018. For LTCHs that fail to submit quality data for FY 2018, we are establishing an annual update to the LTCH PPS standard Federal rate of −1.0 percent (that is, the annual update for FY 2018 of 1.0 percent less 2.0 percentage points for failure to submit the required quality data in accordance with section 1886(m)(5)(C) of the Act and our rules) by applying an update factor of 0.99 in determining the LTCH PPS standard Federal rate for FY 2018.

For FY 2018, consistent with the amendments to section 1886(m)(3) of the Act provided by section 411 of MACRA, for LTCHs that submit quality data, we are recommending an update of 1.0 percent to the LTCH PPS standard Federal rate. For LTCHs that fail to submit quality data for FY 2018, we are recommending an annual update to the LTCH PPS standard Federal rate of −1.0 percent.

III. Secretary's Recommendations

MedPAC is recommending an inpatient hospital update in the amount specified in current law for FY 2018. MedPAC's rationale for this update recommendation is described in more detail below. As mentioned above, section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Consistent with current law, depending on whether a hospital submits quality data and is a meaningful EHR user, we are recommending the four applicable percentage increases to the standardized amount listed in the table under section II. of this Appendix B. We are recommending that the same applicable percentage increases apply to SCHs.

In addition to making a recommendation for IPPS hospitals, in accordance with section 1886(e)(4)(A) of the Act, we are recommending update factors for certain other types of hospitals excluded from the IPPS. Consistent with our policies for these facilities, we are recommending an update to the target amounts for children's hospitals, cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa of 2.7 percent.

For FY 2018, consistent with the amendments to section 1886(m)(3) of the Act provided by section 411 of MACRA, for LTCHs that submit quality data, we are recommending an update of 1.0 percent to the LTCH PPS standard Federal rate. For LTCHs that fail to submit quality data for FY 2018, we are recommending an annual update to the LTCH PPS standard Federal rate of -1.0 percent.

IV. MedPAC Recommendation for Assessing Payment Adequacy and Updating Payments in Traditional Medicare

In its March 2017 Report to Congress, MedPAC assessed the adequacy of current payments and costs, and the relationship between payments and an appropriate cost base. MedPAC recommended an update to the hospital inpatient rates in the amount specified in current law. We refer the reader to the March 2017 MedPAC report, which is available for download at *www.medpac.gov* for a complete discussion on this recommendation. MedPAC expects Medicare margins to decline from 2015 to 2017.

Response: We agree with MedPAC, and consistent with current law, we are applying

an applicable percentage increase for FY 2018 of 1.35 percent, provided the hospital submits quality data and is a meaningful EHR user, consistent with statutory requirements.

We note that, because the operating and capital prospective payment systems remain separate, we are continuing to use separate updates for operating and capital payments. The update to the capital rate is discussed in section III. of the Addendum to this final rule.

[FR Doc. 2017–16434 Filed 8–2–17; 4:15 pm]

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